12 January 2016
EMA/649218/2014
Inspections and Human Medicines Pharmacovigilance Division

Overview of comments received on 'Draft revision of EudraVigilance access policy for medicines for human use' (EMA/759287/2009)

From Stakeholder 01 to Stakeholder 393

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

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Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
1		I would like to comment on a very specific and narrow issue that I have encountered as a consultant in Accession and Candidate Countries. One of the key issues for authorities in these countries is the approximation to the very strict pharmacovigilance standards within the EU/EEA. The adjustment to the best practices requires substantive efforts, both on the side of MAHs in these countries and the authorities/ministries which need to make their own domestic pharmacovigilance systems compliant with EudraVigilance standards. Many of the national authorities in the Accession and Candidate Countries face major difficulties to finance the tools and the workforce which is needed to handle the data streams. As many of these countries are already connected to the UMC they will certainly benefit from an improved communication stream and an enhancement of the interoperability of pharmacovigilance systems. However, the revision of the access policy does not seem to foresee better access for the NCAs of Candidate and Accession Countries as such. As a consequence these countries are still facing massive problems when it comes to the approximation to EU standards as required in the pre-accession phase. As a further consequence international companies which are MAHs in both the EU and in Accession and Candidate Countries have better access to EudraVigilance information leading to an information imbalance between MAHs and NCAs in the Candidate and Accession Countries. Stakeholders should be aware that Candidate and Accession Countries are strongly encouraged in the negotiation phase with the European Commission to build up pharmacovigilance systems which are fully compliant with the EU pharmacovigilance legal framework. Hence, it would be desirable to offer Candidate and Accession Countries, based on their performance and readiness, a transition period with better and direct access to the EudraVigilance data sets. Due to the investments needed, the brain drain and the need to create a pharmacovigilance “culture” in the country the approximation to EU standards on the technical and operational side is a massive problem in the pre-accession phase. The EudraVigilance access policy should provide Candidate and Accession Countries with more incentives and should provide NCAs, based on bilateral agreements, with direct access to the EudraVigilance system.	
2		I am a general practitioner and academic researcher at Queen Mary University of London. I have chaired a NICE guideline on lipid modification and therefore require the full range of data that relates to trial analysis. I object to the EMA Censorship of independent analysis of trial data and do not think they should behave in this way. The EMA should make data available not selectively dictate whether they agree with the	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		results of the analysis. I also disagree with the FDA interpretation of patient trial consent and consider that in agreeing to a trial the subject implicitly accepts that the results and the anonymised data will be available for public scrutiny subject to the usual caveats on secure governance.	
3		I write as a citizen of Europe. My health as well as my loved ones is and will be impacted by the decisions you are making. In you draft on page 23, you seem to give this agency a lot of censorship power:"Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication."While I agree completely with your oversight in avoiding re-identification, this extra censorship power does not seem warranted. It should be up to the scientific community, the publishers and the peer reviewers to object to a paper or contradict it in other studies. It does not seem appropriate for this agency to be the sole guardian of what results should be revealed to the scientific community and the public. I am behind you in any effort you make in improving transparency and sharing of so many life-saving results.	
4		My name is Catalin Bogdan Pepelea and I work in Germany as an Anaesthesiologist. A paragraph in your new proposal regarding access to your EudraVigilance database raises a few questions: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." 1. Why does the EMA get to decide what an "incorrect analysis" is? The peer review process takes care of that. Same for unsupported inferences. 2. I thought we had courts of law where any citizen can complain about misleading/false statements that cause a prejudice to him/her. Doesn't this mean that EMA substitutes itself to a court of law?3. What does "satisfaction of the Agency" even mean? I hope this paragraph will be removed ASAP.	
5		I think it's great that you're increasing transparency in general, but i think you don't go far enough. Specifically, i don't think that you should be able to prevent publication in the event that you detect what you consider to be "incorrect analyses, unsupported inferences, or misleading statements". Scientists often disagree on things and this is part of what makes science effective - the ability to say what you want and present alternative views - instead of being forced to go along with the crowd. So i want you to	

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		do just that - allow scientists to do what they want and criticize each other after publication. By saying you should have the ability to censor analyses in this way you are going against transparency in the very policy that is supposed to be increasing it. I urge you to reconsider.	
6		As a member of the public I would like to response to the public consultation on the EMA's updated EudraVigilance access policy. Regarding this clause: The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication. It does not appear to be appropriate for the EMA to have the right to veto publication of data on the basis of "incorrect analyses, unsupported inferences, misleading statements". Whether publications have incorrect analyses, unsupported inferences or misleading statements should remain a matter of public debate, not a matter for the EU medicines agency to unilaterally decide behind closed doors. This appears to be equivalent to state censorship by the EMA. There is additionally a conflict of interest where the publication in question may be critical of the EMA itself. The EMA should not put itself in a position where it can exercise an interest to prevent such publication; it is in the EMA's interest to be as open and transparent as possible.	
7		In the interests of patients it is important that access to EudraVigilance does *not* require researchers to agree to pre-submission approval by EMA. I draw your attention to the well-thought out and well-informed views below. At the very most the Agency should have a fixed period of a few weeks to comment on a draft paper, with no absolute right to prevent publication. If the Agency is very concerned then they could of course send their comments to the journal directly while the paper is undergoing peer review. Dr Ben Goldacre, author and co-founder of AllTrials: Protecting individual patients' privacy is necessary and good. But the EMA also says it should be allowed to suppress anything in an academic paper that it regards as "incorrect analyses, unsupported inferences, [or] misleading statements." This is a profoundly outdated world view. Simply because they are the body collecting this public data from EU patients that does not give them the right to control how it is used. This seems to simply represent state censorship of scientific discussion and analysis of public health data. If there are flawed analyses, or over-interpretation of risk signals, then that is a matter for public discussion and debate, not censorship by the medicines	

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		regulator. It also puts the regulators in a very conflicted position: it is likely that some analyses of this data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls (and many have been made in closed and un-minuted discussions). It is quite wrong that the EMA should be given the right to censor analyses critical of its own analyses. Lastly, it is worth noting that this is not a new phenomenon. Regulators have frequently argued against transparency, saying that clinicians may be confused by poor quality or contradictory analyses of patient data, but this concern is not proportionate to the true risk. There are 28,100 scientific journals in print today, with over a million articles published each year, and over 23 million papers indexed in PubMed to date. Work of poorer quality is routinely conducted and published already: it is managed – to a reasonable degree – in the academic ecosystem of evidence synthesis and critical appraisal, before it can impact on practice. Any harm that the EMA might suggest could theoretically arise from a fractional increase in the total quantity of weak academic publications must be balanced against the huge benefits of wider access to patient data. Síle Lane, Director of Campaigns, Sense About Science and co-founder of AllTrials: The EMA wants to put barriers in the way of transparency and ultimately control how data are talked about. In contrast some parts of the pharmaceutical industry are actually encouraging sharing and ask to see any analysis of their data only *after* it has been submitted for publication. Compared to this, the EMA's proposal looks outdated. The EMA is going to have to answer some embarrassing questions about why it seems to think it should control scrutiny of side effects data when many of the companies involved in producing these data don't. Dr Virginia Barbour, Medicine & Biology Editorial Director, PLOS and co-founder of AllTrials: In 2011 a number of journal editors including me for *PLOS, The BMJ, NEJM* and a few others were consulted by EMA about whether we as editors would consider early release of safety data as prejudicial to subsequent journal publication and unanimously we said of course not. So it's troubling and puzzling that the EMA now says that researchers need to have their analyses approved before publication. It's essential for public health that there are no barriers to rapid public release of safety data; we need public scrutiny of these data, not decisions made behind the closed doors of the EMA. Professor Carl Heneghan, Director, Centre for Evidence-Based Medicine and co-founder of AllTrials: Information contained in serious adverse event reports is often quite detailed and does pose problems with identification of individuals. Therefore the protection of personal data is warranted. However, the fact the Agency considers it can stop publication because of concerns over unsupported inferences or misleading statements is worrying. Furthermore, the agency also considers it can stop	

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		publication because of what it considers “incorrect analyses,” this means it will require a significant team of statistical reviewers and will find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the agency to openly publish these analyses, for independent scientific scrutiny. Consequently, what it is proposing is unworkable, and what is clear is regulators are using these measures to prevent more open scrutiny of its databases. This is unacceptable and will lead to delays and inappropriate use of resources. What is also needed is for the regulator to give examples of where incorrect analysis, unsupported inferences or misleading statements have been dealt with in the past and what they mean by these terms. Providing transparent and timely information should be a priority of regulators if the full benefits and harms of treatments are to be realised. I continue to be surprised and perplexed that the European Medicines Agency, as a public body, doesn’t think this is a fundamental priority of its work. This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use”. I support the AllTrials campaign. Here are a few key points. Principles of access for research organisations A. I object strongly to the following condition: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and should be removed. B. I am also concerned by the following principle: “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.”	

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		The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Require research organisations to submit the results of their research for publication. No weasel words: "appropriate efforts to publish their research." Proactive publication of ICSR data. I support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. I am concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
8		I read with sadness that in your latest proposal you write: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." The big problem with this is that it effectively puts the EMA in the position to do censorship of scientific results. Scientific publications are already, as you are no doubt aware, subject to peer review. A key aspect of peer review is that the	

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		reviewer should not have conflicts of interest. EMA being the entity that holds the data and makes the official judgement of the results of clinical trials have a clear conflict of interest here. It is easy to see why EMA would have an interest in censoring analyses that draw conclusions that differ from those of EMA and thereby could challenge the position of EMA as the experts. It is in the best interest of the public that the data from clinical trials are scrutinised freely by as many researchers as possible and that their results are disseminated freely. Placing EMA in a position to censor such research only hinders this.	
9		Your proposal in its current form fails on one key point. 1. You want the right to delay/suppress publication if you believe that data is incorrect or misleading. This is wrong. You're collecting the data, and responsible for distributing it, you should not be the arbiter of what is fit for publication. It should be published and then discussed by those who analyse such data. The last thing we want is the politicisation of data.	
10		I understand you are proposing to restrict publication of trial data for various reasons: 1 Privacy for fear of patient identification. 2 Flawed analyses. 3 Incorrect interpretation 4 Misleading. While I agree with reason 1 for suppression, reasons 2,3,4 should not be grounds for suppression. If your team thinks that reasons 2,3,4 exist, then the data should still be published, but you should then add a non-removable front page with your concerns with the data. Or perhaps publish it on a separate site clearly marked as being of lesser reliability.	
11		Re: updated EudraVigilance access policy. I am a research fellow working in the area of medical clinical trials. I am writing regarding the updated access policy, particularly the right to censor reporting of independent analysis of information if it doesn't agree with the analysis. Although respecting the need to ensure privacy and prevent re-identification of patients, I am concerned that the Agency wishes to be sole arbitrar of whether any independent reporting involves incorrect analyses, unsupported inferences, misleading statements or the protection of personal data before submission for publication. My opposition to this is due to a number of reasons: 1) Nine global companies have agreed to greater transparency than the European regulator is proposing. Therefore, this regulation would be out of date before it begins. 2) Although the Agency is the body collecting this public data from EU patients, that does not give them the right to control how it is used. This seems to simply represent state censorship of scientific discussion and analysis of public health data, issues which should be a matter for public discussion and debate, not censorship by the medicines regulator. This is especially relevant where results may be open to various interpretations. It is important that all these various views are aired publicly and	

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		debated. 3) There is also the potential for a conflict of interest as it is likely that some analyses of this data may draw close attention to regulatory decisions made by the EMA itself. It is quite wrong that the EMA should be given the right to censor analyses critical of its own analyses. 4) What is proposed appears unworkable as it will require a significant team of statistical reviewers and will inevitably result in the Agency finding itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the agency to openly publish these analyses, for independent scientific scrutiny. 5) Public health is served by robust and open discussion and debate regarding health research findings. There have been many instances where original opinions and judgements have changed over time as more data comes to light. As a matter of public safety, all data should be available to everyone with only minimal provisions to ensure privacy of patients. In conclusion, please change the proposal allowing the EMA to supress independent analyses of data. It would be preferable if, in the interests of patient safety, the agency did its best to promote greater transparency and make all data available for public review and discussion.	
12		Being a member of the Drug Commission of the German Medical Association I would like to ask you to provide free access to drug safety data for researchers and to abstain from censoring the resulting publications. Any misinterpretation of data can be balanced by the ensuing scientific debate rather than by suppressing a report in the first place. Both science and democracy are based on the principles of transparency and plurality which need to be reflected by EMA policies.	
13	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Reference number EMA/759287/2009 Rev. 1 (4/8/2014) Ref. section 5.4.4.1. (Reports of suspected adverse reports in EVPM): "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." This provision is unjustifiable. The EMA would be the body collecting public data, but it absolutely should not be controlling how they are used. Such a situation would amount to censorship behind closed doors of scientific discussion and analysis of public health data which, instead, should be open to public scrutiny. Furthermore, there ought to be no barriers to the prompt public release of safety data.	
14		I have had the opportunity to read though your draft proposals. I have read them in the light of my experience of the civil law courts in the UK. In the civil courts expert	

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		witnesses such as psychiatrists or orthopaedic consultants deliberately distort the benefits of medicines in order to make a winning argument for the party they represent and who pays them. It is important to expert witnesses to be re-employed by solicitors or barristers so they give the solicitors or barristers. The people who have low funds or without funds are prevented from showing the falsehood of what the expert witnesses claim because they are denied access to trial results. Previous to the publication of “Cracked” ISBN: 9781848315563 a book written by James Davies Senior Lecturer Social Anthropology and Psychotherapy at The University of Roehampton (London UK) details some of the misleading and dishonest research results that have been presented in Professional Journals and conferences.“Bad Pharma” ISBN 978-0-00-735074-2 a book written by Ben Goldacre in 2012 details how drug companies mislead doctors and harm patients.Many litigants in the UK civil courts were charged with having a personality disorder by the Judge making the civil court judgement. The reason being: the litigant did not trust what the doctor told them about the effectiveness of treatment. The two books mentioned above showed that the patients were right in what they believed and the expert witnesses provided false evidence to the judge. Expert witnesses deliberately providing false evidence under oath is acceptable to the UK courts even though a non expert witness deliberately giving false evidence would be charged with perjury and could end up going to prison. The web site "https://healthunlocked.com"lists many people who do not benefit from treatment prescribed by the medical authorities. There is a need to access the trial results so that people can see for themselves whether they fit a particular criteria of health disability. They also need to find out how long the trials ran for and to look for evidence that the drug being used may present evidence of addition. Many trials are of short duration. Many drugs which are used on the human population are used for periods of time far longer than what the trial ran for. Also many people when they need to come of the drugs after they have been on them for a long period of time find that there are side effects when coming off them. This often does not show up as having been investigated in the original trials. My GP in an NHS surgery does not have the time to hunt down trial results. Nor does the medical consultant in an NHS hospital have the time to hunt down trial results. If both of these people do look for trial results they often only look at the abstracts not the whole trial. The whole trial when read often gives a very different result from the abstract. As a patient with a long term health disability which is incurable I have a great deal of interest in long term medical issues and I have the time to track down trial results for particular medications. I as a member of the general public am prevented from seeing the results of trials that have	

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		a bearing on my health condition. I formally request that patients who have a health disability which may be affected by treatment using these medicines have access to the trial reports of these medicines.	
15		'The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication'. No. This is wrong. EMA may require sight of analyses pre-publication (though a month would be more reasonable than 6 weeks) but it cannot simply censor analyses that it disagrees with. The researchers must, in good faith, consider the issues raised by EMA, but EMA must not compromise the openness of the data by giving itself the unlateral right to suppress publication. It may have a duty in the case of protection of personal data, but must not use this as a smokescreen for preventing publication of analyses that are uncomfortable.	
16		I agree with a statement by Prof Carl Heneghan (see below) that it seems extraordinarily inappropriate for the EMA to take part in the censoring to scientific papers. There is a well-established process for this already. I think that the EMA is already culpable for having been part of a set up that has greatly restricted access to health trial data that should have been in the public domain and that it needs to rethink its role in society. See comment number 7 from Michael Kovari regarding the exact opinion of Professor Carl Heneghan, Director, Centre for Evidence-Based Medicine and co-founder of AllTrials, Dr Ben Goldacre, author and co-founder of AllTrials**,** Síle Lane, Director of Campaigns, Sense About Science and co-founder of AllTrials**,** Dr Virginia Barbour, Medicine & Biology Editorial Director, PLOS and co-founder of AllTrials**.** Information contained in serious adverse event reports is often quite detailed and does pose problems with identification of individuals. Therefore the protection of personal data is warranted. However, the fact the Agency considers it can stop publication because of concerns over unsupported inferences or misleading statements is worrying. Furthermore, the agency also considers it can stop publication because of what it considers "incorrect analyses," this means it will require a significant team of statistical reviewers and will find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the agency to openly publish these analyses, for independent scientific scrutiny. Consequently, what it is proposing is unworkable, and what is clear is regulators are	

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		using these measures to prevent more open scrutiny of its databases. This is unacceptable and will lead to delays and inappropriate use of resources. What is also needed is for the regulator to give examples of where incorrect analysis, unsupported inferences or misleading statements have been dealt with in the past and what they mean by these terms. Providing transparent and timely information should be a priority of regulators if the full benefits and harms of treatments are to be realised. I continue to be surprised and perplexed that the European Medicines Agency, as a public body, doesn't think this is a fundamental priority of its work.	
17		I am concerned about this update. Protecting individual patients' privacy is very important. But the proposition that anything in an academic paper that is regarded as "incorrect analyses, unsupported inferences, [or] misleading statements." can be suppressed is unworkable and unacceptable. It will lead to delays and inappropriate use of resources. Providing transparent and timely information should be a priority of regulators if the full benefits and harms of treatments are to be realised.	
18		This is a response to your proposed changes to the policy on EudraVigilance. I am specifically objecting to this clause: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication."Protecting individual patients' privacy is necessary and good. But this clause is a profoundly outdated world view. Simply because the EMA are the body collecting this public data from EU patients, that does not give them the right to control how it is used. If there are flawed analyses, or over-interpretation of risk signals, then that is a matter for public discussion and debate, not censorship by the medicines regulator. It also puts the regulators in a very conflicted position: it is likely that some analyses of this data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls (and many have been made in closed and unminuted discussions). It is quite wrong that the EMA should be given the right to censor analyses critical of its own analyses. Lastly, it is worth noting that this is not a new phenomenon. Regulators have frequently argued against transparency, saying that clinicians may be confused by poor quality or contradictory analyses of patient data, but this concern is not proportionate to the true risk. There are 28,100 scientific journals in print today, with over a million articles published each year, and over 23 million papers indexed in PubMed to date. Work of poorer quality is routinely conducted	

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		and published already: it is managed – to a reasonable degree – in the academic ecosystem of evidence synthesis and critical appraisal, before it can impact on practice. Any harm that the EMA might suggest could theoretically arise from a fractional increase in the total quantity of weak academic publications must be balanced against the huge benefits of wider access to patient data. This clause should be amended to remove any EMA right to filter data in this way.	
19		I don't like the idea that in order to access data in the EudraVigilance database, researchers will have to agree to the condition that the EMA will be able to censor analyses of the data which it doesn't agree to. This goes against the ethos of making the data open. If someone produces an incorrect analysis, the correct route is to point out what is wrong and give the correct analysis, not to censor them. This makes me fear that the EMA will censor things inappropriately and apply its own biases when deciding what is 'correct' and what is not.	
20		When going through the document a couple of issues emerged that should be discussed or clarified. 1) As already mentioned in my comment from July 7th it still remains unclear why are case narratives are visible for MAHs and research organizations but not for other authorities or WHO. Users of WHO-Vigibase are mainly regulatory authorities outside the EU with similar local responsibilities so that provision of narratives would assumably facilitate their work. There are other data elements which are not freely available for groups V and VI, such as body weight and height, active substance or, medical history. These elements may be important for evaluation purposes. We cannot see reasons for such restrictions. 2) Duplicate identification and management will become difficult, particularly in spontaneous reporting, if patient initials are not provided to MAHs. Although this is current practice one should rethink this policy also in light of the existing data protection laws. Initials are of utmost importance for duplicate identification. 3) Will access to EV-data be limited to master cases only or is it also possible, e.g. for MAHs, to receive the original data which have been sent e.g. by an NCA? 4) There is no mentioning of press and other media. Will these parties form an additional user group or will they be summarized under the existing ones (if so, which one?). They should at least be mentioned. 5) Access to certain EV-data elements is restricted for a number of user groups. Based on experience they will probably approach the local NCA to run such queries in EV and to provide the missing data elements they have no access to on their own. Would such requestors be treated by EMA similar to research organizations and be provided with the data of interest if the requestor provides some justification. The latter is the preferred option since it would avoid unnecessary burden for the NCAs and eventually different policies among	

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		Member States. 6) Formal aspect to be corrected: the table in Annex 2 changes the headline from page 48 onwards: last column then reads “Field ICH or EU” instead of “Stakeholder Group V and VI”	
21		I agree with Dr Ben Goldacre, author and co-founder of AllTrials: "Protecting individual patients’ privacy is necessary and good. But the EMA also says it should be allowed to suppress anything in an academic paper that it regards as “incorrect analysis, unsupported inferences, [or] misleading statements.” This is a profoundly outdated world view. Simply because they are the body collecting this public data from EU patients that does not give them the right to control how it is used. This seems to simply represent state censorship of scientific discussion and analysis of public health data. Regulators have frequently argued against transparency, saying that clinicians may be confused by poor quality or contradictory analyses of patient data, but this concern is not proportionate to the true risk. There are 28,100 scientific journals in print today, with over a million articles published each year, and over 23 million papers indexed in PubMed to date. Work of poorer quality is routinely conducted and published already: it is managed – to a reasonable degree – in the academic ecosystem of evidence synthesis and critical appraisal, before it can impact on practice. Any harm that the EMA might suggest could theoretically arise from a fractional increase in the total quantity of weak academic publications must be balanced against the huge benefits of wider access to patient data." and with Professor Carl Heneghan, Director, Centre for Evidence-Based Medicine and co-founder of AllTrials: "Providing transparent and timely information should be a priority of regulators if the full benefits and harms of treatments are to be realised. I continue to be surprised and perplexed that the European Medicines Agency, as a public body, doesn't think this is a fundamental priority of its work."	
22		I would like provide my comments on the update on EudraVigilance access policy. I am a researcher in clinical pharmacology working at Leiden University. Having access to the EudraVigilance database is of great relevance to my research. Currently I am writing a postdoc proposal that plans to make use of this database to better understand cardiotoxicity of certain cancer agents. I have two concerns: 1. I am concerned about the statements regarding the rights to review research manuscripts by the EMA. The fact that the EMA is collecting this type of patient reported data does not mean the EMA should have the right to influence or control scientific publications. Scientific publications by themselves are peer reviewed. If there are concerns about incorrect analysis, or other concerns, these can be discussed during standard peer-review OR afterwards by general public discussion in the scientific literature - as is done for any	

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		other types of scientific research. Please take this in consideration and allow researchers to publish their research based on the database without further restrictions. The FDA adverse events database also doesn't have such restrictions as far as I know. 2. Let me first stress that patient privacy rights are highly important. However, I think that the EMA should reconsider their policy to restrict access to the *anonimized* but raw, individual level reports of adverse events. I do not think that privacy issues in anyway can justify limiting direct access of the database to researchers by first having to specifically apply for access. What is there to gain by doing that, apart from creating extra administrative hurdles? Again, compare with the FDA AE database, that can be downloaded in full by everyone without restrictions. This is public data and should be available to anyone!	
23		I would like to add my voice to the campaign for greater transparency in the dissemination of results of clinical trials, with greater responsibility on the research community itself, not EMA, to evaluate preliminary results. As Professor Carl Heneghan has said: Information contained in serious adverse event reports is often quite detailed and does pose problems with identification of individuals. Therefore the protection of personal data is warranted. However, the fact the Agency considers it can stop publication because of concerns over unsupported inferences or misleading statements is worrying. Furthermore, the agency also considers it can stop publication because of what it considers “incorrect analyses,” this means it will require a significant team of statistical reviewers and will find itself embroiled in numerous long-winded disputes. Indeed, to come to the conclusion that analyses are flawed will require the agency to openly publish these analyses for independent scientific scrutiny. Consequently, what it is proposing is unworkable, and what is clear is regulators are using these measures to prevent more open scrutiny of its databases. This is unacceptable and will lead to delays and inappropriate use of resources. What is also needed is for the regulator to give examples of where incorrect analysis, unsupported inferences or misleading statements have been dealt with in the past and what they mean by these terms. Providing transparent and timely information should be a priority of regulators if the full benefits and harms of treatments are to be realised. I continue to be surprised and perplexed that the European Medicines Agency, as a public body, doesn’t think this is a fundamental priority of its work. [my underlining).	
24		Biogen Idec supports EMA Access Policy which aims to meet the EU principles of transparency and to ensure compliance with EU personal data protection legislation, by providing proactive access to adverse reaction data collected in EudraVigilance.	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
24	Page 21: 5.4.3.2. Methods of access	Download of ICSR data elements as defined for the purpose of signal detection in Excel format; the download is provided at the access controlled, restricted area ~~and~~ of the EudraVigilance website;	
24	Page 22: 5.4.4.1. Reports of suspected adverse reports in EVPM Level 2: An extended number of ICSR data elements but restricted to substances or substance classes which are subject to the research following the receipt of a research request32. This data set corresponds to the data set as provided to MAHs (see point iv of chapter 5.4.3.1.) and will be provided by means of secure data provision.	Question – will industry be notified of this request?	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
24	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Question – what is the time frame that is planned for this standard timescale?	
24	Annex 2:	For stakeholders doing signalling as well as for Group VI, the information provided seems too limited to allow for meaningful assessment of the reported events. Would the agency consider allowing for instance medical history data and medical drug history data to be released to such parties?	
24	Annex 2: Page 31 – 51:	Table heading - 'DATA ~~E~~ELEMENT NAME'	
24	Page 21: 5.4.3.2. Methods of access	Download of ICSR data elements as defined for the purpose of signal detection in Excel format; the download is provided at the access controlled, restricted area ~~and~~ of the EudraVigilance website;	
24	Page 22: 5.4.4.1. Reports of suspected adverse reports in EVPM Level 2: An extended number of ICSR data elements but restricted to substances	Question – will industry be notified of this request?	

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	or substance classes which are subject to the research following the receipt of a research request32. This data set corresponds to the data set as provided to MAHs (see point iv of chapter 5.4.3.1.) and will be provided by means of secure data provision.		
24	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Question – what is the time frame that is planned for this standard timescale?	
25		We agree on the proposed contents of this draft.	
26		1. Introduction - According to the provisions laid down in article 26, paragraph (3) and	

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		article 57, paragraph (1) (d) of Regulation (EC) No 726/2004, the Agency should grant “appropriate levels” of access to EudraVigilance (EV) to the following stakeholders: national competent authorities (NCA), healthcare professionals (HCP), marketing authorisation holders (MAHs) and the general public. According to the provisions laid down in Module IX (signal management) of the Guideline on Good Pharmacovigilance Practices (GVP) (EMA/827661/2011; 20 February 2012; IX.C.1.5. - Roles and responsibilities of marketing authorisation holders), the MAH shall monitor the data in EudraVigilance. Additionally, the EudraVigilance Access Policy for Medicines for Human Use (5.4.3. Group III: Marketing authorisation holders and sponsors) states that pharmaceutical companies have legal obligations to continuously monitor the safety of medicines and are committed to the protection of the public health of citizens in the EU. These obligations and commitment will be made possible through signal detection and analysis tools of the EudraVigilance Data Warehouse and Analysis System (EVDAS). 2. Points to consider - The European Generic medicines Association (EGA) supports the accomplishment of the obligations and commitment related to signal management in the EU. The implementation of the legislation and Module IX of the Guideline on Good Pharmacovigilance Practices (GVP) required an internal reflection within the EGA that raised the following issues: 1. Multiplication of signal detection: EMA, National Competent Authorities (NCA) and the Marketing Authorisation Holders all base their signal detection on the EudraVigilance database. 2. Heterogeneity of dataset for signal detection: as stated in the EudraVigilance Access Policy for Medicines for Human Use the MAHs will be responsible for the evaluation of a signal on a limited dataset; on the other hand, the NCAs have access to a full dataset. An evaluation and, afterwards, a reconciliation procedure must be implemented. Alternatively, the same exercise performed by the numerous MAHs will increase the heterogeneity for signals because of the different methodology, standards and thresholds used. 3. Bias of signal detection methodologies: the uploading of non-company data in the MAH individual databases distorts the internal established threshold for signal detection and leads to a bias in the outcome. Furthermore for large generic medicines companies it means that in the end they have a copy of the EV database. Uploading of data should therefore not be mandatory. 4. Disproportionality between the amount of ICSR reported and the signal detection burden: small and medium-sized (SME) generic medicines companies, with a limited number of ICSRs reported to the EV database will end up employing additional resources to undertake signal activities on a large amount of non-company data which has already undergone assessment by other stakeholders (NCA or other MAH). 3. Proposal - In view of the above issues, the EGA recommends the following pragmatic	

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		proposal regarding the signal detection activities required to be performed by each stakeholder: □ Marketing Authorisation Holder (MAH): o The MAHs should be responsible for the signal detection process related to their own products in their own database and perform the signal detection on this, their own, data; o The evaluation of that MAH signal can be further validated and/or confirmed by using the extended dataset from the EV. In order for this to work and to facilitate the MAHs, the Electronic Reaction Monitoring Report (eRMR) outputs should be produced on a monthly basis, clearly indicating potential signals observed for the product/s concerned. o If the validation/evaluation of the MAH results in a potential signal, the MAH should contact the NCA responsible for the active substance for discussion and further evaluation. In this case the NCA can check the full dataset in EudraVigilance and confirm the signal. □National Competent Authority (NCA)/European Medicines Agency (EMA): o As agreed in the current work-sharing situation, NCAs should be responsible for the management of signal detection of the substances assigned to them. o The NCA responsible for the active substance will receive the validated signals from the MAHs and proceed as appropriate.	
27		We have consulted the revision of eudravigilance access policy for medicines for human use and we need your clarification on some points we think important for a correct understanding. 1) It is stated that this access policy will enter into force six months following the announcement by the management board of the Agency based on an independent audit report, that eudtravigilance database has achieved full functionality, can we have a deadline on when this will be operational? 2) Can you please precise what would be used for queries: INN or trade name? 3) It is not clear for us if e-RMRs reports will include only our product or if they will include all medicinal products? 4) is it mandatory to perform monthly signal detection even for product with few (2 to 5 cases per year) ADR reported? if no, can we have the periodicity recommended. 5) For MAH (stakeholder group III) and for level 1, do you make available PRR you have achieved for all products? 6) is it possible to have a model of e-RMR to see all data that will be reported on the electronic reaction monitoring report? 7) On page 18 of the document it is stated for point 4 of §5.3:" Provision of e-RMRs and other statistical/analytical reports, can you please clarify what do you mean by other statistical/analytical reports?	
28		Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists represents UK wide around 5,000 pharmacists including the majority of hospital pharmacists, pharmacists employed by NHS Primary Care organisations and pharmacists employed by other public bodies such as Prisons and the Care Quality	

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		Commission. The Guild is part of the health sector of the union Unite. We welcome and support the EudraVigilance Access Policy especially as it is being developed to facilitate the continuous monitoring of the safety of medicines and to evaluate benefits and risks of medicines with an overall aim of promoting and protecting public health. Meeting the EU principles of transparency and openness and ensuring compliance with EU personal data protection legislation are also welcomed. We also note that proactive and reactive information disclosure has the necessary safeguards. Our only concern however relates to the following two pieces of information: • The "Accessible ICSR data elements for Stakeholder Groups I to VI" listed under 5.4.2.4. Personal data protection requirements, lists the following 'Patient Characteristics':D.1 Patients' (name or initials) D.1.1.1 Patient Medical Record Number(s) and Source(s) of the Record Number (GP Medical Record Number) And: • The Agency is notified immediately of a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise protected in connection with data held or generated from EudraVigilance. In addition, the Agency is operating a procedure for access and rectification. In case the Agency is not able to identify the relevant ICSRs, it will refer to the NCA from which the reports likely originate. In view of the above details, why is it necessary for information beneath the heading 'Patient Characteristics D.1 and D.1.1.1' to include the patient's name and Patient Medical Record number, since if these data are not really needed why collect them? If these details were not included then this would eradicate any potential accidental or unauthorised disclosure of personal data. By way of example, we note that in organisations that deal with clinical trials, Clinical Trial Sponsors are very keen to ensure that no patient identifiable data comes back to them. All data received is identified by the subject number allocated in that particular trial. There is also a problem with recording the Patients Medical Record Number. We are aware that one of the home countries has moved over to using the CHI (Community Health Index) number for everything. In one particular city it was found that each hospital had its own system of numbering casenotes and some patients who had attended more than one of the hospitals had five or six different numbers allocated to them (one for each hospital). Changing to the CHI meant that every patient had a unique identifier which was used exclusively, irrespective of care setting. As regards the question on Stakeholder Groups III A "Marketing Authorisation Holders" we consider the data set proposed in Annex 1 is sufficient for a MAH to comply with the pharmacovigilance obligations as outlined in Regulation (EC) 726/2004, Directive 2001/83/EC.	

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29		This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use” from the AllTrials campaign. The AllTrials campaign was launched in January 2013 to call for all clinical trials to be registered and results reported. It is an initiative of Bad Science, BMJ, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative, PLOS and Sense About Science. It is supported by nearly 80,000 people and over 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world. Principles of access for research organisations. We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” □ “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: □ “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close	

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		attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: □ “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data We support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	

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30		I am writing in response to this consultation. I am a company director specialising in evidence-based knowledge services. I welcome the proposed regulations in so far as they would provide more access to clinical data for researchers, health professionals and the public. However, in their current form they would permit the EMA to block publication of analyses it disagrees with. This is incompatible with the public interest. In my view, it is likely to lead to harm to patients by introducing bias in the reporting and dissemination of critical information about the clinical effects of health products. Please remove this clause from the legislation.	
31		I object strongly to the following two conditions:“The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.”“A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. Additional question 1." As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection?" Yes. We must ensure that healthcare professionals and the public have useful access to upto-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	

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32		This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use”. I want to ask you not to censor independent analyses! The idea is to try to give all the information to help others judge the value of someone's contribution; not just the information that leads to judgment in one particular direction or another.	
33		Having reviewed the recent EMA's updates to the policy on access to EudraVigilance, I felt compelled to comment. Whilst the EudraVigilance is great for allowing health professionals to access all drug side effect data so that the best available treatments can be prescribed for patients, the updates (whilst improving this further) also take a huge step backwards in allowing the EMA to censor any publication it disagrees with. This is not for the EMA to decide (being one of the bodies that conducts some of these analyses), but rather any flaws or over-interpretations should be down to public discussion and debate. I understand that EMA power to filter out low quality studies has it's benefits i.e. to allow the focus to be on more quality studies, however I believe there is greater benefit from having wider access to patient data on the whole. Please remove this power from the policy updates and continue to make all medical trial data transparent.	
34		I wish to express my concern at any policy that does not include full transparency of drug trial data. I short, I support the AllTrials.net position as outlined here: http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf I oppose any barrier to the availability of medical trial data. I am a medical student - as a doctor and as a patient I demand the right to COMPLETE drug data. Anything less is morally and ethically indefensible.	
35		I write out of concern that you updated policy may in fact seriously restrict free discussion and scientific enquiry in an unintended way, in particular, the new guidelines state: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." The need for protection of personal data is uncontroversial. However, publications in scientific journals already pass through a rigorous process of peer review. To allow an interested party to block publication of statements with which it disagrees ("misleading" or "unsupported"); and analyses that reach awkward conclusions ("incorrect") undermines the entire process of	

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		academic discussion. Such concerns can more properly be raised in letters to the journal, so that an open debate can be held.	
36	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Principles of access for research organisations - We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: 1 - "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." 2 "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: ☐ "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: ☐ "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made	

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		available to the broader scientific community. Proactive publication of ICSR data We support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access. There is disparity in the access provided to the different stakeholder groups listed in Table 1 "Number of ICH E2B(R3) ICSR data elements" (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question: 1. As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
37		I note with some misapprehension the suggestion that the EMA wants the right to block/censor publication of studies which it may disagree with. It is of the utmost importance that all clinical trials/studies are freely open to researchers in the medical and scientific community. Scientists gain lots of information from all studies and usually are quite capable of making judgements on the contribution that each and every study can make in their diverse subject specialties. Please allow free and easy access to all	

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		drug/medical trials wherever possible and let the scientific community be the deciders of what the results can contribute to the field.	
38		I have read the report on the new policy produced by the AllTrials group and wish to add my voice to theirs. One of the key things we have learned in science is that it is not ok for regulators to stop publication of information they disagree with. I'm sure this is intended to stop the inevitable bad publications which will result from open publishing, but it simply isn't worth it. Allow the bad reports to be published and ridiculed. If needs be - the regulator can publish their own rebuttal. I support the full AllTrials response and urge you to follow it in full. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
39	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Though not a healthcare professional, as a researcher and as a citizen I feel very concerned by health data access and its availability to various independent research body. Thus I fully agree with the modifications suggested by the AllTrials campaign, that would increase the accessibility of the data and reduce risks of conflicts of interest within the EMA. Details on these changes are as follow (and in attached file): Principles of access for research organisations - We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: * “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” * “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific	

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		scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: * “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: * “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community.	
40		The medicines regulator should not be able to censor any data, other than that of a personal nature. We desperately need transparency throughout medical research - including on the side effects of products.	
41	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Campaña AllTrials - Esta respuesta a la consulta sobre el "Proyecto de revisión de la política de acceso a EudraVigilance para medicamentos para uso humano "de la campaña AllTrials. La campaña AllTrials fue lanzado en enero de 2013 para llamar a todos los ensayos clínicos sean registrados y los resultados reportados. Es una iniciativa de Bad Science, BMJ, Centre for Evidence-basado Medicina, Cochrane Collaboration, Iniciativa Lind James, PLOS e información acerca del Ciencia. Es apoyado por cerca de 80.000 personas y más de 500 organizaciones incluyendo reguladores; las escuelas de medicina y universidades; organismos médicos y los Reales Colegios; investigación financiadores y más de 200 grupos de pacientes de todo el mundo. Principios de acceso de las organizaciones de investigación Estamos muy preocupados por algunos de los principios en la sección 5.4.4.1. (Página 23) en virtud del cual el acceso a los datos se conceda a los organismos de investigación. A. Nos oponemos firmemente a las dos condiciones siguientes: • "La Agencia tiene el derecho de ver cualquier publicación resultante de datos EudraVigilance antes de su presentación (plazo máximo para la revisión inicial Agencia será de seis semanas) incluyendo un cheque de privacidad en cuanto a posible re-identificación de los pacientes. Cualquier problema planteada por la Agencia en relación con los análisis incorrectos, deducciones sin apoyo, declaraciones engañosas o la protección de los datos personales deben ser dirigidas a la satisfacción de la Agencia antes de su	

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		presentación para su publicación ". • "Un descargo de responsabilidad Agencia debe agregarse al manuscrito. La Agencia se reserva el derecho de volver a redactar la renuncia al manuscrito en los casos de no resuelta desacuerdo sobre la interpretación de los datos. El manuscrito o sus conclusions no debe difundirse en modo alguno sin el descargo de responsabilidad ". Estos principios parecen dar la EMA el derecho de suprimir cualquier cosa en un académico papel que no está de acuerdo con. Esta es una visión del mundo profundamente anticuado. Simplemente porque el EMA es el organismo recaudador estos datos públicos de los pacientes de la UE no le da el derecho a la controlar cómo se utiliza. Esto equivaldría a la censura estatal de discusión científica y análisis de datos de salud pública. Además, esto significa que la EMA requerirá un equipo importante de los colaboradores y estadísticos puede verse envuelto en numerosas disputas prolijo. De hecho, para llegar a la conclusión de que los análisis son deficientes, requerirán la EMA para publicar abiertamente estos análisis, para el escrutinio científico independiente. En consecuencia, lo que se propone es inviable y estos dos principios se debe quitar. B. También están preocupados por el siguiente principio: • "Un panel EMA ad-hoc revisará las solicitudes de acceso a datos de investigación basadas en un solicitud de investigación La Agencia podrá denegar el acceso a los datos si el panel se mantiene convencidos del valor de la salud pública de la investigación o la juzga a propuesta conflicto con la salud pública y las responsabilidades legales de la Agencia ". El panel que revisa las solicitudes de investigación debe ser independiente de la EMA para evitar conflictos de intereses. Es posible que algunos análisis de estos datos pueden acercarse atención a las decisiones regulatorias realizadas por la propia EMA, ya que estos son a menudo cerca de las llamadas. C. Por último, creemos que el siguiente principio podría reforzarse para exigir la investigación organizaciones a que presenten los resultados de su investigación para su publicación: • "Aquellos dado acceso a los datos EudraVigilance debe hacer los esfuerzos apropiados a publicar sus investigaciones ". Es necesario que haya de concederse la expectativa de que el acceso a estos datos para fines de investigación en la expectativa de que los resultados de dicha investigación serán puestos a disposición del más amplio comunidad científica. Publicación proactiva de datos ICSR Apoyamos el objetivo de la EMA de conceder un acceso más proactivo para la seguridad caso individual datos del informe (ICSR). Los datos que se publican de manera proactiva deben estar al día y no retenidos para su publicación en lotes. Una mejora que openFDA introdujo fue inmediata el acceso a los datos más actuales sobre los eventos adversos de la FDA informes de bases de datos del sistema. El acceso inmediato a grandes cantidades de datos se beneficiarán los pacientes, trabajadores de	

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		la salud, médicos, farmacéuticos, reguladores e investigadores. Las restricciones de acceso Hay disparidad en el acceso proporcionado a los diferentes grupos de partes interesadas que figuran en la Tabla 1 "Número de ICH E2B (R3) elementos de datos ICSR" (página 11), que a nuestro juicio es difícil reconciliarse con los principios de apertura. La EMA debe tender a facilitar el acceso a la mayor cantidad información posible. Facilitar el acceso a más información acerca de común adverso eventos para un tratamiento no comprometen la confidencialidad del paciente ya que los datos se aplicarán a ungran número de individuos. La EMA puede redactar la información de identificación del paciente de informes sobre efectos secundarios raros. Nos preocupa que ni los profesionales de la salud (Grupo II), ni la investigación organizaciones (Grupo IV) tendrán acceso a las narraciones de casos o resúmenes (Anexo página 2 H.1 50 y la página H.5.r 51). Los investigadores nos han dicho que en su experiencia, estas narrativas puede ser muy útil para entender el contexto de los acontecimientos adversos graves en el curso de un tratamiento. Otra restricción significaría que los profesionales de la salud lo haría ser incapaz de averiguar qué medicamentos a un paciente había sido previamente prescrito (Anexo 2 D.8.r página 37). Esta información es útil para los profesionales de la salud puedan identificar las posibles interacciones entre los tratamientos. Pregunta adicional *1.* En cuanto a grupo de interesados II "Los profesionales sanitarios y el público", ¿verdad considera útil para obtener salidas de datos adicionales de la base de datos europea de sospechas de reacciones adversas (www.addrreports.eu) como presentaciones tabulares o salidas presentados como casos individuales, r*espetando plenamente la protección de datos personales?* Sí. Debemos asegurarnos de que los profesionales sanitarios y el público tienen acceso útil para arriba información actualizada sobre los eventos adversos graves contenidas en la base de datos. Proporcionar el acceso a estos datos en formatos adicionales les permitirá hacer un mejor uso de los datos	
42		Sense About Science's "AllTrials" campaign has alerted me to the EMA's current consideration of the access policy for the EudraVigilance database. I would like to echo the AllTrials concerns regarding the current proposal (see attached) which, I am lead to believe, contains a condition that gives the EMA the ability to block publication of analyses it disagrees with, on the grounds of "incorrect analyses, unsupported inferences, [or] misleading statements". I would argue that the determination of whether an analysis and its inferences are appropriate or not is not within the purview of a regulatory body such as the EMA, but rather should be handled by the peer review system and the scientific community writ large. I am of the opinion that the transparency and scientific utility of the database will be drastically undermined if these	

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		conditions are included in the proposal.	
43		This is a response to the consultation on the "Draft revision of EudraVigilance access policy for medicines for human use. I fully support the concerns and objections raised by the AllTrials campaign. Please accept them as my own.	
44		I hope you'll listen to the responses of campaigns like AllTrials.	
45		I agree with the All Trials document, (below), & wish there to be no censorship of information at all. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
46	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I am writing to express my concern about the principles in section 5.4.4.1. (page 23) of the proposed legislation (Reference number: EMA/759287/2009 Rev. 1). Particularly I would like to express my objection to the following two conditions: - “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” - “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These conditions appear to allow the EMA to censor academic research, a situation which i hope you will agree is undemocratic and very unscientific. Such censorship could prevent meaningful research from being conducted and discussed responsibly, and could undermine the purpose of this legislation. I write this email as a European citizen, a scientist, and a patron of the AllTrials Campaign. I hope that my concerns will be taken into consideration.	
47		As a researcher, I wish to express concern over the possibility that your clauses on data review and disclaimer could be used to ultimately control the outflow of data by EMA. This is both unnecessary and impracticable. On the other hand, I strongly support the release of additional data on adverse reactions.	
48		I wholeheartedly support all the points made in Sile Lane’s response to you concerning publication of adverse event data. I am afraid that only full transparency will do. We have to live with the possibility that analyses will sometimes be controversial. It is not for the EMA to take on arbitration of these behind closed doors. To do so would inevitably require substantial resourcing which it can ill afford - and leave it open to	

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		loss of credibility as an independent agency. The place for such debates is in the open media. The recent debate about statins shows that the mechanisms of scientific debate through the medical literature remains effective.	
49		Safety data are underreported in many clinical trials. Any data on safety that could be available should be accessible.	
50		Please do not allow the medicines regulator to censor analyses of side effects data that it disagrees with.	
51		Full access of all data (including adverse reactions) from clinical trials of medicines must be available to both those who use and those who prescribe the drugs. This is extremely important for the safety and efficacy of medications in individuals.	
52		I am a practicing physician in the US. I was alerted to the EMA's proposed changes to its policy on access to its EudraVigilance database by the AllTrials organization. I agree completely with their attached response. The highlighted changes are in direct conflict with the EMA's guiding principle "We communicate in an open, transparent manner with all of our partners, stakeholders and colleagues." The academic community requires open access to all research data in order to make informed judgments on the safety and value of medical interventions. We also require the ability to publish our findings in a way that minimizes outside influence and preserves academic integrity. We rely upon regulatory bodies around the world to uphold these principles.	
53		I write to you concerning the revision of the policy on access to EudraVigilance. I read the draft for the new policy with mixed feelings. The provisions for increased and more detailed access will make independent research and validation much easier, and seem well and good. However, the possibility of the EMA to block publication of independent analysis is directly counter to the whole idea and should be removed.	
54		I understand you are consulting on updates to your EudraVigilance access policy. The proposal would give researchers access to more detailed and systematic records from the database but it also contains a condition that would give the EMA the ability to block publication of analyses it disagreed with. This condition should not be included and all data should be available for access. Please refer to the submission by the AllTrials campaign which I wholly support.	
55		I am a practising GP dependent on timely and correct evidenced based research. I urge you to agree and put into practice the AllTrials response to the consultation on the "Draft revision of EudraVigilance access policy for the medicines for human use". You are the body that collects public data from EU patients but you do not have the right to control how this data is used. Also, the panel that reviews research requests should be	

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		independent of the EMA to prevent conflicts of interest. I am convinced that if you fully agree and act upon the AllTrials advice, patients will benefit. We cannot have a censored view of scientific research data because then if fails to become scientific and it fails to become research.	
56		I draw your attention to the AllTrials campaign response, http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf, to the consultation on the "Draft revision of EudraVigilance access policy for medicines for human use".	
57		I am writing in support of the All Trials Campaign concerning updates to your EudraVigilance access policy. I see no reason to disagree with their assertion that the following two clauses should be removed: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible reidentification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." I believe the above clauses would unduly shackle research to our mutual detriment. Please do let me know if this view appears mistaken.	
58		Not to censor independent analyses.	
59	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for	I am really disappointed to see that the EMA is still trying to prevent full publication of results and analysis of drug trials. In particular I am very concerned by some of the principles in section 5.4.4.1 (page 23) under which access to the data is granted to research organisations. The independent response should be sufficient and requiring that the EMA has to re-analyse and agree them is unnecessary duplication and a waste of tax-payer's money. Please work on improving the principle that the data should all be available for appraisal by interested parties so that there is less chance of interested parties doctoring their results. Please work on supporting the rights of patients and the general public over corporations!	

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	extended data.		
60		Please do no censor independent analyses. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data	
61		I agree with the comments from the AllTrials campaign on this draft revision of EudraVigilance access policy for medicines for human use.	
62	(third bullet point on page 23;para 5.4.4.1. Reports of suspected adverse reports in EVPM)	I am an interested party; (retired) research scientist, user of medicines, and I happen to have Ben Goldacre's "Bad Pharma" as my bedside book. So I was interested to come across your "Draft revision of EudraVigilance access policy for medicines for human use" I leave it to others to review the whole thing in detail, but it does seems to me that the paragraph. The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication. [1] your own website says "We do not research or develop medicines The Agency does not research or develop medicines. It also does not operate laboratories on its premises or elsewhere for this work, and is not involved in conducting clinical trials. Research and development work on medicines is carried out by pharmaceutical companies or other medicines developers themselves.They then then submit the findings and test results for their products to the Agency for evaluation. THE EMA'S ROLE IN THIS AREA IS LIMITED TO PROVIDING CERTAIN SERVICES TO STIMULATE INNOVATION AND SUPPORT THE DEVELOPMENT OF SAFE AND EFFECTIVE MEDICINES IN THE EU, INCLUDING PROVIDING SCIENTIFIC ADVICE AND PROTOCOL ASSISTANCE AND SUPPORT TO RESEARCH ACTIVITIES. (emphasis added).	It is a bit over the top. I think you should leave it to the reviewers of the paper to detect "incorrect analyses, unsupported inferences,". That is not your job! In this area,your job is just to provide scientific advice and assistance [1]
63		I support following the attached AllTrials response to the updated EudraVigilance access policy.	
64		Upon learning of your desire to seek powers to allow you to censor analyses of side effects data that your members disagree with, I was immediately struck by the complete and utter lack of morality shown by each of you! In short, you are suggesting to use coercive tactics to force researchers to “allow” you to decide what research they can and cannot have access to. And especially when negative information exists to support that a drug, process, pesticide or organism produces negative side effects and	

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		CAUSES HARM TO HUMANS, you want to be able to legally deny access to that vital information just because you don't agree with it! This is nothing short of BLACKMAIL! YOU don't get to decide what is and isn't necessary information! The FACTS do. What you have proposed is unconscionable and perhaps your resignations are in order!	
65		I am a strong supporter of transparency with regards to clinic trial data and a life-long sufferer of numerous chronic diseases and a long term interest in the development of drugs. I would like to add my voice by reiterating the points raised by Sense about Science and the AllTrials campaign.	
66		I am a supporter of the AllTrials Campaign and, I´d like to share my objections with the current policy on access to EudraVigilance. My strongest objections are related to the following points: - "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." - "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, I proposed that these two principles are removed.	
67		The EMA should not have the ability to block publication of analyses it disagrees with. We need openess to get the best out of the system. I fully agree with the comments made by the AllTrials campaign.	
68		As a scientific-practitioner I would urge you not to censor independent analyses. Independent analysis is what makes science and thus medicine work.	
69		I am concerned by the section that states:	

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		Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication. I feel that the Agency is taking on a burden it should not. It is the role of peer review and public scrutiny to validate the analysis, methods and conclusions of research, not of publishers. As a regulatory body, it also puts the EMA in a conflicting position, and would delay publication of clinical data unnecessarily. Re the protection of patient privacy there is of course no objection.	
70		I'm emailing to express my concern about plans by the EMA to censor the publication of reported side effects of European approved drugs. Such censorship serves pharmaceutical companies in obtaining approval for their medications but leaves the general public at great risk. Please don't censor independent analysis of medicines in Europe.	
71		A. I object strongly to the following two conditions: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” What is proposed is unworkable and these two principles should be removed. B. I am also concerned by the following principle: “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the	

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		results of that research will be made available to the broader scientific community. Proactive publication of ICSR data.	
72		I wish to add my voice to those calling for free access to Clinical Trial data for all pharmaceutical substances. I fully endorse the position of the authors of the All Trials campaign, to be found via the link below.	
73		I appreciate and applaud the policy as it gives researchers access to more detailed and systematic records from the database, but, If I understand this correctly it seems to contain conditions that would give the EMA the ability to block publication of analyses – and this should not be so.	
74		I object strongly to the following two conditions: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed.	
75		I support the all trial campaign 1. Simply because the EMA is the body collecting public data from EU patients does not give it the right to control how it is used.	
76	Page 23: 5.4.4.1. Reports of suspected	I have concerns about Section 5.4.4.1 in the "Draft revision of EudraVigilance access policy for medicines for human use". I do not believe the Agency should have the right to suppress publication if it has "issues" with it. I believe that publications should be available for anyone to judge: the Agency's judgments are not infallible. This is	

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	adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	effectively a form of censorship, and I disagree with it in the *strongest possible* terms. I write as a concerned UK citizen.	
77		I object to the following two principles: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed.	
78		I am writing in response to the consultation of the EudraVigilance access policy. The proposal would give researchers access to more detailed and systematic records from the database which is a good thing, but it also contains a condition that would give the EMA the ability to block publication of analyses it disagreed with. I COMPLETELY DISAGREE with EMA having the right to censor any data with analyses of side effects that it disagrees with. Researches should have access to all clinical trial information. We must ensure that healthcare professionals and the public have useful access to up-to-	

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		date information on serious adverse events contained within the database.	
79		All data in scientific studies about drugs MUST be public. Medicine is a matter of safety and health of people, not of markets and industries.	
80		I signed the petition circulated in response to your pharmacovigilance consultation because the EMA must not censor data that researchers should be free to view, analyse, interpret for themselves and share for academic, professional, and public scrutiny. The EMA is conflicted in making any decision on the pharmacovigilance data that can be viewed because as the regulatory body, it has a vested interest in appearing to approve for marketing only drugs that are 'safe' and therefore potentially has a low threshold for blocking access to reports that might be seen to suggest otherwise. The more people who can see and analyse all data the better for the safety and effectiveness of medicines in public use. Further, the EMA cannot set itself up as a 'peer reviewer' of researchers' work with a say-so on work undertaken. Professor Heneghan summarises the issues well and assuming his interpretation is correct, the EMA is setting itself up for huge conflict and justifiable charges of censorship. The conditions that the new policy would impose are not compatible with a free and open system of medicines appraisal.	
81		I'm writing to register my sincere concern at your proposal to block the publication of analyses you disagree with on EudraVigilante. This sounds to me like a massive loophole which would allow personal and private interests to interfere with that most fundamental of rights, healthcare.	
82		Please do not censor independent analyses.	
83		I respectfully request that results of trials should be fully in the public domain, and not modified in any way by the EMA, except where this is essential in order to preserve patient confidentiality.	
84		Please do not censor independent analyses.	
85		I welcome the update to the EudraVigilance access policy, with its increase in transparency. I am concerned however about the clause regarding the EMA controlling publication on the basis of "... issues raised by the Agency concerning incorrect analyses, unsupported inferences [and] misleading statements...". I have no issue with the protection of personal data, however. My concerns are: 1. These sorts of issues are handled already (to a greater or lesser degree) by public scrutiny and peer review; 2. Some cases will be a matter of degree or interpretation and there may be a large workload (and hence delays in publication) involved in communicating and addressing issues raised by the Agency; 3. In some cases publications may contain analyses of the	

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		Agency's own actions. It would be inappropriate for the Agency to have the authority to deny publication in these cases, and it is important for the continuing healthy running of the Agency that its workings should be open to scrutiny and criticism.	
86		I fully agree with the comments already made by the AllTrials campaign. The EMA should not have the right to supress papers it disagrees with. Nor should the EMA be allowed to deny access to data.	
87		I would urge you to please not reserve the right to censor data obtained by the above system - if you feel oversight is required then adding a footnote to such data setting out your reservations with it would allow doctors to make their own decisions as to whether the analyses were useful.	
88		I would like the EMA not to censor independent analyses.	
89		I am writing in support of the submission made by the AllTrials campaign regarding this draft and trust you will amend as per their suggestions.	
90		We should share all information to save time, effort, resources and ultimately the lives of prospective patients as well as lab animals.	
91	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Because I agree entirely with the contents of the AllTrials campaign, I reuse their comments with their permission and my full agreement. Comments on draft revision of EudraVigilance access policy for medicines for human use. This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use” from the AllTrials campaign. The AllTrials campaign was launched in January 2013 to call for all clinical trials to be registered and results reported. It is an initiative of Bad Science, BMJ, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative, PLOS and Sense About Science. It is supported by nearly 80,000 people and over 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world. Principles of access for research organisations We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.”	

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		"A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data. We support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 "Number of ICH E2B(R3) ICSR data elements" (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible.	

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		Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
92		There should be no censorship or editing of side effects raw data. Comments or cleansed data sets can be made available in parallel.	
93		I am a Senior Lecturer at UCL London, please register my concern at the proposals to edit the register in any way. I believe that all data should be open to all and that anything less is an immoral abuse of volunteers' willing participation.	
94		In the interest of safer medicines for all of us there must be no censorship of data or analyses submitted to the EudraVigilante database even if EMA disagrees with their conclusions.	
95	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency	This is a response to the consultation on the "Draft revision of EudraVigilance access policy for medicines for human use" from the AllTrials campaign. We areveryconcerned by some of the principlesin section 5.4.4. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions. "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported	

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96		Do not censor independent analyses.	
97	Page 23: 5.4.4.1. Reports of suspected adverse reports in	We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: - “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues	

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	EVPM The Agency will have a standard timescale for response to requests for extended data.	raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." - "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: - "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." - The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: - "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - We support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers.	

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98	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for	I am writing to voice my support of the AllTrials campaign assessment and comments on the above document (Reference number: EMA/759287/2009 Rev. 1). In particular: I am concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. I strongly object to the following two conditions: 1) “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” 2) “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated	

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	extended data.	in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. I also object to the following principle: "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community.	
99		Modern medicine is built entirely on the scientific method of investigation to understand the risks and benefits of any new potential medication or other medical intervention. This necessitates multiple investigations from multiple independent sources, the sharing of data, and independent review of both the data and the conclusions. Without these important steps, science devolves into superstition and marketing of snake oil. Companies and individuals within governments profit greatly from lack of transparency and lack of peer review. Without these important tools, unsafe or less effective medications and therapies can be introduced into the pharmacoepia. With greater transparency comes more reliability and safety. When there is no transparency, companies also benefit from lessened liability when something does go wrong with one of their products. Please scrap this ridiculous plan that would destroy modern medical science.	
100		I am writing to express my concern about the update to the EudraVigilance legislation. This appears to be yet another piece of EU legislation that seems to enable regulators, who are after all, public funded, and should therefore have….	
101		Please allow researchers access to the EudraVigilance database where reports on all suspected adverse reactions from approved drugs in the EEA are recorded. If the EMA has an analyses that it disagrees with, it can simply put a notice at the start of the	

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		publication in a text box.	
102	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	5.4.4.1. Reports of suspected adverse reports in EVPM • Those given access to EudraVigilance data should make appropriate efforts to publish their research. This needs strengthening to make it explicit that those given access to the data are expected to publish the results of their research.	
103		What use is the publishing of some, but not all of the analysis of side effects of drugs? It is the same as only reporting the good things and not the bad, or only reporting what works - a subtle form of scientific dishonesty. It is also poor oversight. I would equate it to a poor parenting practice of only feeding children what they want to eat (probably cakes and candy) - because they do not like to eat vegetables and a proper balanced diet. Any condition that would give the EMA the ability to block publication of analyses it disagreed with puts politics and other interests in the way of good science and the health of millions of people. Just don't do that!	
104		I'm writing in response to your proposed changes to EudraVigilance. I have been informed about this via the AllTrials campaign and totally agree with their response, in that EMA should not have the ability to block publication of analyses it disagreed with, which these proposed changes introduce. I have read their full reponse in detail and completely agree with it, so have attached it for reference.	
105		Please do not to censor independent analyses. This proposal contains a condition that would give the EMA the ability to block publication of analyses it disagreed with which infringes on freedom of publication and objective reporting of trial data. I'm in agreement with AllTrials response as attached.	
106		While I thank you for the EudraVigilance database I am concerned that the clause - "The Agency has the right to view any publication resulting from EudraVigilance data	

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		before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." is too open to abuse.	
107		Censoring analyses that that the agency doesn't agree with is unacceptable and dangerous. Analyses should be always available for peer review and open to the academia.	
108		Please keep results from trials totally open and accessible without editing the substance of their results at all when published on your database.	
109		I am just writing to express my concern about the following two clauses in the Consultation on Updates to EudraVigilance Access: - “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” - “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” To give the EMA the right to censor or suppress papers it does not like would seem to be a dangerous move, and would also surely result in a slightly circular situation where results could not be shared until they had approval, but approval could not be granted until the results had been shared (since the wider scientific community would surely need to be part of the process of evaluating the validity of the findings in question). Even if this is not the case, if important results end up being kept out of the public domain while the EMA involves itself in long-winded wranglings over things it doesn't like/isn't sure about, this could adversely affect patients whose lives might depend on the treatments dealt with in the papers in question. As such, these clauses would seem to be impractical and potentially harmful, and should surely be removed.	
110		Will somebody please grow up and stop interfering in publicly purchased. I wish to make my own choices about all chemicals that I might introduce into my body; I appreciate that vulnerable people might need help with this, but the only possible way is to make all data freely available even if this is potentially confusing. It is most	

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		definitely NOT for you (or others) to decide what should or should not be read or used. I expect all potential censoring paragraphs to be removed from this policy.	
111		Please do not allow the medical regulator to allow any form of data analysis in pharmaceutical trials. In doing so, the results would not be valid and indeed may endanger lives. For accurate analysis all data must be considered and none censored no matter how inconvenient the unwanted results to a particular trial might be.	
112		I am writing to ask that full access to data about rare side effects is available to independent researchers for re-analysis. Although rare I believe it is vitally important that patients are aware of potential risks and that health care professionals have the full information upon which to manage risks. I also think an independent review panel is vital when allowing third parties access to data. It should not be composed of employees or associates of the EMA, alongside health care professionals, researchers and also members of the public to ensure a systematic and open review of requests	
113	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	This is a response to the consultation on the "Draft revision of EudraVigilance access policy for medicines for human use" Principles of access for research organisations I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. I object strongly to the following two conditions: • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should	

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		be removed. I am also concerned by the following principle: • “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: • “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data. I support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in my view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. I am concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). These narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions	

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		(www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. Healthcare professionals and the public must have useful access to up-to-date information on serious adverse	
114		Please not to censor independent analyses.	
115	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	This is a response to the consultation on the "Draft revision of EudraVigilance access policy for medicines for human use" from the AllTrials campaign. The AllTrials campaign was launched in January 2013 to call for all clinical trials to be registered and results reported. It is an initiative of Bad Science, BMJ, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative, PLOS and Sense About Science. It is supported by nearly 80,000 people and over 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world. Principles of access for research organisations - We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: □"The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." □"A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed.	

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		B. We are also concerned by the following principle: “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - We support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data	

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		outputs from the European database of suspected adverse reactions *(www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection?* Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
116		I wish to lend my support to those protecting knowledge that benefits all when we can learn from mistakes or debatable publications. I am attaching the file of a position that I support.	
117		I agree with comments suggested by "AllTrials campaign / Sense About Science", please do not introduce barriers to data sharing.	
118		There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - We support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access There is disparity in the access provided to the different stakeholder groups listed in Table 1 "Number of ICH E2B(R3) ICSR data elements" (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain	

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		additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up- to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
119		I think it's very important to defend independent analyses of medical data.	
120		I am old enough to remember the Thalidomide tragedy of the 1950's & 60's & the profound impact it had, and is still having, on individuals & society alike. This led directly to more robust regulations for drug development and transparency in prescribing & usage. I feel that certain proposals in the EudraVigilance access policy for medicines for human use will have a detrimental effect on information available to clinicians, pharmacists and patients alike. I direct your attention to the submission from AllTrials, of which I'm sure you are aware. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf I am just a member of the general public, with no medical background whatsoever, who has to take regular medication for a genetic condition. I have to trust and rely on my GP, Consultant & pharmacist to prescribe the most effective medication for me & to keep me fully informed of what side effects I may experience and if these need further attention. How are they to do this if full disclosure of information is being prevented? Your proposals would effectively suppress publication of anything you disagree with. This is a retrograde step and needs serious reconsideration if you are to maintain the current levels of trust of both medical professionals & public alike. The understanding of Science & progress are inextricably linked and your proposals would deter greater knowledge. I respectfully request that you reconsider your proposals – you cannot move forward if you are taking backward steps.	
121	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency	I am very concerned by the following principles in section 5.4.4.1. (page 23) I object strongly to these two conditions: The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.	

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	will have a standard timescale for response to requests for extended data.	A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer. I am also concerned by the following: An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency. I am also concerned by the following principle: An ad-hoc EMA panel will review requests for research access to data based on a research request. The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency. And I believe the following principle - Those given access to EudraVigilance data should make appropriate efforts to publish their research could be strengthened to require research organisations to submit the results of their research for publication.Proactive publication of ICSR data. I support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data . Data being published proactively should be up to date and not withheld for publication in batches. One improvement that open FDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1: Number of ICH E2B(R3) ICSR data elements (page 11) .This is hard to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2H1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse event s reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37) . This information is useful for healthcare professionals to be able to identify possible interaction s between	

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		treatments. Additional question 1. As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes.	
122	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: - "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." - "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: -"An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to	

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		prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: - “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data We support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: - “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data We support the EMA’s aim of granting proactive access to more individual case	

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123		Suppressing data is not science, if any data is hidden, that which remains is rendered worthless. Please act in the interests of knowledge and science.	
124		I am writing to express my concerns about the proposal to censor use of the EudraVigilance dataset. I am also concerned about the attempt to frame this as increasing transparency, when in fact it is a plan to increase opacity and aggravate the asymmetry of information access between industry and the public. I do hope that justice prevails, and these plans are abandoned.	
125	Page 23: 5.4.4.1. Reports of suspected adverse	This a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use”: Concerning principles of access for research organisations: I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations.	

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	reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	A. I object to the following two conditions: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to suppress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. I am also concerned by the following principle: “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is	

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126		Please, do not censor independent analyses of all clinical Trials!	
127	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a	I object strongly to the following two conditions in section 5.4.4.1. (page 23): • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved	

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	standard timescale for response to requests for extended data.	disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed.	
128		Researchers need access to more detailed and systematic records from the database without the EMA blocking publication of analyses it disagrees with.	
129		Please ensure that there can be no censoring of side effects data made available through the EudraVigilance database. There should be free and unrestricted access to this data to support researcher, doctor and patient understanding of the effects of drugs that may be prescribed.	
130	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended	I don't believe your suggestions put forward in section 5.4.4.1 (page23) are especially good ideas. In particular, that: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." And: "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These sounds like they would give EMA the right to supress anything it doesn't like.	

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	data.	That simply sounds bad from a research point of view as well as impractical.	
131	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use”. I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. I object strongly to the following two conditions: - “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” - “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. I am also concerned by the following principle: - “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, I believe the following principle could be strengthened to require research	

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		organisations to submit the results of their research for publication: - “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data I support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in my view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. I am concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). These narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that I as a healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for me as a healthcare professional to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up- to-date information on serious adverse events contained within the database.	

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		Providing access to these data in additional formats will enable them to make better use of the data.	
132		I believe it is critical that there is no chance of drug company bias or regulatory censorship and agree wholeheartedly with the attached.	
133		I fully support the positions taken up by the AllTrials campaign on the principles of access for research organisations, proactive publication of ICSR data, restrictions on access as outlined in their comments dated Sep 11 2014.	
134	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I am writing to ask you to please ensure healthcare professionals & the public have clear & transparent access to all data & up to date information on serious adverse events contained within the database. I am very concerned by the principles in section 5.4.4.1 (page 23) where access to the data is granted to research organisations.	
135		The policy of the agency with regard to making available data from clinical trials, including RCTs, and including those conducted by pharmaceutical companies has shown some signs of greater transparency in recent months. However, the current proposals to restrict access to ADR reports (and even to redact the interpretations made of them) will do a great deal to reverse those moves towards greater access and to undermine the validity of the system. I object to those proposals. Over generations, science has developed mechanisms to ensure that the truth will be found by research. Those mechanism include peer review, publication, and replication. As with all human enterprises, this process is fallible. However, the principle has served mankind well over the centuries. The more eyes that are cast on a problem, the greater the likelihood of a beneficial outcome eventuates. Individual scientists make mistakes, but the enterprise of science is designed to correct those mistakes. By giving administrators privileged access (as you currently propose) you would undermine that epistemology. I wish therefore to register my objection to the proposals by Eudravigilance. You would serve patients, and science, better if you were to adopt the	

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		principles proposed by the AllTrials network or by Sense about Science in the UK.	
136		I understand there is significant concern that the proposal to give researchers access to more detailed and systematic records from the database also contains a condition that would give the EMA the ability to block publication of analyses it disagreed with. This may amount to censorship which is outdated and counterproductive. I would ask that independent analyses remain uncensored.	
137		This is a very short email, a more detailed one will follow. I think your draft does not give you enough powers to disagree with the findings of drug companies. You represent us, not drug companies.	
138		I am writing as an EU citizen, an independent medical journalist and a supporter of the AllTrials campaign. I am concerned that the proposed changes to access to the Eudravigilence database will constrain scientific research and independent analysis. In particular, I object to the following conditions: • “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” • “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” This could amount to unilateral censoring of independent data that the agency disagrees with and is not in the spirit of transparency expected from the EMA. I urge you to withdraw these conditions.	
139		I support the concerns and critical views on the update draft expressed by Síle Lane (Director of Campaigns) at Sense About Science.	
140	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency	This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use” from the AllTrials campaign. The AllTrials campaign was launched in January 2013 to call for all clinical trials to be registered and results reported. It is an initiative of Bad Science, BMJ, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative, PLOS and Sense About Science. It is supported by nearly 80,000 people and over 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world. Principles of access for	

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	will have a standard timescale for response to requests for extended data.	research organisations - We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: • “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” • “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: • “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: • “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - We support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published	

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		proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
141		I'm concerned about the clause allowing analyses you disagree with to be censored. All must be published, for transparency.	
142		I strongly object to the right of the Agency to add a disclaimer to scientific manuscripts, and to the prohibition to publish or cite in meetings ("The manuscript or its conclusions must not be disseminated in any way without the disclaimer", pag. 23). I also object to the right of an "EMA-panel" to refuse access to the data. I feel that the data should be freely accessible to researchers. Moreover, I strongly support the hypothesis of giving free access to up-yo-date information about reported adverse effects of drugs.	

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143		Please consider carefully the detailed response sent by the 'AllTrials' campaign to the "Draft revision of EudraVigilance access policy for medicines for human use". I fully support their considered reply on this matter.	
144		Please do not give the EMA the right to supress any material with which it disagrees. This would amount to censorship of scientific discussion and analysis of public health data and is not in the public interest. Additionally, the panel reviewing requests for data access should be independent of the EMA to prevent conflicts of interest.	
145		I am concerned about proposals to allow the EMA to block the publication on analyses on approved drug side effects. Who will be responsible for deciding which results to withhold? In order to advance medicine in a scientific paradigm it is necessary that the results of all clinical trials both positive and negative are available to researchers. Of course this may negatively affect the profit margin of pharmaceutical companies, but without this transparency drugs will be administered with incomplete knowledge of their effects. I believe that every citizen has the right to know the results of clinical trials for drugs administered by doctors. Please do explain if my concerns are unfounded.	
146	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	This is a response to the consultation on the "Draft revision of EudraVigilance access policy for medicines for human use". We are very concerned by some of the principles in section 5.4.4.1 (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer". These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are	

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		flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and should be removed. B. We are also concerned by the following principle: “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require Require research organisations to submit the results of their research for publication. “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” Proactive publication of ICSR data - We support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access There is a disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B (R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments.	

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147	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I'm responding to your invitation to comment on the draft revision of EudraVigilance access policy for medicines for human use. I am very concerned by section 5.4.4.1. covering access to data for research organisations. I object strongly to these conditions: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." and also "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." They appear to give EMA the ability to suppress observations in a researcher's paper. The agency collecting public data from patients should not have the right to control its use - censorship of scientific discussion and analysis of public health data. Please remove both. I am also concerned by the following: "An ad-hoc EMA panel will review requests for research access to data based on a research request. The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." and am convinced any panel that reviews requests must be independent of EMA to prevent conflicts of interest. Lastly I ask that the following principle could be strengthened to require all research organisations to submit the results of their research for publication: "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There must be an expectation that access to these data for research purposes is granted on the basis that results of that research will be made available to the broader scientific community.	
148	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a	I object strongly to the following two conditions: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be	

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	standard timescale for response to requests for extended data.	disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed.	
149		I am writing as an individual, and potential researcher, and I thank you for the opportunity to respond to the consultation. I have several concerns that I would wish to be considered, and would want the guidance amended to reflect these; Principles of access - I object to the conditions associated with section 5.4.4.1. (Page 23) that the Agency has a right to view any publication before submission, and that the manuscript cannot be disseminated in any way without the disclaimer. While I accept that these may be driven by a laudable aim of ensuring standardisation and full analysis, I believe that effect will acta in a way that will be seen as censorship, will potentially delay data submission through extended argument prior to publication, and will act as a control mechanism in a way that is invidious and wrong. I am also concerned by the following principle: □"An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." This seems to me to be self-serving and the nature of scientific debate must include examination of ALL health and legal responsibilities. Finally I strongly believe that we should have a condition inserted whereby research organisations are expected to publish if they are accessing the data. It cannot be used a fishing expedition. This would also be in line with increased proactive publication of ICSR data which I support hugely. This openness and commitment to proactive publication does seem to be undermined by the restrictions on access in Table 1 "Number of ICH E2B(R3) ICSR data elements" (Page 11); I think that the EMA should provide as much access as possible especially to information adverse events. In particular it would be helpful if both healthcare professional 9 Group II and research organisation (Group IV) should have access to both narratives and summaries. Additional question 1. As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain	

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		additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. This must be ensured.	
150		I would urge you to safeguard that independent researchers have access to all trial data regardless of findings as patient safety should never be compromised.	
151	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Please find below my comments to EudraVigilance access policy. It is in line with the comments of AllTrials. Principles of access for research organisations We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: - “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” - “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to suppress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: - “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the	

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		EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: - “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - We support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	

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152		I agree with AllTrials campaign. EMA should not censor independent analysis of trials data. I am in favour of removing the condition that would give the EMA the ability to block publication of analyses it disagrees with.	
153		I am a supporter of the All trials campaign and urge you to address the concerns raised in the All trials response to your consultation.	
154		I support the AllTrials group response on this matter. The default position should be openness, the interests of patients should come first before the interests of industry. Any problems with patient identity could be easily dealt with.	
155		I am writing to declare my support for the position taken by the AllTrials campaign regarding the proposed updates to the EudraVigilance policy. It is most important that researchers and clinicians may have access as freely as possible to data on suspected side effects. Proper precautions must naturally be taken to protect patient confidentiality. But I believe de-identification can in most cases be easily performed by redacting the data, e.g. replacing exact figures for age and other variables with categorical interval data. The key principle must be that data should be as available as possible, with minimal scope for discretionary judgement on data release requests. Also, any controversies over interpretation are likely best dealt with in the open. The EMA should not assume responsibility for interpretation made by independent researchers. I appreciate this opportunity to contribute my opinion in open consultation.	
156		I object strongly to the following two conditions: The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Open debate is essential. Problems will arise, but the net effect on the world will be beneficial. I am sure that deep in your heart you realise that is true.	
157		I would like to object to any attempts to withhold data from general access. The	

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		disgraceful examples of cherrypicking and skewing of research data has shown that the pharma companies and the institutions they fund cannot be trusted to act in the public interest at large. The following references to EMA powers at best will undermine the intended benefit to the public of all data. At worst, it will render the changes worthless. "EudraVigilance is the database where reports of side effects from approved drugs in Europe are recorded. The proposal would give researchers access to more detailed and systematic records from the database but it also contains a condition that would give the EMA the ability to block publication of analyses it disagreed with."	
158		It is vitally important that all clinical trials to be registered and results reported in a fully open and transparent manner. In particular: I do not believe that the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. In addition, the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. I fully agree with all the comments on the draft revision of EudraVigilance access policy for medicines for human use from the AllTrials campaign (Reference number: EMA/759287/2009 Rev. 1, dated 11th September 2014).	
159		I would like to register my strong objection to giving the EMA the right to suppress anything in an academic paper or an analysis that it disagrees with. This is a profoundly outdated world view. This would amount to state censorship of scientific discussion and analysis of public health data, which is unacceptable.	
160		As a general practitioneer I'm very concerned about the EMA planing to censor urgently needed critical and independent analysis of clinical trial data. I support the attached letter of the all trials campaign.	
161	Page 23: 5.4.4.1. Reports of suspected	in reference to the proposed policy EMA/759287/2009 Rev. 1, I am writing to represent the following: - section 5.4.4.1 page 23: I object to the right of EMA to expect satisfaction on all issues raised in preview of publications before submission; I do not object for all questions regarding privacy checks and the possible reidentification of	

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	adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	patients. - I strongly advise the composition of an independent panel to review data access requests. - I strongly advise a monitoring policy on effective publication of results (or documented efforts for publications, with reviews and penalties) for all research requests. - I support appropriate access for researchers to anonymized case narratives.	
162	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I strongly support absolute transparency regarding these issues, since that could improve the lives of many patients and save efforts and resources. This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use” from the AllTrials campaign. The AllTrials campaign was launched in January 2013 to call for all clinical trials to be registered and results reported. It is an initiative of Bad Science, BMJ, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative, PLOS and Sense About Science. It is supported by nearly 80,000 people and over 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world. Principles of access for research organisations - We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” - “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the	

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		right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: - “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: - “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - We support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious	

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163	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	This a response to the consultation on the "Draft revision of EudraVigilance access policy for medicines for human use" from the AllTrials campaign. The AllTrials campaign was launched in January 2013 to call for all clinical trials to be registered and results reported. It is an initiative of Bad Science, BMJ, Centre for Evidence based Medicine, Cochrane Collaboration, James Lind Initiative, PLOS and Sense About Science. It is supported by nearly 80,000 people and over 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world. Principles of access for research organisations - We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific	

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		discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: • "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: • "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data- We support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 "Number of ICH E2B(R3) ICSR data elements" (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean	

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		that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
164		I'm writing to voice my concern regarding section 5.4.4.1. (page 23). It seemingly gives EMA free reign in censoring any part of publications it disagrees with. This should not be part of the responsibilities of EMA. EMA should provide open access to publications, not enforce its views.	
165	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	About the Principles of access for research organisations, I am concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. I object strongly to the following two conditions: • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should	

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166	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for	I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. I object strongly to the following two conditions:• "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its	

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167	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	The AllTrials campaign was launched in January 2013 to call for all clinical trials to be registered and results reported. It is an initiative of Bad Science, BMJ, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative, PLOS and Sense About Science. It is supported by nearly 80,000 people and over 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world. Principles of access for research organisations - We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: 1. "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." 2. "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a	

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168		I would like to register my disagreement with some aspects of these updates. Specifically this section: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” Protecting individual patients’ privacy should be the only criteria by which the Agency should be able to withhold publication until the concerns have been addressed. The agency must not be able to suppress any other content, even if they believe it is wrong (in their view). We are not idiots and the information will be reviewed, but in the public domain and not behind the closed doors the EMA.	
169		The first section of this is reasonable - a privacy check which may allow the re-identification of patients is clearly an important part of the role of publishing data. This should stay. However, censoring 'incorrect analysis ' is a seperate concern, and goes goes far beyond the remit of the EMA - because who decides what 'incorrect' is? This must be a role for the scientific community at large. The EMA may have a stake in contributing their opinion, but it cannot be the only opinion and the final arbiter of what is 'correct' and publishable. I think it would be reasonable for the EMA to publish a stated opinion on the conclusions contained in a paper, in the same way that company accounts are audited by accounting companies as to the truth and fairness of their contents. However I strongly disagree with the outright censorship which the paragraph	

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		above would appear to allow. “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” Interestingly, I think I would support the above (as the antidote for the EMA) to the removal of the ability of censorship; but only as a purely additive addendum to a paper. It may not censor the original conclusions. It provides a mechanism for EMA to give feedback (when it wishes) on what it may consider to be poor research, and to set out the the explicit places where it disagrees with any conclusions or analysis - in the same way an auditing firm may withhold their sign off of company accounts. It does not appear to represent censorship in this form, and could potentially be used as a powerful tool to drive up the quality of research when used in a constructive manner - disagreement is healthy when transparent and properly dealt with. With regard to this principle; “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” This has value as a gatekeeper to those who shouldn't have access to the data for whatever reason; but the panel simply must be independent of, or have a majority composition of members outside of the EMA, such that the EMA cannot influence the outcome of a vote. There appears to be such a clear conflict of interest here that a series of loud alarm bells went off in my head. Unless I misinterpret the power of this committee, in it's current form this is unacceptable - although perhaps not intended for use as such, unchecked it would appear to represent a clear opportunity for censorship via the back door in future. Finally; “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” What is the definition of 'appropriate efforts'? This is too woolly for my liking. Incomplete or inconclusive research may still have value. I believe it should be mandatory to publish - this is a simple, enforceable definition. The EMA could simply include (by agreement with the 'publisher') in a statement of opinion that the research is incomplete or inconclusive to mark it as such. This neatly absolves the 'publishing' researcher from further effort or 'responsibility' for it, and acts as a marker for the reader that the paper is 'not to be trusted'. Furthermore, that any conclusions drawn from it are the responsibility of the reader, and *not* the author or the EMA. Apologies for the length of the email - I hope my opinion was constructive to the debate.	

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170		Please, do not censor independent analyses. I agree totally with the AllTrials comment. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
171		All data is subsidised by us, the tax payer through research funds. Logically, all RAW data should therefore be made available to ALL tax paying individuals within the European Union.	
172		I disagree with the EMA stance, in wanting the right to censor analyses of side effects data that the EMA disagrees with.This goes against open, transparent quality research. I am writing this email to voice my opinion on the matter.	
173	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I wish to place on my record my view that it would be wrong for your agency to be able to "censor" independent researchers use of data, cf sections 5.4.4.1. Psychiatric patients have suffered greatly in the past because of suppressed research results.	
174		I support full access to all trial data. Censoring data is bad for science, bad for doctors and bad for patients. Please allow unrestricted access to all data so that patients can be prescribed the most appropriate drugs based on their needs rather than those of the pharmaceutical companies.	
175		It seems to me very important to pay attention to the analysis in the pdf below. This really matters for the future of our health and our medical progress. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
176		I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-	

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		EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
177	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I'm a fourth year graduate student at the university of Oxford. I'm very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. I object strongly to the following two conditions: • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Please put transparency and freedom of publication, and therefore the health of the public, before anything else.	
178		I strongly feel that researches should have free access to trail outcome and toxicity data. Patients enter clinical trials so that their suffering and treatment can benefit others. Any ability to limit access to data generated can potentially reduce this benefit. If there is to be a body overseeing access it should be entirely independent of the MDA. It is essential that all trial data is published and available for research	
179	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for	Generally I agree with the principles given in the policy document. However I do have strong concerns about the following (section 5.4.4.1): "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer."	

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	response to requests for extended data.	1) While the proper protection of patient privacy is of course very important, this seems to go much further and would seem to give the Regulator the right arbitrarily to censor scientific publications. This is not acceptable and not the proper function of a Regulator. If there are incorrect analyses, misleading statements etc, then these should be addressed and resolved by the normal processes of peer review and public discussion and debate within the scientific community. No one Agency is or should be in a position to be sole judge and jury in these matters. 2) It seems to me that this is in any case unworkable. To determine whether there are incorrect analyses etc, the Agency would have to complete the peer review process alluded to in 1). Further, they have set themselves a time limit of 6 weeks to do this. There are 28,100 scientific journals in print today, with over a million articles published each year. How could this task possibly be resourced?	
180		I'm writing to respond to your request for comments. I fully support the AllTrials position that has been submitted: please remove the conditions in your policy that allows the EMA to delay or censor the publication of analyses. The scientific community and peer review process is well capable of self-policing.	
181		Do not to censor independent analyses.	
182		I am concerned by some of the principles under which access to the data is being restricted. In my opinion, immediate access to greater amounts of data will benefit patients, health workers, doctors,pharmacists, regulators and researchers.	
183		What follows is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use” from the AllTrials campaign, which I whole-heartedly and without reservation support. Few issues in modern medicine are as important as the one of clear research results and free and open access to those results. Please read this response and give it your consideration. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
184		I would like to register a serious concern to the EMA regarding the issue of side-effects only being made public when the EMA agrees with the data. I believe that the data should be publicly available to independent researchers especially. Many observers can spot many problems and solutions. I make this submission on behalf of All-Trials and applaud progress towards transparency so far.	
185	Page 23: 5.4.4.1.	As a teacher of science and a European citizen and strong supporter of Evidence based medicine I generally welcome the proposed changes. I have one area of concern,	

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	Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	rooted in the principles outlined 5.4.4.1. (page 23). I don't believe it is appropriate for the agency to block findings it disagrees with the use of the data or the methadology. While I believe it right and appropriate that the EMA should raise concerns about any methodology and place reasons for any disagreement it has with any conclusions the public domain, discussed, I believe that that such publications should be allowed to go through the normal peer review process rather than blocked by the regulator. In answer to the question 'would you consider it useful to obtain additional data outputs from the European database of suspected adverse effects?' I most certainly would.	
186		I agree with the All Trials Campaign and regarding the access to EudraVigilance changes in policy in particular A. Principles of access for research organisations Research Organization should be able to publish the results of their analyses of data independent from the opinion of the database holder. "This would amount to state censorship of scientific discussion and analysis of public health data." The results of analyses and conclusions are the responsability of the authors, not the holders of the database. "Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny." In fact, openFDA gave access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Additional question regarding obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu). Yes. Healthcare professionals and the public need access to up-to-date information on serious adverse events contained within the database and an easier format helps with better use of the data.	
187		The truth shall make you free! Please do not support following amendments they are outrageous censorship and undermine freedom of information we are ALL entitled too “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” • “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword	

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		the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer."	
188	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I urge the EMA to make only changes that increase openness and reduce the power of drug companies or other vested interests to slant or suppress information. As a health journalist, I try to provide my readers with accurate, honest and unbiased information. This isn't possible when 'inconvenient' findings are suppressed or left unpublished, which is why I support the AllTrials campaign. It is essential to have the fullest possible information about important concerns such as side effects. So I support the EMA's proposal to give researchers access to more detailed and systematic records from the Eudravigilance database. However, I am worried about some of the proposed conditions in Section 5.4.4.1. First: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These two conditions should be removed, as they would give the EMA the ability to suppress anything it disagreed with. This in turn would increase the likelihood of pressure being applied to EMA by vested interests to hide unflattering information. Second: "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." It's important that research requests should be reviewed by an independent panel, to avoid the risk of conflicts of interest. Third: "Those given access to EudraVigilance data should make appropriate efforts to publish their research." This should be strengthened to ensure that researchers using this information make their findings publicly accessible. In total, I support the comments made by the AllTrials campaign.	
189		As a scientist I welcome your work attempting to give researchers access to more detailed and systematic records from the database. It is, however, totally inappropriate and unethical for for the EMA try to block publication of analyses it disagrees with.	

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190		I object strongly to the following two conditions: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
191	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I am a supporter of the AllTrials campaign. This is a response to the consultation on the "Draft revision of EudraVigilance access policy for medicines for human use". The AllTrials campaign was launched in January 2013 to call for all clinical trials to be registered and results reported. It is an initiative of Bad Science, BMJ, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative, PLOS and Sense About Science. It is supported by nearly 80,000 people and over 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world. Principles of access for research organisations I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. I object strongly to the following two conditions: - "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." - "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because	

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		the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. I am also concerned by the following principle: - “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - I support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. I am concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have said that in their	

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		experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question - 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. You must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
192		Please refrain from censoring EudraVigilance data ~ without full disclosure independent analysts cannot make the informed decisions they're aiming for. You may have good reason to suspect that certain data is false or misleading, but if you don't credit others with the intelligence to notice any / all flaws themselves, you discredit all their work and put everyone's health at risk; complications that full disclosure could have prevented happen all the time. If you wish to make it clear to independent analysts that you believe certain data is unworthy of their attention, present them with your reason/s when you present them with that data ~ the more information they have the quicker they'll reach a sensible conclusion.	
193		Data concerning safety of drugs affect citizen’s health. It is mandatory, above all for health agencies, share these data and inform the public about risks and safety of drugs. If not pharmacovigilance becomes meaningless.	
194		I do not agree with this if it allows you to censor independent analyses you don’t agree with. It is equivalent to stifling freedom of speech. We do not live in a totalitarian state. Our strength comes from people having freedom to express their views without fear of suppression or oppression in order to maintain a balance and prevent people with power from abusing it. Being able to suppress analysis you don’t agree with is an abuse of your power.	
195		Endorsement of Comments on draft revision of EudraVigilance access policy for medicines for human use from the AllTrials campaign http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	

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196		I completely endorse the comments on draft revision of EudraVigilance access policy for medicines for human use from the AllTrials campaign (see below). Indipendent analysis must not be censored, anyway. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
197		I strongly oppose any attempts at limiting access to EudraVigilance information. The details and reasons, as formulated by the AllTrials campaign (see attached) should be sufficient - however, I wish to add a statement of my own. I have been a computer science professional for the last 15 years. In that time, I have encountered countless incidents of software bugs which were caused by - Insufficient testing - Testing based on flawed assumptions - Poor testing due to (largely) involuntary bias by the tester. This is most commonly the case when the person creating the software also tests it. - Non-repeatable testing, i.e. when multiple executions of the exact same conditions are impossible, because the conditions are not sufficiently recorded or published. These are by far the most common causes for bugs that get shipped to the customer. And these causes can all be largely prevented by processes that enforce the sharing of testing procedures and results. In response to this problem, we founded spriteCloud, a company dedicated to bringing fair, impartial testing procedures to our customers development teams - and the response from our clients is overwhelmingly positive. A software test is largely equivalent to a clinical trial**.** Differences exist in what gets tested, and how it gets tested, but the underlying processes are identical, and an intrinsic part of the scientific method: you record all conditions you test, all test procedures, and all test results. Then you share the test results for others to verify. Failing to do any of that leads to bugs. We can laugh off the infamous "blue screen of death" that has plagued most everyone working with computers, but the same cannot be done for the real, personal death that badly tested medicine can cause. Without full access to test procedures and results, doctors cannot ensure that the medicine they prescribe is safe. The only available method for improving the quality of drugs is to share all test results equally. As a professional whose work life revolves around verifying other people's contributions, I strongly urge you to take heed of the AllTrials response, and reconsider your proposal.	
198	Page 23: 5.4.4.1. Reports of suspected adverse	This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use”. I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. I object strongly to the following two conditions: - “The Agency has the right to view any publication resulting from EudraVigilance data before submission	

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	reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	(maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." - "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to suppress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. B. I am also concerned by the following principle: - "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: - "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community.	
199		I completely agree with All Trials position on this question http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
200		Please see attached the correspondence from AllTrials Campaign which I support http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
201	Page 23: 5.4.4.1. Reports of suspected	I am extremely concerned that your organisation seems to want to censor some trials data (section 5.4.4.1). The whole point of having access to all clinical trials is that it should be all clinical trials and not just those that you agree with. If you believe that there are incorrect analyses, unsupported inferences, or misleading statements, then it	

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	adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	would be reasonable to make such comments as an addition at the bottom of the unaltered trial report, but any such comment must include, and be supported by, reasoned, scientific argument explaining why you consider the analyses to be incorrect, the inferences are unsupported, or statements are misleading, and the authors of the report must be given the opportunity to add a response after your comments because it may be that your view is a misunderstanding of the report, or is just wrong, because you cannot have the amount of knowledge of all medical matters that would be required for you to comment on all trial reports. I am also concerned at the conflict of interest in the EMA reviewing requests for access to data, as some such accesses may draw attention to the EMA's own decisions, and the EMA should not be able to prevent such access. The review panel should be entirely independent of the EMA. Finally the statement on publication should read "Those given access to EudraVigilance data must make every effort to publish their research."	
202		I would urge the EMA to remove those conditions in section 5.4.4.1 which appear to give the EMA the right to veto or require the editing of publications and to control access to data on the basis of criteria that it does not necessarily make public. It is for the broader scientific community, not a self-appointed censor, to analyse, question, and seek to improve the data on which decisions affecting the lives - and indeed deaths - of millions of people may depend.	
203	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny.	
204	Page 23: 5.4.4.1. Reports of suspected	We at The Copenhagen Trial Unit are concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. We object strongly to the following two conditions: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period	

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	adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	for initial Agency review will be six weeks) including a privacy check as regards possible Re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication" "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles seem to give the EMA the right to suppress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from trial participants does not give it the right to control how they are used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, such actions would entail that EMA should have a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles ought to be removed. We are also concerned by the following principle: "An ad hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of EudraVigilance data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals and the data ought to be depersonalized. The EMA can redact identifiable patient information from reports on rare adverse events and effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to patient or participant narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). In general, the EMA should work for more transparency not only regarding drugs, but also regarding devices and other interventions/treatments.	
205		I object strongly to the following two conditions: • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period	

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		for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." I am also concerned by the following principle: • "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency."	
206		I am writing in response to the request for comments on updates on the access to EudraVigilance policy. I am concerned by proposals that "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These proposals appear to amount to censorship of analyses that the EMA does not agree with, and thus is antithetical not only to scientific freedom but also to the underlying values of the European Union, as expressed in Article 11 of the Charter of Fundamental Rights of the European Union: 1. Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. The decision to suppress analyses with which the EMA disagrees are likely to be vulnerable to legal challenges under EU law, and also potentially under Article 10 of the European Convention on Human Rights when the EU accedes to it. Citizens of the Union do, of course, have a right to privacy, and it may be acceptable to impose checks on whether or not privacy rights have been respected, but this is an entirely different issue to restricting publication of analysis which the EMA disputes. If the EMA disputes the	

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		analysis of EudraVigilance data, it can publish a response setting out why it disputes the analysis. The researchers can then respond, publicly. The public and the media can then come to an informed view, and other scientists can contribute to discussions and debate. But proposals to limit public discussion of these analyses entirely run absolutely counter to the scientific progress and modern democratic ideals. Citizens of the European Union also have rights to access information (Article 11 of the CFREU; Article 10 ECHR). The agencies of the EU are obliged to 'conduct their work as openly as possible' (Article 15 TFEU). Proposals that review panels could limit access to the data 'if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency' potentially represent a form of censorship. Such panels will be necessary to protect privacy rights, but should be independent of the EMA to dispel and real or perceived concerns about conflicts of interest, especially should the proposed analysis dispute that of the EMA.	
207		As a patient with a history of 34 years of suffering serious side effects and irreversible damage, natural justice must be served. Interference from commercial interest to this justice Must not be allowed. Novonordisk, Abbott and Beyer are all running cartels to stop access to information to stop patients suing claims.	
208		Please decide to allow independent analysis of shared drug trial results. Not only is it the right thing to do, it is also the smart thing to do, as that regulatory regime that garners more truth will be as the farmer that gets a bigger better crop. That's the long view. Some may argue the reverse, and believe that whatever maximizes benefit to the company maximizes benefit to society, but these views are wrong. This is the short view, the view of a poor farmer with no confidence. It is up to you to determine if the long view (with appropriate measures taken to ensure harvesting the result of good decisions) prevails.	
209		We need full disclosure of ALL clinical trial data. Sharing anonymised patient data about drug effectiveness and side effects of ALL clinical trials is an absolute must to ensure the transparency the EMA claims these changes enhance. Patients and medical professionals need to know that ALL the data is in the public domain if public trust in drug trials and the validity of claims about drug effectiveness and the side effects of drugs is to be maintained.	
210	Page 23: 5.4.4.1. Reports of	My response to your consultation is that which has been said very well by the AllTrials campaign. I have included the text of their response to you below: Principles of access for research organisations - We are very concerned by some of the principles in section	

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	suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: i) “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” ii) “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community.	
211		In response to the consultation on the above I would be grateful if it could be noted that I agree with the comments submitted by Sile Lane for the Alltrials campaign. It is essential that doctors and patients have full information on the adverse effects of	

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		medicines.	
212		It is good that the access policy will allow researchers access to more detailed and systematic records, but if the EMA can then block publication of some analyses, then the access policy is pointless.	
213		As a student who took part in the AllTrials campaign, because I believe in transparency and free sharing of information, I want to express my concern about the new policy that was recently proposed by your agency. Members of the AllTrials campaign released an official statement (available here: http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf) in which they say they believe that the two following principles (1: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” and 2: "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.”) are not simply a new form of peer review, but may give the EMA the right to supress anything in an academic paper that it disagrees with. That would be unreasonable and wrong. As the AllTrials official statement puts it: "Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data." In addition to that, I want to join the AllTrials campaign in requesting that the panel who examines research request is independent from the EMA and granting access to all the information needed to healthcare professionals and research organizations.	
214		This seems to be counter to the purpose of independent analysis of medical trial results. By nature, independence should lead to some form of public response to meta trials of medical data. Specifically, the purpose of publication is to allow others to review the results of any analyses and critique them. The censorship proposed adds a layer of secrecy to such analyses which is counter to the concept of independent analysis.	
215		In context of the public consultation on the Draft revision of EudraVigilance access	

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		policy for medicines for human use, please find EORTC's comments/questions in attachment. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
216		I would agree with the AllTrials group that the following two conditions in the "Draft revision of EudraVigilance access policy for medicines for human use" willhave a chilling effect on scientific discussion and the robust analysis of public health data: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These two conditions are overly weighted to the Agency view, too concerned at controlling the process of scientific review, show a lack of faith in the scientific community and should be dropped.	
217		The EMA should not have the right to censor access to side-effects data. It is important that healthcare professionals be able to use a complete range of data and decide the validity of this themselves.	
218		Please do not provide any medicinal regulator apparatus (or indeed, anyone) the right and/or power to censor information about adverse side effects in the EudraVigilance database. Do provide the public and researchers direct access to the data, but do not let anyone censor them! There are very many rare diseases which afflict people all over the world. Many of those afflicted suffer from a severe lack of research in these areas. I myself have two children with autoimmune diseases, one of which is extremely rare (juvenile dermatomyositis). Making the uncensored data freely available would enable independent researchers to make meaningful contributions which might not be possible if the database is censured. I urge you not to allow any form of censure with regard to data over side effects.	
219	Page 23: 5.4.4.1. Reports of suspected	I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. I object strongly to the following two conditions: • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
	adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. I am also concerned by the following principle: • "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls.	
220	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for	Concern has been raised about the statement below. While I fully support the right to review publications for protection of personal data, the two clauses are contradictory in the case of interpretive disagreement. The disclaimer that there is disagreement about interpretation of the data should be used, instead of "issues raised must be addressed to the satisfaction of the Agency". I would suggest you instead state "issues raised by the Agency must be addressed prior to submission of any manuscript. In the case of continued disagreement a disclaimer to this effect must appear in the submission." 5.4.4.1 The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences,	

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	response to requests for extended data.	misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication. • A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.	
221		Do not water down or bow to commercial pressures the legislation for academics to view and use patient data stick to the recommendations of the AllTrials campaign that is backed by nearly 80,000 people and over 500 organisations including regulator; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups across the world.	
222		I reiterate what Prof Heneghan stated: What is proposed is unworkable, and what is clear is regulators are using these measures to prevent more open scrutiny of its databases. This is unacceptable and will lead to delays and inappropriate use of resources.	
223		In support of the All Trials Campaign, I am write to express my view that the EMA should not be allowed to block the publication of analyses it disagrees with.	
224		I am very concerned at the recent proposal that the EMA should have the power to add disclaimers to, prevent dissemination of, or refuse access to, publications of research containing information that they disagree with. Please can you explain how interfering with the free dissemination of such research (based on public data) in this way can possibly be justified?	
225		I am a UK Medical Student and a strong advocate for the AllTrials Campaign, which seeks to enable me and my colleagues to use evidence-based therapies with full and up-to-date knowledge. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
226		PHARMIG, the Association of the Austrian pharmaceutical industry, welcomes the opportunity to review the Draft Revision of EudraVigilance access policy for medicines for human use. Please find our comments below. Comment: Access is granted to authorised personnel of a MAH at headquarter level. Proposed change (if any): The EUQPPV could also reside at affiliate level. Please consider using other terminology for “headquarter level” since this could be misleading. Comment Marketing authorisation holders shall record all suspected adverse reactions in the Union or in third countries which are brought to their attention, whether reported spontaneously by patients or healthcare professionals, or occurring in the context of a	Proposed change (if any): We suppose that clinical studies are excluded from this requirement. Please explain this point in a more detailed way.

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		post-authorisation study.	
227		There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community	
228	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Principles of access for research organisations. I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. I object strongly to the following two conditions: • “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” • “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.”These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data.Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny.Consequently, what is proposed is unworkable and these two principles should be removed.	
229		This is my comment on the draft revision of EudraVigilance access policy for medicines for human use. I believe complete transparency is in the best interests of everyone affected by this access policy. I strongly disagree with the following proposals from your draft revision as it would unjustly give your organisation the power to censor or edit analyses: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." "A standard Agency	

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		disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." Furthermore, research requests should be reviewed by an organisation of absolutely no affiliation to the EMA so I disagree with the following principle from your draft: "An ad-hoc EMA panel will review requests for research access to data based on aresearch request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency."	
230		I support the proposal of Alltrialls. For the sake of science you should consider the proposal.	
231		I would like the EMA to know that I do not approve at all of their desire to censor analyses which they do not agree with. I'm sure there are many expert voices in the EMA whose own analyses carry much weight but they will undoubtedly make mistakes and should not be allowed to stifle independent scientific debate. Please accept the right of our healthcare professionals to know the full information. I'm a strong supporter of AllTrials and my viewpoint is expressed much fully and eloquently by their co-founder Ben Goldacre: "Protecting individual patients' privacy is necessary and good. But the EMA also says it should be allowed to suppress anything in an academic paper that it regards as "incorrect analyses, unsupported inferences, [or] misleading statements." This is a profoundly outdated world view. Simply because they are the body collecting this public data from EU patients that does not give them the right to control how it is used. This seems to simply represent state censorship of scientific discussion and analysis of public health data. If there are flawed analyses, or over-interpretation of risk signals, then that is a matter for public discussion and debate, not censorship by the medicines regulator. It also puts the regulators in a very conflicted position: it is likely that some analyses of this data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls (and many have been made in closed and unminuted discussions). It is quite wrong that the EMA should be given the right to censor analyses critical of its own analyses. Lastly, it is worth noting that this is not a new phenomenon. Regulators have frequently argued against transparency, saying that clinicians may be confused by poor quality or contradictory analyses of patient data, but this concern is not proportionate to the true risk. There are 28,100 scientific journals in print today, with over a million articles published each year, and over 23 million papers indexed in PubMed to date.	

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		Work of poorer quality is routinely conducted and published already: it is managed – to a reasonable degree – in the academic ecosystem of evidence synthesis and critical appraisal, before it can impact on practice. Any harm that the EMA might suggest could theoretically arise from a fractional increase in the total quantity of weak academic publications must be balanced against the huge benefits of wider access to patient data."	
232		I support that AllTrials campaign for a wider openness of trials' data I please you to review the draft on EudraVigilance access policy as requested by AllTrials.	
233	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I object to section 5.4.4.1, which appears to give the EMA the role of judging the 'correctness' of analysis and conclusions in an academic paper and the power to suppress publication of any work not to the EMA's satisfaction. The scientific community already has mechanisms for verifying such things in full public view. The EMA should not have these powers for two reasons: to discharge the responsibility properly would require enormous effort to be expended and by preventing publications from reaching the public domain, the normal scientific discourse will be impeded and the scientific process biased.	
234		I would like to respond to the draft revision of EudraVigilance access policy for medicines for human use. Whilst I accept that there is a need to protect patients against re-identification, I do not accept that the Agency should have a veto on publication based on 'incorrect analyses, unsupported inferences or misleading statements'. This is for the scientific community to establish, not a single centralised Agency. I agree with the AllTrials campaign that an independent panel should review requests for research access.	
235		EMA please don't censor independent analyses! The proposal would give your researchers access to more detailed and systematic records from the database but it also contains a condition that would give the EMA the ability to block publication of analyses it disagreed with. This is unnecessary! Please reconsider your stance.	

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236		The draft updates to the EudraVigilance Access policy would appear to give The European Medicines Agency the right to censor or block the publication of analyses it disagreed with. This cannot be right.	
237		As part of the AllTrials group please register this contact as my objeciton to the proposals to allow the EMA to censor data. Please see the attached document which I support. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
238		Please find enclosed F-Hoffmann-La Roche comments. EMA proposes to grant MAHs access only to data on their own drugs. This precludes any type of disproportionality analysis, as well as MAHs use of Eudravigilance data to investigate class effects as described in EU GVP IX B.3.5 Signal assessment - Proposed recommendation: would be that MAHs be granted equal access to information for all drugs, not just their own.	
239	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I am a proud supporter of the Alltrials campaign and I fullheartedly support their concerns over the draft revision of EudraVigilance access policy section 5.4.4.1. I believe that those principles are unethical and fundamentally anti-science as they circumvent the core principles of the peer review process. As a proud citizen of EU, I urge You to reassess this draft and formulate a new one which would be in line with scientific principles.	
240		This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use”. I feel it is important that all results from all clinical trials are reported.	
241		I fully support the comments presented to the EMA by the AllTrials campaign (reference number: EMA/759287/2009 Rev. 1) addressing the draft revision of EudraVigilance access policy for medicines for human use. I feel is it important to ensure that healthcare professionals and the public have useful access to up-to-date information on	

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		serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
242		I am writing to express my concern as to the EMA's proposal to allow censorship of analyses of side effects data. The scientific community operates on the principle of sharing analytical and methodological procedures when presenting results and each independent research coming to their own conclusions from the data and analyses presented to them. Any censorship of this process prevents us gaining an understanding of the effectiveness of drugs in Europe. Please also see the attached AllTrials response for a more detailed discussion of these concerns. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
243		I am glad to see that you are looking to improve the evidence available for doctors making pharmacological decisions about their patients however I am concerned by the idea that you would censor some research efforts by refusing to grant data use. I know that it is the best interests to prevent release of incorrect data analysis or conclusions but I think having a written warning of the agencies concerns on the paper is better than preventing publication. This will allow users of the research to come to their own conclusions without the possibility that vital research will never be able to have an impact on healthcare as it is not published. I would also mention that data access should be granted whether or not the agency can see the public health improvements that could result from the research. History has shown us that the most unlikely research or even accidents can bring big breakthroughs to science and healthcare.	
244		No Estoy de acuerdo con la postura que se cita en el asunto del presente mensaje; Estos principios parecen dar a la EMA el derecho de suprimir cualquier cosa en una comunicación académica que sea discordante. Lo que constituye una óptica anticuada. Simplemente porque la EMA es el organismo que concentra los datos públicos de los participantes en proyectos de investigación científica en la Unión Europea, lo que no le da el derecho a controlar su utilización. Esto equivaldría a la censura estatal de discusión científica y el análisis de datos del orden de la salud pública.	
245		I would like to express my support for all the points made by the AllTrials campaign in their submission 'Comments on draft revision of EudraVigilance access policy for medicines for human use'. Uncensored anonymised trial data must be made freely available to all stakeholders, which includes healthcare professionals, independent scientists and patients. Anything less is unsatisfactory.	
246		I am concerned about the proposal of the EMA to be the 'gatekeeper' . This seems	

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		almost medieval. These days openness of scientific information (& indeed potential conflicts of interest) is key. This is the path to scientific progress & improved medicine.	
247		This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use”.There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
248		This database should be open to everyone.	
249		I hope that you will maintain access to all the available data on side effects of medication. I believe noone should have the possibility nor the right to restrict access to this important information. Noone should be allowed to censor what information about side effects is available to researchers. Please do not allow the European Medicines Agency to restrict access to data it does not agree with.	
250		There is disparity in the access provided to the different stakeholder groups listed in Table 1 “ Number of ICH E2B(R3) ICSR data elements ” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 p a g e 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse event s reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37) . This information is useful for healthcare professionals to be able to identify possible interaction s between treatments. Additional question 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection?	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
251		I am writing with regards to the recent consultation on the 'draft revision of vigilance access policy for medicines for human use'. The proposal would give researchers access to more detailed and systematic records from the database, but it also contains conditions that would give the EMA the ability to block publication of analyses it disagreed with. I have grave concerns that the EMA would have the right to suppress academic information on this basis. I am urging you not to censor independent analyses.	
252		I was disconcerted to hear that the European Medicines Agency proposes to enforce a check for "incorrect analyses, unsupported inferences, [or] misleading statements" before the publication of any research using data from the EudraVigilance database. Certainly, none of those things are desirable - but making the EMA the gatekeeper and arbiter of what constitutes them strikes me as potentially very problematic. I do agree that there need to be safeguards to protect the privacy of the patients whose data are being used, but that does not mean that such thorough control of the content of all derivative research is necessary, or desirable. I urge you to rethink these conditions, for the sake of the independent researchers who work with your data, and the community at large that will benefit from their work. Thank you for your time and consideration.	
253	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended	same as the AllTrial Campaign, I am also very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. I object strongly to the following two conditions: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view.	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
	data.	Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship (which is probably also industry-influenced) of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. I am also concerned by the following principle: “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. I support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in my view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality, as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. I am concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		told The AllTrials Campaign that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Your Additional question 1, „As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection?" Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
254		Please, no censorship!	
255	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Principles of access for research organisations I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. I object strongly to the following two conditions: - "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." - "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are	

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		flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. I am also concerned by the following principle: “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. I also believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - I support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in my view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. I am concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between	

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		treatments. Additional question 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
256		I understand that the policy on access to EudraVigilance is being updated, and that it contains a condition that would give the EMA the ability to block publication of analyses it disagreed with. I believe that this is not a transparent and inclusive stance, and with this email, am expressing my disagreement with the inclusion of that condition.	
257	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use”. I support the views of the AllTrials campaign which are the following. I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. I object strongly to the following two conditions: • “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” • “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny.Consequently, what is proposed is unworkable and these two principles should be removed. B. I am also concerned by the following principle: • “An ad-hoc EMA panel	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: • "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community.	
258		I find it alarming that a regulatory body based within a scientific community, such as yourselves, feel the need to take such a paternalistic approach to the access of data. If people wish to include incorrect analyses, unsupported inferences or misleading statements in their reports, then the scientific community will rebuke and admonish them for doing so - as it has and always will do.	
259		Please don't block independent analysis: in cases where you suspect vexatious criticism, at least agree to arbitration by a genuinely disinterested third party.	
260		EURORDIS welcomes the proposal the revision of the EudraVigilance access policy. For the public, the launch of www.adrreports.eu and subsequent developments is certainly a major step towards increased transparency on the safety/toxicity of medicines for human use in Europe. EURORDIS also welcomes the proposed changes, in particular the possibility to exchange information with the W.H.O Centre for Pharmacovigilance and international agencies. The provision of new measures for the protection of personal data is in line with our recommendations when we encourage patients to report. Patients will report more often adverse drug reactions they suspect only if they trust the recipient of their reports, i.e. Eudravigilance and national/European pharmacovigilance authorities will protect their privacy. To this end, EURORDIS is encouraging patients to include precise and detailed information in their reports (narrative texts), to achieve a high quality reporting. When commenting the adverse drug reaction, patients may indicate the centre where they are treated or provide information such as concomitant medications, use of OTC products, or use of illicit products etc., information that they do not necessarily share with their doctors. They can only do so if the highest degree of data protection is ensured. For these reasons, the text should read: "The study intends to cover both the public	

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		health aspects related to the off-label use of medicinal products and in particular the balance between its benefits and risks, and the regulatory framework for the off-label use of medicines" Another general comment is on the duration of the work to be conducted: taking into account all that needs to be done, from data collection to the analysis, one year should be needed. Specific comments 5.4.4. Group IV: Research Organisations, Page 23 An ad-hoc EMA panel will review requests for research access to data based on a research request. The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency. EURORDIS proposes patients' representatives are part of the panel. EURORDIS agrees with the minimum set of explanation for the request: the primary research question to be addressed, the methodology to be used, the way that the results of the study will impact on public health, the name and contact details of the person nominated to safeguard the EudraVigilance data for the research purpose. The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. EURORDIS fully agrees. We propose patients' representatives are consulted regarding the evaluation of possible re-identification. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication. A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer. EURORDIS supports these measures well in line with our concerns regarding the use of individual data by third parties in general, in relation with the risk of inappropriate secondary analysis. However, in cases where these requirements would not be fully respected, the policy does not explain which consequences/actions the EMA could decide vis-à- vis the research organisation that would not respect them.	
261		I would like to draw your attention to the comments and arguments put forward in the following document, published by Síle Lane, Director of Campaigns, Sense About Science, regarding the AllTrials campaign. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	

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262		I agree with the AllTrials Campaign objections and proposals!	
263		We agree with the comments that realize AllTrials (see attached file) about draft revision of EudraVigilance access policy for medicines for human use. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
264		Under no circumstances should the EMA be in a position to determine the value of research for the dissemination of data. Only the many eyes and minds of the wider scientific community is capable of determining the quality and usefulness of data. The EMA's job is to collect, collate, and analyse the data provided; NOT, to determine who gets to see that data. The EMA must be held to account for its decisions and only full and transparent access by the wider scientific community can provide this safeguard. Redaction in rare cases where patients could be identified would be acceptable but only if verified by suitable independent third party.	
265		Whilst I am very much in favour of much of what is proposed I am extremely concerned to note that EMA proposes to block analyses with which it disagrees. There may of course be sound reasons for doing so but I would urge the publication of those analyses TOGETHER with EMA's reasons for disputing those analyses. Simply to block publication might appease litigious companies but to do so is to miss the whole point of transparency.	
266		I am very concerned by your draft. Please, let access to the data granted to research organisations in a unrestricted way.	
267	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended	I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. In particular, the conditions that appear to allow the Agency to prevent publication of any material containing arguments that do not conform with its own opinion. Not only does this appear to give the EMA disproportionate control over what can be published, it also appears to go beyond the remit of the Agency and could lead to suppression of dissenting opinions and scientific discussion, none of which would be of benefit to patients. To decide on the merit of publications and to come to the conclusion that analyses are flawed will not only require sufficient resources but will also require the EMA to openly publish these analyses for independent scientific scrutiny. Furthermore, the idea that one body should be sole arbritrar goes against all principles of open scientific debate and would eliminate the oversight provided by open discussion and independent review to the detriment of patient care. I am also concerned by the principle in the draft suggesting that EMA itself will be able to refuse access to the data	

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	data.	according to its own criteria. In order to maintain openess and transparency, an independent panel should be responsible for these decisions to avoid potential conflicts of interest, especially when it is possible that some analyses of the data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. Finally, the principles of open access and greater transparency have become increasingly important. If anything, as long as patient confidentiality is ensured, the default position should be to allow open access. Time and time again, this has proven to be of greater benefit to public health and patient care. Rather than attempt to restrict access as many pharmaceutical companies would prefer, the EMA should be firmly on the side of the people who will benefit, or in the case of incomplete knowledge suffer, the most, i.e. the patients and the doctors who prescribe to them. Only in the presence of all the facts can appropruiate decisions be made.	
268		As a Swiss physician I strongly agree with the AllTrials Campaigns concerns about the EMA's consultation to its EudraVigilance access policy and urge you not to censor independent analyses! See the AllTrials detailed response attached. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
269		I object strongly to the following two conditions: - "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." - "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should	

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		be removed.	
270		After reading the letter by Síle Lane attached to this email, I decided to express my concern to you about the draft revision of the EudraVigilance access policy for medicines for human use, as is commented on in the letter. Transparency in medical science is vital to the good healthcare that everyone depends upon and the proposed revision does not foster but forestall the necessary transparency to further improve healthcare.	
271	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	This is part of a response to the consultation on the “Draft revision of Eudra Vigilance access policy for medicines for human use” from the All Trials campaign. We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: “The Agency has the right to view any publication resulting from Eudra Vigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.”“A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to suppress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed.	
272		I would like to add my voice to the comment that free availability of the data should allow publication of analyses without the possibility of EMA blocking this. Disagreements over analyses and interpretations should be publicly aired.	
273		This is a response to the consultation on the “Draft revision of EudraVigilance access	

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		policy for medicines for human use" from the AllTrials campaign. The revision grants EMA the right to suppress anything in an academic paper that it disagrees with. This would amount to state censorship of scientific discussion and analysis of public health data. Please do not to censor independent analyses.	
274		We agree with all the points AllTrials has put forth. Transparency and full disclosure is vital. Done properly this could benefit all of mankind. Time to move out of the Dark Ages!	
275		I write with comments on the updates to the EudraVigilance access policy. The proposal to make more detailed information available for researchers is welcomed and will benefit the medical community. However, I have some concerns. The policy requires that the EMA approve all analyses of data prior to publication. This is costly and not useful. There will be significant cost for the EMA to review publications, particularly if there is a dispute, costing time and money. It is much better to allow the wider scientific community to analyze the publication, because this reduces publication time and can provide a deeper review of the publication's methodology. Although this runs the risk of knee-jerk reactions, the open debate created is much better due to its independence. This also means that a stricter requirement to make research available should be included. Making further information available to healthcare professionals and researchers would also be welcomed, such as case narratives and summaries, as these can provide further information that can show problematic interactions between treatments, among other things. Thank you for soliciting comments and it is my hope that the policy is improved.	
276		As a private individual and supporter of the All Trials campaign, I fully support the All Trials comments on the draft revision of EudraVigilance access policy for medicines as detailed at: http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf I do not believe that the EMA should have the power to block publication of analyses that it disagrees with.	
277		This is a response to the consultation on the "Draft revision of EudraVigilance access policy for medicines for human use" from the AllTrials campaign. I wish register my objection strongly to the following two conditions: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal	

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		data must be addressed to the satisfaction of the Agency before submission for publication." “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to apply CENSORSHIP against anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data which rightly belongs in the public domain. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. This is rightly the purpose of open and independent peer review in the domain of ethical scientific debate, not as the self-appointed role for the EMA.	
278		This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use”. I fully support the response given by Sense about Science / AllTrials Campaign, shown below. I also wish to add my own personal comments. From a personal perspective I am someone who is reliant on medication due to a long-term condition, but also someone who looks after her health and lives healthily. From a professional perspective I am a health librarian and therefore understand the importance of evidence-based practice. Therefore I wish my doctors and myself to have all the evidence we need in order to be able to make a fully informed decision when deciding which medicines I should be prescribed. I do not want to put myself in danger due to my doctors not having access to all the trial data for a drug e.g. side-effects, withdrawals due to adverse effects etc. I value my health and my life, and the lives of others. Please see below the All Trials Campaign response: http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
279		I am writing to express my concern regarding the proposed right to censor scientific publications entailed in the draft policy. I fully understand that the protection of subject privacy is essential but this should be addressed by ethics review before the study is commenced otherwise the agency is permitting a violation of privacy, and then later suppressing the results. The data will still remain. Second if the agency does not agree with the scientific merit of the publication it should state such in a publicly accessible	

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		manner, not secret suppression. There is nothing wrong with requiring authors to attach a disclaimer to any publication that breaches agency policy. The scientific community will weed out bias and fraud eventually if commercial, political, academic or other vested interest is not permitted to censor.	
280	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	As a supporter of the AllTrials.net initiative, I am are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations, e.g.: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check...” And "A standard Agency disclaimer must be added to the manuscript." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. What is proposed is most likely unworkable and these two principles should be removed. As the AllTrials initiative comment suggests, I agree that the panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. Finally, I too believe that the following principle could be strengthened to require research organisations to submit the results of their research for publication: “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community.	
281	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended	This is a response to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use”. I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. I object strongly to the following two conditions: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything	

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	data.	in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. I am also concerned by the following principle: “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - I support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in my view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. I am concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries	

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		(Annex 2 H.1 page 50 and H.5.r page 51). Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments.	
282		Please allow open access without restrictions on data analysis. What possible benefit could restriction serve other than to allow data distortion to remain un-detected. We need to know what the drugs we take do and independent analysis is essential to underpinning this knowledge.	
283		I hope this does not happen. As a layman this seems to hark back to the times of the inquisition where people were arrested if they did not agree with what other people wanted them to believe	
284		I am a research scientist at the University of Ulster. The following attached response from AllTrials mirrors my own view. I have refrained from copying it here to reduce redundancy.http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
285		I support the AllTrials response to your consultation EMA/759287/2009 Rev. 1 attached particularly their comments about Principles of access for research organisations A. In view of the serious short-comings in regard to EMA's handing of the research data it has held in the past it has a lot to do to prove its bona fides now and there should be no question of it being judge and jury at least until they have been established. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
286		I wish to register my support of the Alltrials Campaign's response as detailed here: http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
287		I am a medical student from Italy and I agree with the AllTrials proposal. Simply because the EMA is the body collecting public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Also, the following principle could be strengthened to require research organisations to submit the results of their research for publication: "Those given access to EudraVigilance data should make appropriate efforts to publish their research." Finally, as future healthcare professional, I want a useful access to up-to-date information on serious adverse events contained within the database to be ensured.	

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288		I share the concern of AllTrials Campaign on some of the principles under which access to the data is granted to research organisations. I urge the EMA not to censor independent analyses and to provide access to as much information as possible. Furthermore, the panel that reviews research requests should be independent of the EMA to prevent conflicts of interest.	
289		Along with All Trials, for the reasons stated in their response to you, I urge you not to censor independent analyses in the updates to your EudraVigilance access policy.	
290		I am pleased to hear about the recent proposal to grant researchers greater access to individual case safety report (ICSR) data, however I am concerned to hear that this access would be granted on the condition that- “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” Although measures to ensure patient privacy should be supported, it is my belief that the EMA should not be able to suppress what it regards as 'incorrect analyses, unsupported inferences [and] misleading statements'. Instead, the existence of flawed analyses should be determined through public scrutiny of these publications; they should not be censored by the EMA.	
291		informed by the campaigners of the "AllTrials Campaign", who already contacted you, I hereby state my support for this campaign and it's comments on your draft. I am especially concerned about the following passages: The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication and A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer. I agree with the campaigners, that science has to be open and free and mustn't be censored. It is iIrrelevant, if it happens deliberately or not - the chance of censorship itself is unacceptable. Please remove this passages and follow the other proposals of the AllTrials Campaign.	

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292	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Thank you for allowing further comment on the policy on access to EudraVigilance. In review of the latest changes I've noted an item on page 23 which fails to pass the transparency policy we hope can be achieved. Here is that excerpt: - The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication. Please alter the document to insure each stakeholder's ability to review any and all submissions as they are submitted, without delay and/or review. Privacy issues can be handled within each particular study prior to receiving the data and anything less allows for unilateral censorship which is what we are all striving to avoid.	
293		I support fully the statement AllTrials has submitted to the EMA. We cannot tolerate any form of censorship in healthcare research. Further, the EMA has a clear conflict of interest when being its own judge, as independent research might show that the EMA's handling of an issue was less than optimal. According to laws of public administration, it is clearly unacceptable to allow an agency to be in a position to evaluate itself. Finally, it has been amply documented, for example in my book,"Deadly medicines and organised crime: How big pharma has corrupted health care," that corruption in drug agencies occur and that it seems to be widespread in the FDA. Therefore, in the worst case, censorship by EMA staff may be seen as proxy censorship by the company whose sales might be threatened by the independent research.	
294	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for	Principles of access for research organisations - I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. I object strongly to the following two conditions: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
	extended data.	in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B I am concerned by the following principle: “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, i believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - I support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. I am concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries	

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		(Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu<http://www.addrreports.eu>) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up- to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
295		I understand EMA seeks the right to censor independent analyses of side effects data with which it is not in agreement. I totally disapprove of censorship in any form and urge transparency in every E.U. matter.	
296		All data from any well designed trial should be freely available and interpretation can then be made appropriately. If one organisation or interested party chooses one specific interpretation which ignores or distorts the data they are free to do so as long as all the facts are in the public and scientific community domain. This allows all to see how interested parties are geared to one way of thinking which, in itself, is interesting. However, to only allow scrutiny of selected data and introducing a censor approach to publication of experimental outcome is such a backward step that it beggars belief and will undermine any future trust in any scientific research. I implore you to reconsider your proposal.	
297		I am concerned about some aspects of the proposed changes to policy. The AllTrials response dated 11 September (attached) sums up my worries about these changes. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
298		I am writing to express my concern regarding proposed changes to the abovementioned. After having a relative adversely affected by medication side effects, I feel strongly about this issue. Of particular concern to me are the proposed principles set out below: 1. The agency will have the right to view publications before submitting	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		for publication 2. The agency has the right to reword the disclaimers attached. This seems to me to potentially give the EMA the right to restrict evidence it disagrees with. Furthermore the proposal that an ad hoc panel, which is not fully independent to the EMA, can refuse access to data if it is unconvinced of the value to public health could represent a conflict of interest; the panel need to be wholly independent to prevent bias.	
299		Give researchers access to more detailed and systematic records from the database but without block publication of analyses it disagreed with.	
300	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	As a cancer survivor who spends time supporting cancer research I am seriously concerned about some clauses in your recent paper. The two items of concern are in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These two principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with.!! This is an extraordinary statement and one that flies in direct contrast to my ideas of an open view of ALL research. It is an idea that is no longer is valid in modern society. Because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used.!! This like an old soviet idea of the world in that WE know better than the general public..!! This is certainly NOT democratic..!! This would amount to an unelected state body censoring scientific discussion and analysis of public health data. We strongly recommend that some adjustments are made before any further actions are taken in this matter.	
301		I object especially to the following two draft conditions: • “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission	

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		for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. I believe that this is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health.	
302		I fully agree with and support the AllTrials response to the The European Medicines Agency (EMA) consulting on updates to its EudraVigilance access policy. Data is data and should not be edited or open to editing, science and knowledge only progresses when we can all learn from each other, edited data is meaningless, it will lead to unnecessary repetition of research or a misinterpretation of the research. Please we must have all research available to all to progress our knowledge and understanding of medicine.	
303		We as physicians cannot accept any censorship of analyses considering side effects noted in independent trials. Please do not censor the analyses, although you disagree with the results!!!	
304		I support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database.Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers.	
305		All non-patient-identifiable information regarding drug trials should be openly, easily and transparently available to the public. Please do not sensor it. Patients will be harmed if you allow this information to be suppressed.	
306		Having followed recent campaigns regarding medical trials the above consultation has been brought to my attention by the AllTrials group. Although there may be some merit in some level of filtering in such a system to prevent the sheer quantity of information becoming overwhelming, I share the concerns raised by AllTrials that the proposed amendments to the policy may be unworkable and, more worryingly, raise the problem of cover-ups and censorship. Recent changes in legislation have greatly advanced Europe's legal framework regarding medical trials and I would urge that this policy be	

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		reconsidered to avoid jeopardising these advances.	
307		The proposal to allow the EMA to rebuke or deny access if analysis, inferences and comments of data accessible from clinical studies is definitely not consistent with academic publishing which assumes that erratic, illogical or random associations will soon be rebuked by critics and researchers to the reports or views which lacked substance. Would the association of chloramphenicol eye drops association with bone marrow aplasia or one influenza vaccine to narcolepsy been ruled out as illogical or extremely unlikely by several EMA experts? The assumption usually made in the scientific community is that hypothesis which lack statistical validity eg case reports with discussion seldom warrant changing policies but encourage others to investigate if there is a statistical correlation and comment. Transparency has no meaning if interpretation is censored. It is reasonable that authors should state that conclusions drawn are the authors.	
308		I have read and support the comments sent to you by the AllTrials campaign. It is entirely inappropriate for the EMA to do anything to obstruct publication of research reports.	
309		My name is David Silvestre and I´m writing you to in order to express my disagrement with some of the measures proposed by your organization on the update to the EudraVigiliance access policy. As already stated by independent organizations (All trials, BMJ, Cchrane Collaboration, PLOS, etc) reseachers, doctors, and people in general mus have open access to all the data related to trials side effects and this data can be used for free publication, being the scientific community responsible for judging if its biased or not, not by EMA. Hoping that this message will be taken into account in your decision,	
310	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to	I would like to see the following two conditions removed from: section 5.4.4.1. (page 23) as counter productive and unworkable : - “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” - “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These	

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	requests for extended data.	principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. To come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny.	
311		As a member of a patients' organization, I would like to take part to the consultation. First I would like to answer your question: • As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes, I think that a larger access to this data and therefore the opportunity to have more and more detailed elaborations can contribute in better understanding the risk/benefit pèrofile of a drug or medical device. I would also like to comment on the following part of the document: • Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication. I don't think it is within the remit of the Agency to evaluate things such as "incorrect analyses, unsupported inferences, misleading statements" which are usually evaluated through a comprehensive peer-reviewing process before publication. It is my opinion that the protection of personal data should be assessed by the agency through the specified "privacy check as regards possible re-identification of patients".	
312		I am writing to comment that I fully support the response to you by Sile Lane, Director of Campaigns, Sense About Science. In particular: 1. Regarding the principles set out in section 5.4.4.1, I object to the two conditions • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." which amounts to the EMA having the right to suppress any view it does not agree with; these two principles should be removed. 2. Regarding the following principle: "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." I believe this assessment must to made by a body independent of the EMA to avoid potential conflicts of interest.	
313		I object strongly to the following two conditions: • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer."	
314		Information on side effects should be available to everyone, even if the information is unfavourable. Stop playing with people's lives.	
315		I am protesting your dark ages policy of censoring research data on side effects if it does not tally with your own agenda. All data should be available to health professionals, academics and the public alike. Nothing should be hidden. There is no need for patient confidentiality to be breached even if data is freely available; there are mechanisms for safeguarding this and you are well aware of this fact. Such arguments are red herrings. I am not a health professional; however, as one who, along with my family, may be prescribed medication from time to time I have a right to access any information regarding the same. I also expect that information I can access provides full disclosure of research findings - not just the bits you deem fit for public consumption.	
316		I wish to register my objection to the part of your proposals whereby you may suppress publications that use your data for reasons including "incorrect analyses". This is entirely the wrong way to deal with such issues, far better to allow the publication but also publish your objections at the same time. That way the community can arrive at an informed view. I also share the other concerns of the AllTrials campaign, but it was this item in particular I wish to bring to your attention.	
317		I am writing to protest the idea of allowing the medicines regulator to censor side effects data. Allowing censorship in any way of the all trials data simply encourages more corruption of the type that has already condemned many patients to death. The	

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		demand for censorship privileges must be denied.	
318	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Firstly I support the increased transparency and access to data by members of the scientific community, that your policy details. However I don't think it goes far enough and in particular I am concerned about some of the conditions of data access by research organizations detailed in section 5.4.4.1. (page 23). I object strongly to the following two conditions: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” This essentially gives the EMA the right of censorship of scientific publications. This is unacceptable and goes beyond the EMA's remit. If flawed analyses are published as a result then so be it: members of the scientific community are capable of identifying these analyses and disregarding them. Flawed research is published everyday, so this would not be any different from the status quo. In any case, the benefits to the general public of full unconditional access to EudraVigilance data far outweigh any small harms that could possibly arise from such access. When data is analyzed multiple times by different researchers then it is inevitable that they will identify problems that the EMA has missed. This is not intended as a criticism of the EMA's ability to analyze the data. As a future doctor I believe that the scientific community should have full access to EudraVigilance data, as a tool to make the best decisions possible for patients. The idea that a regulator should have the ability to censor use of this data is wrong and is inconsistent with the current world view. The priority should always be full transparency because that is the best way to protect patients from harm. If I were to cause avoidable harm to a patient simply because the scientific community was unable to freely access and analyze existing data, then I would feel rightly aggrieved. I support the All Trials campaign and their further suggested EudraVigilance access policy amendments, of which I am sure you are aware.	
319		This would amount to state censorship of scientific discussion and analysis of public health data.	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
320		Having read the draft revision, there is one condition that I feel is not in keeping with the intention of the policy: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” As this would effectively amount to censorship of scientific discussion and analysis of the public health data that is being published, I believe the condition should be removed.	
321		This amounts to state censorship of scientific discussion and analysis of public health data, something which I personally find unacceptable - and I am NOT alone. We ask you to rethink your decision before it is too late.	
322	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Regarding the mentioned document I would like the concern, that the paragraph under 5.4.4.1 reading „Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” may be overly strict. While the protection of personal data is of course necessary, the definition of a “misleading statement” may be very much open to interpretation and arbitrariness. Research around pharmaceuticals and their side effects is often seen very critically by some members of the scientific community, due to the obvious competing financial interests of the companies involved and various scandals in the recent past. To rebuild trust, a great deal of transparency is necessary in all areas, where information could be suppressed or altered. Transparency also from the EMA. I suggest that the EMA should voice its concerns in cases where it sees possibly misleading conclusions, but put its trust in to the editors of the publishing paper whether or not this is in fact a reason for non-publication.	
323		I welcome the proposal that would give researchers access to more detailed and systematic records from the EudraVigilance database. However, I completely disagree with the condition that would give EMA the ability to block publication of analyses it disagreed with. This issue is extremely important for people’s health so it should be scrutinised for as many people as possible. You should allow the scientific community to discuss all possible findings and topics as this would take to higher scrutiny, safer medicines, and richer discussion which can trigger new inventions.	
324		It is essential for the integrity of the process that full access to all trial and medical	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		data and analyses thereof be fully available to anyone who wishes to access them. Restricting access to analyses would be contrary to the norms of science and enable suppression of results which a party would rather hide. This practice has been common in the past.	
325		I support AllTrials and I hope you will read their response to EudraVigilance access policy consultation.	
326		I object strongly to the following two conditions: • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." I am also concerned by the following principle: • "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency."" Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: • "Those given access to EudraVigilance data should make appropriate efforts to publish their research." From someone who will need accurate medical data in my lifetime (just like you).	
327	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard	The AllTrials campaign was launched in January 2013 to call for all clinical trials to be registered and results reported. It is an initiative of Bad Science, BMJ, Centre for Evidence- based Medicine, Cochrane Collaboration, James Lind Initiative, PLOS and Sense About Science. It is supported by nearly 80,000 people and over 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world. Principles of access for research organisations We are very concerned by some of the principles in section 5.4.4.1. (page 23) under whichaccess to the data is granted to research organisations. A. We object strongly to the following two conditions:	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
	timescale for response to requests for extended data.	"The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - We support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting	

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		System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments.	
328		I wish to express my support for openness and against any kind of censorship by government agencies or small academic groups. I. Firstly, I am fine with the EMA asking researchers to take a second look at their findings because the EMA thinks it sees errors. I am fine with the EMA putting a caution after (or before) reports where agreement cannot be reached. But the EMA should not be able to prevent publication to scientific and medical professionals for more than 90 days. And the EMA should not be able to prevent free and open publication to the general public for more than 365 days. II. Secondly, all research partly funded by the public through government or public institutions should be available to the public within 365 days of its first publication in a journal (with a national security exception). This is especially true for medicine and pharmaceuticals. Work paid for by tax dollars properly belongs to taxpayers and citizens. Government funders should not allow the conversion of this publicly owned intellectual property into a private copyrighted resource for the private profit of journal publishers – especially not without a reasonable time limit, such as 365 days. The business model of private journal publishers depends on the conversion of public property to private property without full compensation for the value lost to tax payers. This is unjust and should be illegal. A 365 day limit before open access seems a reasonable compromise. I am a UK citizen living in Canada and those are my feelings on the proposed updates to EudraVigilance.	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
329		I wish to comment on the upcoming possible changes to the way information is shared and made available regarding drugs and drug trials. I ask that the EMA not censor independent analyses of any trials - Sharing of all data is vital for future growth of good medicines.	
330		I concur fully with the below comments from AllTrials campaign and add my voice to theirs.	
331		Please, consider not to censor independent analyses.	
332		I am writing to voice my support for the AllTrials campaign's position on the “Draft revision of EudraVigilance access policy for medicines for human use” (Reference number: EMA/759287/2009 Rev. 1). Do not censor independent analyses!	
333		As a member of the public, I am an interested party. I am concerned that information about trials is published as fully as possible and this included allowing trial sponsors to share anonymised data from the trial participants.	
334	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I have some concerns with some of the updates to your updated policy on accessing data from EudraVigilance. 1. Principles of access for research organisations: I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. I object strongly to the following two conditions: - “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” - “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny.	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		Consequently, what is proposed is unworkable and these two principles should be removed. I am also concerned by the following principle: “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: - “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. 2. Proactive publication of ICSR data - I support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database.Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. 3. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments.	

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335		The proposal that the EMA should be able to censor data is a backwards move that could lead to less transparency and is against the interests of patients.	
336	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations - I object strongly to the following two conditions: · "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny.	
337		I just want to express my strong support to the comments already posted by the AllTrials campaign to the proposed EMA EudraVigilance access policy.	
338		I have heard from those running the All trials campaign that you are updating your EudraVigilance access policy. I am writing in support of their position.	
339		A cornerstone of EudraVigiliance is that it is 100% transparent and there is no whiff of censorship. The following clause is therefore not fit for purpose: "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." The concerns it is trying to address (misuse of information) cannot possibly be placed in the remit of the Agency. If this really is a concern (which	

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		I'm sceptical of), the way to deal with it is to create a truly independent body that commands international respect, to which media organisations (or the public) can turn for comment should someone extract and publicize controversial conclusions.	
340	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Principles of access for research organisations. I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. I object strongly to the following two conditions: • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly out dated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. I am also concerned by the following principle: • "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: • "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There needs to be an expectation that access to these data for research purposes is granted on the expectation that the	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - I support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 "Number of ICH E2B(R3) ICSR data elements" (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. I am concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told members of my organisation that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data. Independent Cancer Patients Voice is a group of people who, having been treated for cancer, have undertaken education & training to add the important, effective and realistic patient perspective to cancer research. These proposed changes are paternalistic and undermine individuals' right to choose – re donation of health data for quality, peer reviewed research which will benefit future generations.	

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341		I hereby inform you that I fully support the views of the AllTrials campagne, as expressed in the document attached.	
342	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I am writing to respond to the consultation on the “Draft revision of EudraVigilance access policy for medicines for human use” organised by the EMA. Specifically I would like to object to two conditions in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” The EMA should remove these conditions, because as currently worded they would allow the EMA to bar the publication of analyses they disagree with. While the EMA has understandable concerns about protecting the public data, this does not mean it has the right to control scientific inquiry. Furthermore, I am concerned that the 'ad-hoc EMA panel will review requests for research access to data based on a research request" will be overcome with Conflicts-of interest if the wording is not clarified. The panel should be independent of the EMA, parties making the request, parties involved in gathering the data as well as the pharmaceutical industry. The wording "those given access to EudraVigilance data should make appropriate efforts to publish their research.” should be changed to mandate publication of research, in Open Access Journals. It should be an expectation (not a suggestion, as currently worded) that research derived public data is published in a medium that is accessible to all.	
343		I would like to express my support for the AllTrials response and encourage you to not censor any medical data.	
345		I support the AllTrials campaign which launched in January 2013 to call for all clinical trials to be registered and results reported. The campaign is supported by nearly 80,000 people and over 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world. I support the section on "reporting aggregate results of the clinical investigation" (Section V.K.). People who participate in clinical trials expect to be given the results of the trial(s) they participated in and that the	

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		results will be shared publicly. I agree with providing participants with aggregate results in a "clear and comprehensible manner." The value of sharing individual patient data has been proven time and again. Scientists have been reviewing patient data from trials since the 1970s, and those reviews have led to many medical advances including better survival rates from chemotherapy, improved heart disease treatments and higher childhood cancer survival rates. The guidance needs to include an element informing patients that clinical investigators will be able to share non-identifiable data from their trials with other researchers.	
346		I am very concerned by some of the principles in section 5.4.4.1.(page 23) under which access to the data is granted to research organisations I object strongly to the following two conditions: •"The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to suppress anything in an academic paper that it disagrees with. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed.	
347	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a	I am extremely concerned by some of the principles in section 5.4.4.1.(page 23) under which access to the data is granted to research organisations I object strongly to two conditions: •"The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword	

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	standard timescale for response to requests for extended data.	the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to suppress anything in an academic paper that it disagrees with and would amount to state censorship of scientific discussion and analysis of public health data. Consequently these two principles should be removed.	
348	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Principles of access for research organisations We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: • "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require	

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		research organisations to submit the results of their research for publication: • “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - We support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments.	
349		Please do not censor independent analyses.	
350		I have strong concerns about the draft revision of Eudra Vigilance access policy for medicines for human use, particularly the regulations that might allow for the EMA to review data and suppress scientific findings/analyses it does not like. I am very much in favour of open access and the sharing of (anonymised) research data to allow for any and all scientists to examine and assess data. In this way we will most effectively facilitate scientific and medical advances. It is particularly important in this case where drug side effects, some of which can be very serious, are concerned. My concerns are explained in more detail in the response written by the All Trials Campaign -	

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		http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf I urge you to consider these issues before going ahead with the regulations.	
351	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I am writing to comment on section 5.4.4.1 in the current draft revision of the EudraVigilance access policy. The proposal for the EMA to have a right of veto over any paper written based on EudraVigilance data is practically unworkable, and in contrast to both academic principles of openness and realities of how research accountability works. Deciding whether a scientific study is robust and interesting is the job of peer review, not the EMA which simply happens to be the maintainer of this database of public data. What is proposed, as written, is close to state censorship. Additionally, making such decisions via the standard academic route provides a greater manpower, breadth of expertise, and impartiality than could be obtained by a team of pre-publication validators within EMA. Hence I believe this aspect of the draft policy should be removed.	
352	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	In this email I would like to make a couple of points in response to the “Draft revision of EudraVigilance access policy for medicines for human use”, specifically regarding the principles of access for research oganisations in Section 5.4.4.1. It appears sensible that the Agency wishes to review any draft publications based on EudraVigilance data to ensure that no patients can be re-identified, although I wonder whether this requirement is not superfluous because all patient data should be anonymised before it is submitted to EudraVigilance. However, I am most concerned by the requirement "Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." Eliminating such issues from publications is currently effectively dealt with by the process of peer review, so there is no need for the Agency to attempt to take on this task itself. However, there is a risk that the Agency could abuse the powers in Section 5.4.4.1 to suppress publications with whose conclusions it disagrees. It is irrelevant whether or not the Agency formulated this Section with the aim of being able to suppress researchers' work: any regulation which leaves open the possibility of abuse is unacceptable and must be re-worded. For the same reason it is troubling that "the Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data." The role of the Agency is to collect and make available data, not to comment on the validity of conclusions which	

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		researchers draw from it. Assessing the validity of conclusions is the realm of peer review and the usual process of scientific discussion by publications. I urge you in the interest of fair and effective scientific research to remove the two principles quoted above.	
353		This Draft "Revision of EudraVigilance access policy for medicines for human use" (EMA/759287/2009, Revision 1, dated 4 August 2014) describes proposed policy to be applied to EudraVigilance for the access of six stakeholder groups, including the public, to individual case safety report (ICSR) data. It is proposed that the policy become effective six months following the announcement by the EMA Management Board that the EudraVigilance database has achieved full functionality. The proposed access is at the individual ICSR level, which will significantly expand the utility of safety data that are currently available to the public in aggregate form for a limited number of medicinal products. Overall, it appears that the purpose of the document is to clarify stakeholder expectations and requirements for access to single case EudraVigilance data. The access policy is intended to facilitate the continuous monitoring of the safety of medicinal products in the EEA, while protecting patient data privacy, and to enable detection and evaluation of new safety signals, as well as timely benefit-risk assessments.	
353		National Competent Authorities receive case safety reports for medicinal products directly from consumers, healthcare professional, and others. To ensure consistency across the EEA while supporting both transparency and patient data protection, the practices and possible constraints within Member States regarding the information currently provide to MAHs will need to be evaluated and considered as the EudraVigilance access policy is finalized.	
353		We agree with the statement on page two regarding a separate consultation on possible stakeholder access to suspected unexpected serious adverse reactions (SUSARs).	
353		Throughout the document reference is made to the ICH implementation guide[1] for the E2B(R3) ICSR message and the EU-specific regional supplemental implementation guide[2] for the E2B(R3) message. Data currently residing in EudraVigilance has been transmitted using the ICH E2B(R2) message specification. Further, it is proposed that stakeholders be provided data as E2B(R3) files (only). Extensive testing with the new	

[1] Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs)
E2B(R3) Data Elements and Message Specification (http://www.ich.org/products/electronic-standards.html)
[2] Draft EU Individual Case Safety Report (ICSR) Implementation Guide (EMA/51938/2013)

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		E2B(R3) specification will be needed and the draft EU regional implementation guide will need to be finalized before extensive development and user acceptance testing can be achieved. The ICH E2B(R3) Implementation Guide will be supplemented by an ICH Q&A document and this should be taken into account. Furthermore, forward compatibility of an E2B(R2) to E2B(R3) data conversion, and responsibility for same, must be evaluated to ensure full utility of legacy data. We note that the ICH Backwards Forwards Compatibility (BFC) document is not referenced; it may be helpful for the various stakeholders to guide understanding of E2B(R3) output that is derived from E2B(R2) data elements.	
353		Specific question asked by the Agency: "1. As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? " Comment: The aggregate data currently bring provided on www.adrreports.eu for CAP products appears adequate for stakeholder group II when expanded to all medicinal products authorised in the EEA. However, it is not possible to associate data elements that would be included in an individual case report. To promote transparency in this regard, a set of constrained data elements could be provided in tabular form to supplement the broader set of data now provided in the aggregate on the European database of suspected adverse reactions without compromising personally identifiable data.	
353		Specific question asked by the Agency: "2. As regards stakeholder groups III. A "Marketing Authorisation Holders" do you consider the data set proposed in Annex 1 (Table column PV obligations – Level 2) as sufficient for a MAH to comply with the pharmacovigilance obligations as outlined in Regulation (EC) 726/2004, Directive 2001/83/EC, the Commission Implementing Regulation (EU) 520/2012 and the Good Pharmacovigilance Practice Modules?" Comment: It would appear that the intended reference is Annex 2. Annex 1 outlines reporting principles and classification rules for ICSRs. Annex 2 is a tabular listing of proposed availability of specific data elements for MAHs to meet pharmacovigilance obligations (Level 2) and for research purposes. Independent research and PV obligations should appear in separate columns; Research access would retain the specifics listed in the current column, whereas MAH PV obligations should include, in addition, ICH H.1 (Case narrative), page 50, for use in signal evaluation, benefit-risk assessment, causality reviews, and to provide context for Reporter's comments. In addition, C.1.6.1.r.2 (Included documents), page 31, ICH	

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		c.4.r.2 (Included documents), page 34, and ICH H.5.r.1a and H.5.r.1b (Reporter comments in native language), page 51, should be available to an MAH upon request. The value and role of the 43 EU-specific data elements (8 on page 37, 5 on page 38, 3 on page 40, 10 on page 41, 10 on page 45, 4 on page 46, and 3 on page 49) may become clarified when the EU Individual Case Safety Report (ICSR) Implementation Guide is finalized and software tools are developed to analyze these data elements. Note that several column headers and footnotes in the Annex 2 table require correction. See additional specific comments below.	
353		We appreciate the opportunity to participate in the public consultation process; we would be glad to meet with EMA representatives to clarify any of our comments. Proposed changes to the text are underlined. "Para" references the paragraph number on the indicated page.	
353	Executive Summary, Page 5, last bullet	Comment: Referenced text, "– The data elements for ICSRs have been updated in line with the ISO ICSR standard and the ICH E2B(R3)/EU ICSR Implementation Guide (Table 1 and Annex 2)." This is an aspirational statement, as the updating has not yet occurred and the EU implementation guide must be finalized first. It is not clear whether all of the legacy data that were transmitted in E2B(R2) format will be transformed into E2B(R3) data elements, which requires certain manual manipulations, prior to the access policy coming into force. Clarify the proposed plan for providing uniform data elements. Proposed change (if accurate): Revise the bullet as follows, "– The data elements for ICSRs have been updated in line with the ISO ICSR standard and the ICH E2B(R3)/EU ICSR Implementation Guide (Table 1 and Annex 2). Due to various factors, such as differences in data elements and format requirements for E2B(R3) and E2B(R2), not all data elements listed in Annex 2 will be available for all ICSRs made available to the various stakeholder groups under this access policy.	Revise the bullet as follows, "– The data elements for ICSRs have been updated in line with the ISO ICSR standard and the ICH E2B(R3)/EU ICSR Implementation Guide (Table 1 and Annex 2). Due to various factors, such as differences in data elements and format requirements for E2B(R3) and E2B(R2), not all data elements listed in Annex 2 will be available for all ICSRs made available to the various stakeholder groups under this access policy.
353	Chapter 2, Page 7, Para 5	Comment: This paragraph includes exact language from the regulation: "... Eudravigilance database shall contain information on suspected adverse reactions in human beings arising from use of the medicinal product within the terms of the marketing authorisation as well as from uses outside the terms of the marketing authorisation, and on those occurring in the course of post-authorisation studies with the medicinal product or associated with occupational exposure." However, EudraVigilance includes other safety information, e.g. from pre-market settings. Proposed change: Modify this paragraph as follows, "... associated with occupational exposure. The database also contains additional types of case reports, such as those arising from interventional clinical trials. ICSRs from pre-marketing interventional clinical trials are not covered by this access policy."	Modify this paragraph as follows, "... associated with occupational exposure. The database also contains additional types of case reports, such as those arising from interventional clinical trials. ICSRs from pre-marketing interventional clinical trials are not covered by this access policy."

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353	Chapter 2, Page 7, Para 8	Comment: This paragraph addresses specifications to be revealed in future: "Detailed technical specifications related to the practical implementation of the Access Policy are being further elaborated taking into account the overall principles set out in this document." These technical details should be subject to public consultation and finalized in light of feedback, and published in sufficient time for stakeholders to develop, test, and implement any required software systems. Proposed change: Modify this paragraph as follows, "...being further elaborated taking into account the overall principles set out in this document. These detailed technical specifications will be subject to public consultation and will be finalized with sufficient time for stakeholders to develop, test, and deploy any required software systems and process changes."	Modify this paragraph as follows, "...being further elaborated taking into account the overall principles set out in this document. These detailed technical specifications will be subject to public consultation and will be finalized with sufficient time for stakeholders to develop, test, and deploy any required software systems and process changes."
353	Chapter 3, Page 7, Para 9	Comment: The first line of chapter 3 refers to "... continuous monitoring ..." This term is not defined in the draft, although it may correlate with eRMR cycles (EMA Document WIN/H/3406, approved 17 September 2012), i.e., screening of electronic reaction monitoring reports is performed to detect new signals monthly for some products and twice a month for others. Proposed change: Modify this paragraph as follows, "... medicines authorised in the EU with the overall aim to promote and protect public health. Each MAH should develop a safety signal monitoring schedule that is appropriate for the continuous monitoring of the safety of the products for which he has pharmacovigilance obligations in the EU."	Modify this paragraph as follows, "... medicines authorised in the EU with the overall aim to promote and protect public health. Each MAH should develop a safety signal monitoring schedule that is appropriate for the continuous monitoring of the safety of the products for which he has pharmacovigilance obligations in the EU."
353	Chapter 4., Page 9, bullet 7	Comment: Referenced text: "Coding of medicinal product information reported in ICSRs against the XEVMPD and future ISO Identification of Medicinal Products (IDMP) standards as outlined in the Commission Implementing Regulation (EU) No 520/2012;" The xEVMPD is only now being created and the IDMP data elements have not been assembled. Further, plans for future IDMP sustainability, i.e., maintenance, remain under discussion. It is imperative for the Agency to ensure the integrity, fidelity, and sustainability of medicinal product identifiers in ICSRs and the compatibility of legacy data before this system goes live. This will be particularly important when stakeholders evaluate drug-event pairs for the emergence of new safety signals and for signal evaluation.	
353	Chapter 5.4.3.3., Page 21, last sentence in this section	Comment: Referenced text: "Access to a maximum of five signal detection and data analysis experts will be granted as regards point ii, iii, and iv; these experts may reside within or outside the EEA." Reference to "point ii, iii, and iv" is not clear. The rationale behind specifying five experts is not clear. For a large, active or diverse product portfolio, additional experts may be justified. Proposed changes: (a) Clarify the reference to "point ii, iii, and iv." (b) Modify the paragraph as follows, "...	(a) Clarify the reference to "point ii, iii, and iv." (b) Modify the paragraph as follows, "... these experts may reside within or outside the EEA. Additional experts may be justified in certain circumstances, such as

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		these experts may reside within or outside the EEA. Additional experts may be justified in certain circumstances, such as for an MAH with multiple divisions, diverse or large product portfolios, etc.; such exceptions must be agreed by the Agency."	for an MAH with multiple divisions, diverse or large product portfolios, etc.; such exceptions must be agreed by the Agency."
353	Chapter 5.4.4.1., Page 22, Para last	Comment: The following sentence is the only instance in the entire document where the need to protect commercially confidential data is mentioned, "• Data access should observe EU legislation on protection of personal and commercially confidential data." More robust language is needed. Proposed change: Modify the paragraph as follows, "• Data access should ~~observe~~ be in compliance with EU legislation on the protection of personal data and with EU law on the protection of commercially confidential data."	Modify the paragraph as follows, "• Data access should ~~observe~~ be in compliance with EU legislation on the protection of personal data and with EU law on the protection of commercially confidential data."
353	Chapter 5.4.4.1, Page 23, 3rd bullet; also Page 15, Table 5, last bullet	Comment: Referenced text: Page 15 "• Researchers to sign agreement that EMA exercises the right of review for publications based on EudraVigilance data including a privacy check (possible re-identification of patients) " Page 23 "• The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." Point #1: To support the Agency with its review of manuscripts and given the fact that research organisations will, under the proposed revised access policy, now potentially be provided with a broader set of data elements than before, equal to those provided to MAHs, we believe the Agency should involve the relevant MAH(s) in also reviewing the manuscript in advance of publication, for information and comment. We believe it would be reasonable to require this only where the research concerns a specific medicinal product or products, which is/are authorized in the EU, and the concerned MAH(s). Point #2: The following final sentence of Table 5 (Page 15) is not clear viz-a-viz the text on Page 23: "Researchers to sign agreement that EMA exercises the right of review for publications based on EudraVigilance data including a privacy check (possible re-identification of patients)". Therefore, we propose to add a reference to the requirement to sign such an agreement explicitly on Page 23. Proposed changes: (a) Modify wording on page 23 as follows, "• The Agency has the right to view any ~~publication~~ manuscript intended for publication or presentation at a scientific meeting that is based on ~~from~~ EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Where the research concerns (a)	Modify wording on page 23 as follows, "• The Agency has the right to view any ~~publication~~ manuscript intended for publication or presentation at a scientific meeting that is based on ~~from~~ EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Where the research concerns (a) specific medicinal product(s), authorised in the EU, the Agency will share the manuscript with the relevant MAH(s) for information and comment in advance of publication. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication or presentation. An agreement that the Agency and the relevant MAH have this right of review for manuscripts based on EudraVigilance data must be signed by the responsible researcher and the research organization.

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		specific medicinal product(s), authorised in the EU, the Agency will share the manuscript with the relevant MAH(s) for information and comment in advance of publication. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication or presentation. An agreement that the Agency and the relevant MAH have this right of review for manuscripts based on EudraVigilance data must be signed by the responsible researcher and the research organization. If replacement of the responsible researcher is contemplated, a new agreement must be signed in advance." (b) Modify wording in Table 5 as follows, "• Responsible researcher~~s~~ and research organization to sign confidentiality undertaking "• Responsible researcher~~s~~ and research organization to sign agreement that EMA and relevant MAH exercise~~s~~ the right ..."	If replacement of the responsible researcher is contemplated, a new agreement must be signed in advance." Modify wording in Table 5 as follows, "• Responsible researcher~~s~~ and research organization to sign confidentiality undertaking "• Responsible researcher~~s~~ and research organization to sign agreement that EMA and relevant MAH exercise~~s~~ the right ..."
353	Chapter 5.4.4.1, Page 23, bullet 2	Comment: Referenced text: "•□Those given access to EudraVigilance data should make appropriate efforts to publish their research." Results should be published promptly to enhance transparency if there are no unresolved points of disagreement. Proposed change: Revise the bullet as follows, "•Those given access to EudraVigilance data should make appropriate efforts to publish their research within one year of completion."	Revise the bullet as follows, "•Those given access to EudraVigilance data should make appropriate efforts to publish their research within one year of completion."
353	Chapter 5.4.4.3., Page 23	Comment: Referenced text: "Data will be provided to a person nominated by the research organisation to safeguard the EudraVigilance data for the research purpose." Both chapter 5.4.4.4. of the EudraVigilance Access Policy which entered into force in July 2011, and chapter 5.4.3.3. of the 2014 revision mention that: "The identification of 'authorised personnel' is based on the EudraVigilance registration process." However, this is not mentioned in chapter 5.4.4.3. of the 2014 revision. A mechanism of prior authorisation by the Agency is essential, to ensure that access is only provided to the person nominated and authorised by the research organisation. If the Agency proposes to provide data extracts directly to the researcher and the researcher does not have access to EudraVigilance itself, then the EudraVigilance registration process would be outside the scope of the proposed access policy for research.	
353	Chapter 5.4.4.4., Page 23	Comment: Referenced text: "The personal data protection requirements applicable to research organisations are the same as for MAHs as outlined in chapter 5.4.3.5." Point #1: It would appear that the intended reference is chapter 5.4.3.4. (rather than "chapter 5.4.3.5."). Point #2: With regard to providing research organizations access to personal data, we note that research organizations are not necessarily in the same legal position as MAHs with regard to rights and obligations vis-à-vis the data subjects	Revise the last paragraph on page 23 as follows, "For purposes of the EudraVigilance access policy for research, the personal data protection requirements applicable to research organisations are the same as for MAHs as outlined in

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		under data protection legislation, for example in the context of pharmacovigilance. Proposed change: Revise the last paragraph on page 23 as follows, "For purposes of the EudraVigilance access policy for research, the personal data protection requirements applicable to research organisations are the same as for MAHs as outlined in chapter ~~5.4.3.5.~~ 5.4.3.4."	chapter ~~5.4.3.5.~~ 5.4.3.4."
353	Annex 2, Page 30	Comment: Footnotes 36 and 37 are not unique. Proposed change: Remove duplicate and renumber.	Remove duplicate and renumber.
353	Annex 2, Pages 31-51	Comment: Typo, header, 3rd column of table, "EELEMENT" Proposed change: Modify to "ELEMENT"	Modify to "ELEMENT"
353	Annex 2, Pages 35-36, rows 5-6	Comment: Intended meaning of footnotes 33, 37, 38, 39 is not clear. Footnote 33 (page 23) refers to Research Request; Footnote 37 (page 30) refers to gateway receipt, etc. Footnotes 38 and/or 39 may be appropriate for element D.2.2b, D.2.3, etc. Proposed change: Apply footnotes to convey intended meaning.	Apply footnotes to convey intended meaning.
353	Annex 2, Pages 42 and 48	Comment: Footnotes 41 and 45 appear to be duplicates. Neither one indicates the level of MedDRA coding, e.g., LLT, PT, etc. Proposed change: Delete duplicate and indicate the level of coding to be provided.	Delete duplicate and indicate the level of coding to be provided.
353	Annex 2, Pages 42-43 and 48-51	Comment: Intended header in last column may be "Stakeholder Group V and VI" instead of "Field ICH or EU." Proposed change: Adjust to intended meaning, as indicated.	Adjust to intended meaning, as indicated.
353	Annex 2, Page 46, row 7	Comment: Reference to footnote 43, which does not appear in the document. Proposed change: Adjust to intended meaning.	Adjust to intended meaning.
353	Annex 2, Page 50, rows 8-9	Comment: ICH H.1 (Case Narrative) provides important context for MAH signal evaluation, etc, as indicated above. Proposed change: Split "PV obligations" and "Research" into separate columns, as suggested above, and include "Y" for the case narrative in the MAH column.	Split "PV obligations" and "Research" into separate columns, as suggested above, and include "Y" for the case narrative in the MAH column.
353	Annex 3, Page 52	Comment: The initialism "XEVMPD" may be intended, since "eXEVMPD" is not used in the document. Proposed change: Adjust to intended meaning.	Adjust to intended meaning.
353	Annex 4, Page 53	Comment: Key references are missing. Proposed change: Add references as follows, - Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) E2B(R3) Data Elements and Message Specification (http://www.ich.org/products/electronic-standards.html), supplemented by ICH Q & - MedDRA Term Selection Points to Consider (http://www.ich.org/products/meddra.html; This is periodically revised to correspond to MedDRA upversioning, which occurs twice per year)	Add references as follows, 1) Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) E2B(R3) Data Elements and Message Specification (http://www.ich.org/products/electronic-standards.html), supplemented by ICH Q & A

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			2) MedDRA Term Selection Points to Consider (http://www.ich.org/products/meddra.html; This is periodically revised to correspond to MedDRA upversioning, which occurs twice per year)
354		Please do not allow results data to be blocked, it is important to modern medicine that all trial data and results be made available so that trends can be more easily identified by analysing full sets of data. allowing the blocking of data will mean creating holes in the overall picture, putting patients at risk	
355	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	This is my comment, as both a citizen and trained pharmacist with professional experience in clinical trials and advocacy (European AIDS Treatment Group and Médecins Sans Frontières), to the consultation on the "Draft revision of EudraVigilance access policy for medicines for human use". I feel concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. Firstly, and most importantly, I strongly disagree with the following two conditions: - "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." - "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles, unless clarified, seem to give the EMA the right to supress anything in an academic paper that it disagrees with. As it is written now, it reads like state censorship of scientific discussion and analysis of public health data. Moreover, would the EMA have the manpower of statistical reviewers to perform the screening? What about litigations? Consequently, what is proposed is unworkable and these two principles should be removed. Secondly, I am also concerned by the following principle: "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains *unconvinced* (sic) of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." How does the EMA intend to create such panels and	

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		guarantee their independence from conflicts of interest? Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made publically available to the broader scientific community, possibly open access (please follow the 2012 Recommendations from the European Commission on Scientific Information and the open access / open data conditions for Horizon 2020 in that respect!). Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in my view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. I am concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We all must ensure that healthcare professionals and the public have useful access to up- to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
356		I am deeply concerned about the proposal in your consultation document that gives the EMA the ability to block publication of independent analysis that you disagree with. If medicines regulation is to be truly transparent and independent, then it cannot be the case that analyses of medical data can be censored. If the EMA disagrees with the analysis of side effects data, this is not an argument for suppressing it - the EMA can	

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		publish its own analysis in the public domain, and the scientific community can judge which is correct. It is important that our system of regulation is transparent and is, and is seen to be, independent and available for public scrutiny.	
357		Correction. - Risperdal not tried and tested on children - made her worse than ever. There should be complete openness and honesty with regards to any trials of drugs and adverse reactions. I have seen my daughter now 27 suffer from one drug after another and have the most shocking adverse reactions. She has been on about 14 and my younger daughter was only 13 when put on dispersal - none of these drugs have worked and eldest daughter is suffering from the onset on tardive dyskinesia - something bad happened to them both and instead of decent care they got given drugs that affected them both badly. I have seen akathisia - hallucinations - suicidsl thoughts and aggression, I have not got a good word to say about these drugs that cause nothing but misery, whilst much money is being made to experiment on people like my daughter your organisation should be concerned with the well being of people like my daughter and not trying to hide any information on risks due to adverse reactions. So I am in favour of transparency and not cover ups.	
358		The EMA should not have the ability to block publication of analyses it disagreed with.	
359	Page 5, Executive Summary	Royal Pharmaceutical Company (RPC) is pleased to note that, following an appropriate request, researchers will be given access to more detailed drug safety data. This has the potential to improve the public health benefit of the drug safety data.	
359	Page 22, Section 5.4.4.1	RPS recognises the importance of ensuring patient data remain confidential. The requirements laid out for the protection of personal and commercially confidential data are proportionate and do not appear excessive.	
359	Page 23, Section 5.4.4.1	RPS accepts that researchers should justify any request for access to data, and that there may be circumstances where EMA will refuse this request. While the RPS understands the reasons why the EMA would like to see researchers publication prior to submission, we have some concerns around the restrictions the EMA places on this. The consultation document states that the EMA has the “right to view any publication resulting from EudraVigilance data before submission” and that “issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” This approach seems contradictory to the wider move towards greater transparency around patient data in clinical trials, with accompanying support of many pharmaceutical companies. While the RPS accepts the need for ensuring the protection of personal data, we question whether	

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		the EMA is in a position to assess any analyses, inferences and statements included in potential publications by researchers in a detached and unbiased manner given that in some cases researchers findings may be critical of, or not aligned with, the EMA view. Given this potential conflict of interest, the RPS recommends that any review of potential publications be undertaken by a body independent of the EMA.	
360		I am writing as a scientific researcher to express my views on your latest consultation. I am particularly concerned by one condition on access listed in section 5.4.4.1, namely the Agency's right to review publications and raise issues concerning incorrect analyses, unsupported references, etc. This goes against the principle of academic freedom in a profound way, giving the Agency control over the use to which data is put and casting the Agency as an arbiter of what is published, in a way that amounts to state censorship. It is in my view entirely unnecessary. The best way to determine the correctness of analyses, references and so on is through public discusssion, supported by the established process of peer review. Overall, I would urge you to strive for a simpler document, which imposes fewer conditions on the access to information and the uses to which it may be put.	
361	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	The AllTrials campaign was launched in January 2013 to call for all clinical trials to be registered and results reported. It is an initiative of Bad Science, BMJ, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative, PLOS and Sense About Science. It is supported by nearly 80,000 people and over 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world. Principles of access for research organisations - We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions:- "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." - "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a	

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		profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: • “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: - “Those given access to EudraVigilance data should make appropriate efforts to publish their research.” There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data We support the EMA’s aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51).	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
362		I share the concerns and questions raised by the AllTrials campaign, as expressed in the attached. http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
363		As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.adrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? We agree. As regards stakeholder groups III A “Marketing Authorisation Holders” do you consider the data set proposed in Annex 1 (Table column PV obligations – Level 2) as sufficient for a MAH to comply with the pharmacovigilance obligations as outlined in Regulation (EC) 726/2004, Directive 2001/83/EC, the Commission Implementing Regulation (EU) 520/2012 and the Good Pharmacovigilance Practice Modules? We agree. We have some comments in the level of access 1 and 2 for Marketing Authorisation Holders: 1. e-RMR and the related ICSR data element subset as used by EMA and NCA for their signal detection activities. ICSR data elements for the purpose of signal detection (annex 2) will be downloaded in Excel format. We consider that a restriction in the number of ICSRs that can be downloaded should be considered. If we allow MAHs to download all ICSRs from EudraVigilance to their local databases, they could try to consolidate the information. This will imply a high risk of increasing duplicates and information requests about ICSRs to NCAs. 2. Fullfilling the MAH’s PhV obligations. This access will replace the current ICSR interchange between NCA and MAH. We consider that case summary and reporter’s comments when exists are very	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		useful information in signal validation. We also consider that the date of start and end of the ADR should be included in this level of access. Although there are some additional fields like “ADR duration” or “time to onset since the drug was taken”, in some cases the only information available or incomplete dates. The temporal sequence between ADR and drug is crucial for causality assessment. 3. Access to the whole information of ICSR sent directly from MAH to EV. We agree with the proposal.	
364		Openness about reported adverse drug reactions (ADRs) is important to increased public trust in drugs and the work of regulatory authorities. The question is: is showing not interpreted data of reports of value to the public? We think it is far more important to be transparent on all aspects regarding drug safety, including showing data en analyses, which discussions are made on safety issues, before and after registration of a drug. Thereby we think is would be very strange ,and even incompatible that non-interpreted ADR reports will be fully transparent, whereas data and interpretation of registration studies are not. Nevertheless it is good that data about potential ADRs are publicly available. The question is how? What information is useful for the general public to be able to search? At the Netherlands Pharmacovigilance Centre Lareb we embraced the concept on transparency early, and our database has been online since 2005. In the last few years we have come to the conclusion that showing all the individual reports (having privacy regulations in mind) might not be the best way to inform the public. There are a couple of reasons to be considered when showing data on reported ADRs - Although disclaimers are available, very few people really understand how to interpret data from a spontaneous reporting system. Therefor very recently we changed the data available for the public. We now show aggregated data on total numbers of reports on a drug, the distribution on year of report, year of occurrence of the ADRs and age and sex. Also we show the numbers of reported ADRs (PT Medra Terms). In contrary to the choice made in this policy draft, we decide to no longer show the outcome and death. This decision is made on basis of years of experience in showing this data and the consequences or erroneous interpretation - Of course, it is never possible to present all the information from a message, so whatever you show it can never represent the whole context, therefore you should be aware that information it can be misinterpreted and you have to avoid this. So, especially when you make a selection of the available data in a report, and not giving insight into data in the report, as is chosen for stakeholder group II, this is an problem. Of course there is already the problem of the missing interpretation of the assessor, but thereby even if you leave this interpretation to the (public) viewer, selected data can and will lead to of misinterpretations. - For example, death and hospitalization can also have other causes	

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		than ADRs. But the possible other causes are not shown. Not only, bur especially in ADR reports from patient support programs, this is a huge problem. - More recently, data from patient support programmes (PSPs) are considered to be “spontaneous reports” and filed in the Eudravigilance database. The circumstances from PSP programmes may be different from the genuine spontaneously reported data. For example, if a drug used for the treatment of pulmonary hypertension is monitored in a PSP, the reports with a fatal outcome will increase enormously. Not because the drug is associated with a fatal outcome, but because the patients involved may be terminally ill. Without a proper explanation of differences underlying these type of reports, interpretation will lead to erroneous conclusions	
365		I am writing to express my concern about the proposed updates to the EudraVigilance access policy, which would give researchers access to more detailed and systematic records from the database but it also contains a condition that would give the EMA the ability to block publication of analyses it disagreed with. This conflicts with the need for transparency with regard to all accessible data. The issues of confidentiality of patient identifiable data are already adequately addressed.	
366		I'd like to briefly add my own comments to your public consultation on the proposed revision of the EudraVigilance access policy. Speaking as a scientist, I think it's really important that the full data should be widely available, so that data can be freely analysed with the maximum of transparency. It's vital that the access rules should not facilitate (whether unintentionally or deliberately) any form of scientific censorship of "wrong" conclusions.	
367		It is with utter disbelief that any medical regulation body would even consider censoring side effects of medication. I find this extremely worrying as without these being listed it leaves the patient at the mercy of the pharmaceutical corporation. Side effects are a very real worry to both patients and medical staff so for the regulatory body to contemplate this is an outrage and will endangers patients well being and lives.	
368		Question 1 As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Response: The aggregate data currently provided on www.adrreports.eu for CAP products appears adequate for stakeholder group II when expanded to all medicinal products authorised in the EEA. However, it is not possible to associate data elements that would be included in an individual case report. In order to	

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		address that and to provide better access to data elements through and an application programming interface that returns information in a standard data interchange format, EMA could take some learnings from the FDA's openFDA innovation which currently is looking at this issue (https://open.fda.gov) Important elements/tables to assess the relevance of the data are missing in the actual outputs. For example, for selected reaction group and reactions it may be of interest to present the data: - per treatment indication - per seriousness – this is of particular importance with non-serious ICSR reporting - in case of interaction events, per drug/drug class involved in the interaction According to the revised EV access policy, Indication (p48) and Seriousness (p43) should be accessible. When the revised EV access policy is compared to what is currently available on http://www.adrreports.eu/EN/search.html, there are uncertainties as to what would be included – according to our understanding no change is foreseen for the content of the actual website unless suggested during the consultation.	
368		Question 2 As regards stakeholder groups III. A "Marketing Authorisation Holders" do you consider the data set proposed in Annex 1 (Table column PV obligations – Level 2) as sufficient for a MAH to comply with the pharmacovigilance obligations as outlined in Regulation (EC) 726/2004, Directive 2001/83/EC, the Commission Implementing Regulation (EU) 520/2012 and the Good Pharmacovigilance Practice Modules? Response: EFPIA welcomes the enhanced access granted to MAHs under this revised policy. We consider that the sharing of necessary data (to assess "clinical relevance, quantitative strength of the association, the consistency of the data, the exposure–response relationship, the biological plausibility, experimental findings, possible analogies and the nature and quality of the data") is important to facilitate signal detection and analysis and therefore promote the safety of medicines as a whole. However, we consider that the data set is not sufficient to comply with MAHs' PV-related obligations. It would be advisable for independent research and PV obligations to appear in separate columns; research access would retain the specifics listed in the current column, whereas MAH PV obligations should also include, ICH H.1 (Case narrative), page 50, for use in signal evaluation, benefit-risk assessment, causality reviews, and to provide context for Reporter's comments. In addition, C.1.6.1.r.2 (Included documents), page 31, ICH c.4.r.2 (Included documents), page 34, and ICH H.5.r.1a and H.5.r.1b (Reporter comments in native language), page 51, and Data element G.k.2.5: "investigational product blinded" should be available to an MAH upon request. The value and role of the 43 EU-specific data elements (8 on page 37, 5 on page 38, 3 on page 40, 10 on page 41, 10 on page 45, 4 on page 46, and 3 on page	

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		49) may become clarified when the EU Individual Case Safety Report (ICSR) Implementation Guide is finalized and software tools are developed to analyze these data elements. It would be helpful to have clarification whether the company can access data of other MAHs for the same substance. Otherwise, the accessible dataset may not be different from the one already available to the MAH in their database, over which signal detection is already performed, especially if they already have an automated signal detection tool in place. Disproportionality analyses would be helpful in interpreting the data; the possibility to provide this type of analyses to stakeholders should be considered. It would appear that the intended reference is Annex 2. Annex 1 outlines reporting principles and classification rules for ICSRs. Annex 2 is a tabular listing of proposed availability of specific data elements for MAHs to meet pharmacovigilance obligations (Level 2) and for research purposes. Note that several column headers and footnotes in the Annex 2 table require correction, as detailed in the specific comments on text below. This Draft "Revision of EudraVigilance access policy for medicines for human use" (EMA/759287/2009, Revision 1, dated 4 August 2014) describes proposed policy to be applied to EudraVigilance for the access of six stakeholder groups, including the public, to individual case safety report (ICSR) data. It is proposed that the policy becomes effective six months following the announcement by the EMA Management Board that the EudraVigilance database has achieved full functionality. The proposed access is at the individual ICSR level, which will significantly expand the utility of safety data that are currently available to the public in aggregate form for a limited number of medicinal products. Overall, it appears that the purpose of the document is to clarify stakeholder expectations and requirements for access to single case EudraVigilance data. The access policy is intended to facilitate the continuous monitoring of the safety of medicinal products in the EEA, while protecting patient data privacy, and to enable detection of new safety signals as well as timely benefit-risk assessments. National Competent Authorities receive case safety reports for medicinal products directly from consumers, healthcare professional, and others. To ensure consistency across the EEA while supporting both transparency and patient data protection, the practices and possible constraints within Member States regarding the information currently provided to MAHs will need to be evaluated and considered as the EudraVigilance access policy is finalized. We agree with the statement on page two regarding a separate consultation on possible stakeholder access to suspected unexpected serious adverse reactions (SUSARs) from interventional clinical studies. Throughout the document reference is made to the ICH implementation guide for the E2B(R3) ICSR message and the EU-specific regional supplemental implementation	

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		guide for the E2B(R3) message. Data currently residing in EudraVigilance has been transmitted using the ICH E2B(R2) message specification. Further, it is proposed that stakeholders be provided data as E2B(R3) files (only). Extensive testing with the new E2B(R3) specification will be needed and the draft EU regional implementation guide will need to be finalized before extensive development and user acceptance testing can be achieved. The ICH E2B(R3) Implementation Guide will be supplemented by an ICH Q&A document and this should be taken into account. Furthermore, forward compatibility of an E2B(R2) to E2B(R3) data conversion, and responsibility for same, must be evaluated to ensure full utility of legacy data. We note that the ICH Backwards Forwards Compatibility (BFC) document is not referenced; it may be helpful for the various stakeholders to guide understanding of E2B(R3) output that is derived from E2B(R2) data elements. Further information on the analytical methodology and information outputs are needed for MAHs to plan for surveillance activities to fulfill their obligations as regards Eudravigilance data, followed by a suitable transposition period to enable MAHs to plan for implementation. The data accessible through this data access policy is restricted to EEA reports only. As an MAH has a requirement to also submit foreign cases, it would be beneficial for the access to be extended to these reports also. EMA proposes to grant MAHs access only to data on their own drugs. Access should be possible both at the active ingredient and medicinal product levels, to allow for all relevant searches. It would be helpful to have clarification whether the company can access to data of other MAHs for the same substance. If a company is only given access to a dataset for which they hold the marketing authorisation then this data may not be any different than the data in the MAH's safety database over which signal detection is already performed, especially if they already have an automated signal detection tool in place. In addition, having only access to the MAH's substances precludes any type of disproportionality analysis (data mining), as well as MAHs use of Eudravigilance data to investigate class effects as described in EU GVP IX B.3.5 Signal assessment. As an alternative, the agency may consider the provision of this type of analyses to stakeholders. If the EMA has not the capacity itself, please consider giving to a vendor the appropriate access to ICSR data. Regarding access to the data by stakeholder group IV (research organisations), page 23 states that those given access to EudraVigilance data should make appropriate efforts to publish their research. There is a concern that this could result in increased publication in the literature with the only evidence based on the data already within EudraVigilance. If it is not clear that the data is wholly from EudraVigilance, MAHs and the Agency will be required to review the publications which could cause some duplicate entry into the databases. Full	

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		disclosure on the origin of the data should be mandatory for the authors. It is unclear whether MAHs are expected to review EudraVigilance for all cases for potential ICSRs for their products. It is understood that MAHs will be expected to pull cases from Competent Authorities who will report directly to EudraVigilance for their product; however, it remains unclear if MAHs would be expected to pull cases reported by another company when including a MAH's product as suspect. For downloaded cases, MAHs need all product identifiers and all information in free text fields (narrative, senders comment, laboratory test information which could not be coded). Annex 1 should be removed from this document as the content is not relevant to the scope of the document and is found in the Good Pharmacovigilance Practices (GVPs). Reference to applicable regulations / guidelines would be sufficient. We appreciate the opportunity to participate in the public consultation process; we would be glad to meet with EMA representatives to clarify any of our comments. As regards specific comments, proposed changes to the text are underlined. "Para" references the paragraph number on the indicated page.	
368	Executive Summary, Page 5, last bullet	Comment: Referenced text, "– The data elements for ICSRs have been updated in line with the ISO ICSR standard and the ICH E2B(R3)/EU ICSR Implementation Guide (Table 1 and Annex 2)." This is an aspirational statement, as the updating has not yet occurred and the EU implementation guide must be finalized first. It is not clear whether all of the legacy data that were transmitted in E2B(R2) format will be transformed into E2B(R3) data elements, which requires certain manual manipulations, prior to the access policy coming into force. Clarify the proposed plan for providing uniform data elements. Proposed change (if accurate): Revise the bullet as follows, "– The data elements for ICSRs have been updated in line with the ISO ICSR standard and the ICH E2B(R3)/EU ICSR Implementation Guide (Table 1 and Annex 2). Due to various factors, such as differences in data elements and format requirements for E2B(R3) and E2B(R2), not all data elements listed in Annex 2 will be available for all ICSRs made available to the various stakeholder groups under this access policy.	Revise the bullet as follows, Due to various factors, such as differences in data elements and format requirements for E2B(R3) and E2B(R2), not all data elements listed in Annex 2 will be available for all ICSRs made available to the various stakeholder groups under this access policy.
368	Page 5	For this purpose access is being extended from spontaneous reports to reports from non-interventional studies. Would that include access to ALL 'reports from study' that are not marked as 'Clinical Trial' (i.e. including ICSR submissions from compassionate use/expanded access programs?) Proposed change (if any): Please clarify intent here	Please clarify intent here
368	Chapter 2, Page 7, Para 5	Comment: This paragraph includes exact language from the regulation: "... Eudravigilance database shall contain information on suspected adverse reactions in human beings arising from use of the medicinal product within the terms of the marketing authorisation as well as from uses outside the terms of the marketing	The database also contains additional types of case reports, such as those arising from interventional clinical trials. ICSRs from pre-marketing interventional

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		authorisation, and on those occurring in the course of post-authorisation studies with the medicinal product or associated with occupational exposure." However, EudraVigilance includes other safety information, e.g. from pre-marketing settings. Proposed change: Modify this paragraph as follows, "... associated with occupational exposure. The database also contains additional types of case reports, such as those arising from interventional clinical trials. ICSRs from pre-marketing interventional clinical trials are not covered by this access policy."	clinical trials are not covered by this access policy."
368	Chapter 2, Page 7, Para 8	Comment: This paragraph addresses specifications to be revealed in future: "Detailed technical specifications related to the practical implementation of the Access Policy are being further elaborated taking into account the overall principles set out in this document." These technical details should be subject to public consultation and finalized in light of feedback, and published in sufficient time for stakeholders to develop, test, and implement any required software systems. Proposed change: Modify this paragraph as follows, "...being further elaborated taking into account the overall principles set out in this document. These detailed technical specifications will be subject to public consultation and will be finalized with sufficient time for stakeholders to develop, test, and deploy any required software systems and process changes."	Modify this paragraph as follows, "...being further elaborated taking into account the overall principles set out in this document. These detailed technical specifications will be subject to public consultation and will be finalized with sufficient time for stakeholders to develop, test, and deploy any required software systems and process changes."
368	Chapter 3, Page 7, Para 9	Comment: The first line of chapter 3 refers to "... continuous monitoring ..." This term is not defined in the draft, although it may correlate with eRMR cycles (EMA Document WIN/H/3406, approved 17 September 2012), i.e., screening of electronic reaction monitoring reports is performed to detect new signals monthly for some products and twice a month for others. Proposed change: Modify this paragraph as follows, "... medicines authorised in the EU with the overall aim to promote and protect public health. Each MAH should develop a safety signal monitoring schedule that is appropriate for the continuous monitoring of the safety of the products for which he has pharmacovigilance obligations in the EU."	Each MAH should develop a safety signal monitoring schedule that is appropriate for the continuous monitoring of the safety of the products for which he has pharmacovigilance obligations in the EU."
368	Chapter 3, Page 8, Para 2	Comment: We welcome the increased access to EudraVigilance. However, as increased access can in some cases involve a greater risk of leaks, the establishment of efficient safeguards for confidentiality of ICSRs and protection of personal data are of the outmost importance. The text should clarify that the liability in case of leaks or security breaches lies with the institution responsible for holding the data. Proposed change (if any): Please, add the underlined text as shown below: "As a general principle, an adequate level of redaction of personal data included in the concerned assessment reports and other related documents must be ensured, taking into account the application of Regulation (EC) 1049/200112 concerning access to documents as well as	The liability in case of leaks or security breaches that compromise personal data lies with the institution responsible for holding the data."

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		applicable EMA/HMA transparency policies The liability in case of leaks or security breaches that compromise personal data lies with the institution responsible for holding the data."	
368	Chapter 4., Page 9, bullet 7	Comment: Referenced text: "Coding of medicinal product information reported in ICSRs against the XEVMPD and future ISO Identification of Medicinal Products (IDMP) standards as outlined in the Commission Implementing Regulation (EU) No 520/2012;" The xEVMPD is only now being created and the IDMP data elements have not been assembled. Further, plans for future IDMP sustainability, i.e., maintenance, remain under discussion. It is imperative for the Agency to ensure the integrity, fidelity, and sustainability of medicinal product identifiers in ICSRs and the compatibility of legacy data. This will be particularly important when stakeholders evaluate drug-event pairs for the emergence of new safety signals and for signal evaluation.	
368	Section 5.2 Overview reference – opening paragraph, page 10	"Implementation Guide for the Electronic Transmission of Individual Case Safety Reports (ICSRs) and E2B(R3) Data Elements and Message Specification" (Version 5.01, 12 April 2013) – comment E2B(R3) is not yet mandatory. Should this not be noted. There is no mention of existing framework for E2B(R2) transmissions	
368	Table 1 – Group 3 data provisions for Signal detection & Detailed PV obligations	Lack of access to patient identifiers may compromise the MAH's ability to detect duplicates.	
368	Section 5.4	Comment: Would a company be informed if a researcher is looking at their data?	
368	Section 5.4.1.2. Page 19	In the interests of transparency and consistency of evaluation, clarification should be provided in the revised policy on how the Competent Authorities (CAs) in the EEA conduct signal detection and the data fields they use for this purpose. A high-level overview of the analytics used in the EudraVigilance Analysis Toolkit (EVDAS) should also be provided.	
368	Section 5.4.3.1.a) Page 20	With regards to e-RMR reports and data outputs more detailed information will be required to clarify the MAHs' obligations and to enable MAHs to process the data (and therefore comply with their legal obligations). This information could be provided in an Annex to the policy or in a separate guidance document or user manual.	

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		Specifically we request clarification/more information on the following: Data format and report/output content • Please clarify the level of detail included in e-RMRs, with regard to statistical methods or outputs. • Please confirm the output will not be limited to the MAH data, but will include all data • Please clarify the format of the data contained in e-RMR reports. It is expected not to be in PDF, as this would not allow the MAH to manipulate the data for analysis and further statistical treatment. Data Validation and Analysis • Minimal information elements are included in e-RMR. We have some concerns that without sufficient level of detail the MAH's ability to perform validation and further analysis of signals will be limited. • Full information is provided to senders (sender-based access to EVWEB). In order for the MAH to manage safety signals where the ICSRs are not reported by the MAH (which is in many cases), full information should also be provided to the MAH. • Please clarify how further (i.e., follow-up) information on reported cases will be obtained to enable the completion of signal analysis. • Please clarify that MAHs will be able to request redacted cases that are not in the company database (as is the case in the US for cases reported to FDA). • Further guidance is requested on how to use and interpret e-RMR outputs and what is expected by MAHs. For example, will all analyses be completed, or are MAHs expected to do additional analyses on the data provided in e-RMR? • Please clarify that the generation of e-RMR will allow for exploratory analysis and can e-RMR be used to answer ad hoc questions and provide follow up on signals. Downloading of data • It is our understanding that the MAH can download the data, as needed, from the restricted area of the EV website, rather than having to request them individually in each and every case. Please can this be clarified? In addition, it would be helpful for the download to be automated - is this possible - and if so, can further details be provided? Implementation period and request for examples from the database Currently we are not able to start to plan for surveillance activities - to fulfil our MAH obligations to review EudraVigilance data - without further knowledge of the analysis tools and information MAHs will be working with. Therefore, we request consideration of a suitable implementation period in which the clarifications requested above are provided. In addition it would be helpful if the Agency shares an example of an e-RMR	

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		and accompanying related ICSR elements for one product to aid in the planning process.	
368	Section 5.4.3 Page 21	Confirmation is needed in Section 5.4.3 that MAHs (Stakeholder Group III) will have access to EVDAS (EudraVigilance Data Warehouse and Analysis System). The earlier Section 5.3 contains general statements about access to EudraVigilance data and methods of access, including EVDAS. However, there is no specific mention of access in Section 5.4.3 for Stakeholder Group III (MAHs). This is in contrast to Section 5.4.1 of the draft policy relating to Stakeholder Group I, which specifically mentions access to EVDAS. Assuming that MAHs will be granted access to EVDAS we seek clarification on the analytical methods used in EVDAS. If EVDAS is not made available to MAHs, guidance should be provided on how MAHs will perform signal detection without an analysis tool.	
368	Chapter 5.4.3.3., Page 21, last sentence in this section	Comment: Referenced text: "Access to a maximum of five signal detection and data analysis experts will be granted as regards point ii, iii, and iv; these experts may reside within or outside the EEA." Reference to "point ii, iii, and iv" is not clear. - Is the total for the mix of personnel or 5 of each kind of professionals involved in these activities? - Are individuals who manage data in XEVMPD part of the same 5? - There is no mention of any training provisions for these individuals. The rationale behind specifying five experts is not clear. For a large, active or diverse product portfolio, additional experts may be justified. In large pharmas the proposed level of access would not be sufficient to cover the personnel who perform signal detection, and would be inadequate to cover all products, especially if analysis, exploration, ad hoc queries are possible in the systems. Moreover this would prevent acces of other personnel performing research and analysis of external data. Access should be granted proportionally to the extent of the portfolio of innovative products, and factoring the individual MAHs organization Proposed changes: (a) Clarify the reference to "point ii, iii, and iv." (b) Modify the paragraph as follows, "... these experts may reside within or outside the EEA. Additional experts would be justified in certain circumstances, such as for an MAH with multiple divisions, diverse or large product portfolios, etc.; such exceptions must be agreed by the Agency."	(a) Clarify the reference to "point ii, iii, and iv." (b) Modify the paragraph as follows, "... these experts may reside within or outside the EEA. Additional experts would be justified in certain circumstances, such as for an MAH with multiple divisions, diverse or large product portfolios, etc.; such exceptions must be agreed by the Agency."
368	Chapter 5.4.4.1., Page 22, Para last	Comment: The following sentence is the only instance in the entire document where the need to protect commercially confidential data is mentioned, "• Data access should observe EU legislation on protection of personal and commercially confidential data." More robust language is needed. Proposed change: Modify the paragraph as follows, "• Data access should ~~observe~~ be in compliance with EU legislation on the protection of personal data and with EU law on the protection of commercially confidential data."	Modify the paragraph as follows, Data access should ~~observe~~ be in compliance with EU legislation on the protection of personal data and with EU law on the protection of commercially confidential data."

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368	Section 5.4.4.1, page 23, bullet 1	Comment: We welcome EMA's efforts to increase access for bona fide non-commercial Research Organisations with the objective of furthering science to the benefit of patients. EFPIA and PhRMA launched earlier in 2014 a set of joint principles for responsible clinical data disclosure including a system for granting access for external bona fide researchers to conduct secondary research on companies' clinical study data upon request. In line with these principles, a number of companies have already set up Review Boards that assess the scientific validity of the received request proposals before granting access. Based on our experiences, we recommend that EMA ensures that its Panel includes experts in register-based research and in biostatistics, as well as clinicians within the disease area(s) in question, for the assessment of the scientific validity and societal relevance of the received research proposals. Moreover, in order to enable credibility and trust around the Panel's decisions, the Panel's detailed decision-making procedures, assessment criteria and the Panel's final decisions on individual proposals must be made publicly available. We urge the assessment criteria to include considerations as proposed below. Proposed change (if any): • An ad-hoc EMA panel will review requests for research access to data based on a research request33 The EMA panel will include as a minimum 1 expert in register-based research, 1 expert in biostatistics, as well as clinicians within the disease area(s) in question. Their assessment of the received research proposals will include considerations of the following: - Public health relevance of the proposed studies - Scientific rationale - Ability of the requested study data to address the research objective proposed - Ability of the proposed statistical analysis plan (design, methods and analysis) to meet the scientific objectives and whether this adheres to good analysis practices such as outlined in the ICH-E9 guideline, as well as the ENCePP Code of Conduct and Guide on Methodological Standards in Pharmaco-epidemiology - Publication plan for the research which should include timely publication of the research in a peer-reviewed scientific publication in accordance with the Helsinki Declaration - Ethical considerations - Declaration of real or potential conflicts of interest that may impact the planning, conduct or interpretation of the research and the proposals to manage these conflicts of interests - Declaration of source(s) of funding so as to help ensure that access is given solely to bona fide Research Organisations rather than to commercial entities	● An ad-hoc EMA panel will review requests for research access to data based on a research request33 The EMA panel will include as a minimum 1 expert in register-based research, 1 expert in biostatistics, as well as clinicians within the disease area(s) in question. Their assessment of the received research proposals will include considerations of the following: - Public health relevance of the proposed studies - Scientific rationale - Ability of the requested study data to address the research objective proposed - Ability of the proposed statistical analysis plan (design, methods and analysis) to meet the scientific objectives and whether this adheres to good analysis practices such as outlined in the ICH-E9 guideline, as well as the ENCePP Code of Conduct and Guide on Methodological Standards in Pharmaco-epidemiology - Publication plan for the research which should include timely publication of the research in a peer-reviewed scientific publication in accordance with the Helsinki Declaration - Ethical considerations - Declaration of real or potential conflicts of interest that may impact the planning, conduct or interpretation of the research and the proposals to manage these conflicts of interests - Declaration of source(s) of funding so as

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		- Qualifications and experience of the Requestor's research team to conduct the proposed research which must include as a minimum a qualified statistician - There should also be full transparency around the received research proposals, including their proposed objectives, research teams and sources of funding. Safeguarding the confidentiality of the ICSRs and protection of personal data takes priority and therefore, all data should be anonymised before sharing with Research Organisations, and the proposed confidentiality agreements must be supported by appropriate enforcement mechanisms and sanctions in case of breach. • The Panel's decision-making procedures and assessment criteria will be made publicly available on EMA's website. The EMA website will also host a regularly updated log of the received research proposals, including their proposed objectives, requestor(s) and sources of funding, and the Panel's final decisions on these. • An ad-hoc EMA panel will review requests for research access to data based on a research request. The Agency may refuse access to the data if the panel remains unconvinced of the public health value or scientific validity of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.	to help ensure that access is given solely to bona fide Research Organisations rather than to commercial entities - Qualifications and experience of the Requestor's research team to conduct the proposed research which must include as a minimum a qualified statistician - There should also be full transparency around the received research proposals, including their proposed objectives, research teams and sources of funding. Safeguarding the confidentiality of the ICSRs and protection of personal data takes priority and therefore, all data should be anonymised before sharing with Research Organisations, and the proposed confidentiality agreements must be supported by appropriate enforcement mechanisms and sanctions in case of breach. ● The Panel's decision-making procedures and assessment criteria will be made publicly available on EMA's website. The EMA website will also host a regularly updated log of the received research proposals, including their proposed objectives, requestor(s) and sources of funding, and the Panel's final decisions on these. An ad-hoc EMA panel will review requests for research access to data based on a research request. The Agency may refuse access to the data if the panel remains unconvinced of the public health value or

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			scientific validity of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.
368	Chapter 5.4.4.1, Page 23, bullet 2	Comment: Referenced text: "• Those given access to EudraVigilance data should make appropriate efforts to publish their research." Results should be published promptly if there are no unresolved points of disagreement. Proposed change: Revise the bullet as follows, "• Those given access to EudraVigilance data should make appropriate efforts to publish their research within one year of completion."	"• Those given access to EudraVigilance data should make appropriate efforts to publish their research within one year of completion."
368	Chapter 5.4.4.1, Page 23, bullet 3; also Page 15, Table 5, last bullet	Comment: Referenced text: Page 15 "• Researchers to sign agreement that EMA exercises the right of review for publications based on EudraVigilance data including a privacy check (possible re-identification of patients) " Page 23 "• The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." To support the Agency with its review of manuscripts and given the fact that research organisations will, under the proposed revised access policy, now potentially be provided with a broader set of data elements than before, equal to those provided to MAHs, we believe the Agency should involve the relevant MAH(s) in also reviewing the manuscript in advance of publication, for information and comment. We believe it would be reasonable to require this only where the research concerns a specific medicinal product or products, which is/are authorized in the EU, and the concerned MAH(s). The following final sentence of Table 5 (Page 15) is not clear vis-à-vis the text on Page 23: "Researchers to sign agreement that EMA exercises the right of review for publications based on EudraVigilance data including a privacy check (possible re-identification of patients)". Therefore, we propose to add a reference to the requirement to sign such an agreement explicitly on Page 23. Proposed changes: (a) Modify wording on page 23 as follows, "• The Agency has the right to view any ~~publication~~ manuscript intended for publication or presentation at a scientific meeting that is based on ~~from~~ EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Where the research concerns (a) specific medicinal product(s), authorised in the EU, the Agency will share the manuscript with the relevant MAH(s) for information and comment in advance of publication. Any issues	"• The Agency has the right to view any ~~publication~~ manuscript intended for publication or presentation at a scientific meeting that is based on ~~from~~ EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Where the research concerns (a) specific medicinal product(s), authorised in the EU, the Agency will share the manuscript with the relevant MAH(s) for information and comment in advance of publication. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication or presentation. An agreement that the Agency has this right of review for manuscripts based on EudraVigilance data must be signed by the responsible researcher and the research organization. If replacement of the responsible researcher is contemplated, a new

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		raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication or presentation. An agreement that the Agency has this right of review for manuscripts based on EudraVigilance data must be signed by the responsible researcher and the research organization. If replacement of the responsible researcher is contemplated, a new agreement must be signed in advance." (b) Modify wording in Table 5 as follows, "• Responsible researchers and research organization to sign confidentiality undertaking "• Responsible researchers and research organization to sign agreement that EMA exercises the right ..."[...] A confidentiality agreement must be signed by the party applying for extended data access for research purposes. Data may not be transferred to any third party. Any breaches of the confidentiality agreement will followed by appropriate sanctions. [...] The personal data protection requirements applicable to research organisations are the same as for MAHs as outlined in chapter 5.4.3.5. All patient-level data must be anonymised before sharing with Research Organisations.	agreement must be signed in advance." Responsible researchers and research organization to sign confidentiality undertaking "• Responsible researchers and research organization to sign agreement that EMA exercises the right ..." [...] A confidentiality agreement must be signed by the party applying for extended data access for research purposes. Data may not be transferred to any third party. Any breaches of the confidentiality agreement will followed by appropriate sanctions. [...] The personal data protection requirements applicable to research organisations are the same as for MAHs as outlined in chapter 5.4.3.5. All patient-level data must be anonymised before sharing with Research Organisations.
368	Section 5.4.4.2. Page 23	Please provide clarification on how an MAH accesses the extended subset of ICSR data elements in ICH E2B(R3) XML format for substances for which MAH holds marketing authorization(s) in order to fulfill PV obligations/Research (Level 2 Access). We would expect that the MAH can download these elements from the EV Website. Please clarify whether MAH versus non MAH reported cases will be labelled and therefore easily identifiable.	
368	Chapter 5.4.4.3., Page 23	Comment: Referenced text: "Data will be provided to a person nominated by the research organisation to safeguard the EudraVigilance data for the research purpose." Both chapter 5.4.4.4. of the EudraVigilance Access Policy which entered into force in July 2011, and chapter 5.4.3.3. of the 2014 revision mention that: "The identification of 'authorised personnel' is based on the EudraVigilance registration process." However, this is not mentioned in chapter 5.4.4.3. of the 2014 revision. A mechanism of prior authorisation by the Agency is essential, to ensure that access is only provided to the	

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		person nominated and authorised by the research organisation. If the Agency proposes to provide data extracts directly to the researcher and the researcher does not have access to EudraVigilance itself, then the EudraVigilance registration process would be outside the scope of the proposed access policy for research.	
368	Chapter 5.4.4.4, Page 23	Comment: Referenced text: "The personal data protection requirements applicable to research organisations are the same as for MAHs as outlined in chapter 5.4.3.5." It would appear that the intended reference is chapter 5.4.3.4. (rather than "chapter 5.4.3.5."). With regard to providing research organizations access to personal data, we note that research organizations are not necessarily in the same legal position as MAHs with regard to rights and obligations vis-à-vis the data subjects under data protection legislation, for example in the context of pharmacovigilance. Proposed change: Revise the last paragraph on page 23 as follows, "For purposes of the EudraVigilance access policy for research, the personal data protection requirements applicable to research organisations are the same as for MAHs as outlined in chapter ~~5.4.3.5.~~ 5.4.3.4."	Revise the last paragraph on page 23 as follows, "For purposes of the EudraVigilance access policy for research, the personal data protection requirements applicable to research organisations are the same as for MAHs as outlined in chapter ~~5.4.3.5.~~ 5.4.3.4."
368	Section 6	Comment: "This Access Policy will enter into force six months following the announcement by the Management Board of the Agency that based on an independent audit report, the EudraVigilance database has achieved full functionality." Proposed change (if any): Please add or reference the planned date of the independent audit, and of the availability of the audit report.	Please add or reference the planned date of the independent audit, and of the availability of the audit report.
368	Annex 2	In relation to linked reports, is the MAH accessing this information obliged to forward this report (maybe via licence agreements), if the linked id relates to a third party reference? C1.10.r	
368	Annex 2, Page 30	Comment: Footnotes 36 and 37 are not unique. Proposed change: Remove duplicate and renumber.	Remove duplicate and renumber
368	Annex 2, Pages 31-51	Comment: Typo, header, 3rd column of table, "EELEMENT" Proposed change: Modify to "ELEMENT"	Modify to "ELEMENT"
368	Annex 2, Page 30	The following additional fields are required for Level 1 MAH access Stratification and signal strengthening fields: D.2.3 Patient Age Group (as per reporter) D.3 Body Weight (kg) D.4 Height (cm) D.8.r.6b Indication (MedDRA code) (How is this different from field G.k.7.r.2b?) E.i.8 Medical Confirmation by Healthcare Professional G.k.9.i.4 Did Reaction Recur on Re-administration?	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
368	Annex 2, page 30	Comment: Field C.1.1 Senders case identifier should not be available to the public since it to some extend indirectly provide information about the exact branded product Proposed change (if any): Replace Y with N for group II	Replace Y with N for group II
368	Annex 2 Page 31	Comment: Data element C.1.6.1.r. 2 “included documents”: this element is indicated as being not accessible to MAHs (level 2 access). It may be of interest to give a possibility for an ad-hoc access (not systematic) in case of a signal that needs to be validated with only few supporting cases (strong evidence needs to be collated and shared with the same level of information between MAHs and competent authority) and that may potentially affect the labelling of the product. Data protection would need of course to be taken into consideration.	
368	Annex 2, page 31	Comment: Field C.1.8.1 World wide case identifier should not be available to the public since it to some extend indirectly provide information about the exact branded product Proposed change (if any): Replace Y with N for group II	Replace Y with N for group II
368	Annex 2, Pages 35-36, rows 5-6	Comment: Intended meaning of footnotes 33, 37, 38, 39 is not clear. Footnote 33 (page 23) refers to Research Request; Footnote 37 (page 30) refers to gateway receipt, etc. Footnotes 38 and/or 39 may be appropriate for element D.2.2b, D.2.3, etc. Proposed change: Apply footnotes to convey intended meaning.	Apply footnotes to convey intended meaning.
368	Annex 2, Pages 42 and 48	Comment: Footnotes 41 and 45 appear to be duplicates. Neither one indicates the level of MedDRA coding, i.e., LLT, PT, etc. Proposed change: Delete duplicate and indicate the level of coding to be provided.	Delete duplicate and indicate the level of coding to be provided.
368	Annex 2, Pages 42-43 and 48-51	Comment: Intended header in last column may be “Stakeholder Group V and VI” instead of “Field ICH or EU.” Proposed change: Adjust to intended meaning, as indicated.	Adjust to intended meaning, as indicated.
368	Annex 2, Page 46, row 7	Comment: Reference to footnote 43, which does not appear in the document. Proposed change: Adjust to intended meaning.	Adjust to intended meaning.
368	Annex 2 Page 46, last row	Comment: Data element G.k.2.5 “investigational product blinded”: this information is indicated as being not accessible to MAHs (level 2 access) – to have an accurate view of the evidence of a signal, it is important to make sure of the actual suspected drug, so there is a need to share information on the blind status.	
368	Annex 2, page 50 ICH E2B(R3) Data Element H.1	Comment: Ability to access the narrative facilitates better understanding of all factors contributing to an event for medical assessment by the MAH. The case narrative may include element that are not coded (for example details on outcome and rechallenge – time course) and would also facilitate the review while validating a signal. Further, narratives including all relevant medical details are forwarded to competent authorities outside the EU where the MAH has ICSR reporting obligations. Proposed change: Make	Make this data element available also to Stakeholder Group III Level 2, i.e. change cell from N to Y.

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		this data element available also to Stakeholder Group III Level 2, i.e. change cell from N to Y.	
368	Annex 3, Page 52	Comment: The initialism “XEVMPD” may be intended, since “eXEVMPD” is not used in the document. Proposed change: Adjust to intended meaning.	Adjust to intended meaning.
368	Annex 4, Page 53	Comment: Key references are missing. Proposed change: Add references as follows, - Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) E2B(R3) Data Elements and Message Specification (http://www.ich.org/products/electronic-standards.html), supplemented by ICH Q & A - MedDRA Term Selection Points to Consider (http://www.ich.org/products/meddra.html; This is periodically revised to correspond to MedDRA upversioning, which occurs twice per year)	Add references as follows, 1) Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) E2B(R3) Data Elements and Message Specification (http://www.ich.org/products/electronic-standards.html), supplemented by ICH Q & A 2) MedDRA Term Selection Points to Consider (http://www.ich.org/products/meddra.html; This is periodically revised to correspond to MedDRA upversioning, which occurs twice per year)
369		On behalf of Montenegro, one small European country, currently in accession negotiations with EU, as a head of pharmacovigilance department, I strongly support the idea on limited access for Stakeholder Group VI International Medicines Regulatory Authority to Eudravigilance dataset. That would additionally improve our daily work, understanding of EU regulatory network, and finally give better insight in safety profile of medicines. I do not have any other comment on draft text.	
370		I am writing to express my concerns at some aspects of the draft revisions to the EudraVigilance access policy and find I am in general agreement with those concerns raised by the Alltrials campaign in their response to this consultation, a copy of which is attached for reference (although I am sure you are familiar with this already). I am far from blindly following the Alltrials campaign and would generally regard myself as a pragmatist able to recognise where compromise is necessary. However, I do believe strongly in the importance of drafting such documents carefully in order to prevent the occurrence of unintended consequences. Where the opportunity for confusion or obfuscation exists, it will inevitably become a problem and I believe the point raised highlight just such an opportunity. I hope you will take these points into consideration during the consultation process.	

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		http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
371	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Principles of access for research organisations - I have a brain tumour and will die prematurely because of the difficulty in treating this collection of heterogeneous types of tumour. Limited funding is horrendously stretched and the incentives for research are low because while finding better treatments would mean more years of life are returned to patients, quite bespoke treatments need to be developed for each form. Unfortunately one size won't fit all. This means a lot of research is required and with so little funding, the value of enabling researchers to build on existing studies and knowledge, and to avoid spending money duplicating similar studies is immense. Any impediment to this concerns me, in particular some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. I object strongly to the following two conditions: • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. I am also concerned by the following principle: • "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be	

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		independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: • "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - I support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 "Number of ICH E2B(R3) ICSR data elements" (page 11), which appears difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. I am concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told the AllTrials campaign that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. I support the AllTrials campaign view that we must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the	

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		database. Providing access to these data in additional formats will enable them to make better use of the data.	
372		I understand you are taking comments from the public about the consultation of the EudraVigilance access policy, so I would like to add mine. Any suppression of the right of publication of academic papers is effective censorship of scientific discussion. The publication of any papers should be only guided by the established peer-review process and not be restricted by the EMA in any way. There should be a panel for the review of research requests, but it should be independent of the EMA to prevent conflicts of interest. Any access to the EudraVigilance data should be made available to the scientific community, and it must be made very clear that the results from that research are expected to be made available. Immediate access to the most current data will benefit anyone involved in public health and is essential for health practitioners to treat their patients. Information about common adverse effects for a treatment should be made available widely and immediately. Information that can lead to identifying patients with *rare* side effects can always be redacted. Case summaries are useful to identify previous drug usage and potential interactions between drugs and should also be made available, provided the information that can lead to patient identification is redacted. Having access to any additional (and up-to-date) information regarding adverse effects only allows health professional to make use of the precious data stored.	
373		The MEB feels that case narratives should be provided to the MAHs as well as to WHO-UMC: - Users of WHO-Vigibase are mainly regulatory authorities (outside EU, but also still inside EU) with similar local responsibilities so that provision of narratives would assumably facilitate their work. - The proposed access policy provides MAHs with tools for signal detection, but no access is given to the case narratives. These are essential for signal validation and evaluation, also in the context of PSUR preparation, Benefit-Risk assessments, cumulative reviews, etc. Not providing MAHs with case narratives may result in a situation where only regulators can do these assessments. MAHs are responsible for their product and should be provided with the data that enables them to meet this responsibility.	
374		I would like to add my concern about the proposed update to allow the EMA to block the publication of analyses that it disagrees with. I basically endorse the position of AllTrials (http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf), on the basis that debates about the validity of an analysis are best carried out through open scientific debate.	

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375	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	I'm very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: - "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication." - "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. I'm also concerned by the following principle: - "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: - "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data I support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not	

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		withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 “Number of ICH E2B(R3) ICSR data elements” (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. I am concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
376	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard	I’m very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: - “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” - “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
	timescale for response to requests for extended data.	interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. I'm also concerned by the following principle: - "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: - "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - I support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 "Number of ICH E2B(R3) ICSR data elements" (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable	

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		patient information from reports on rare side effects. I am concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II “Healthcare professionals and the public” would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
377		Parkinson's movement, a global patient advocacy group representing several thousand people with Parkinson's, is strongly opposed to some of the proposed revisions being put forward. Specifically we feel that access to the data carries inappropriate restrictions. Whilst we fully understand the desire of the agency to view any publication resulting from the data, the current wording appears to indicate that the agency's opinion on the correctness of analyses and so forth is paramount and that any disagreement with potential authors must be resolved solely to the satisfaction of the agency before publication. At the very least, this stage announced a significant delay or impediments to publication and at worst to a power of veto. Whilst a commonplace restriction imposed by pharmaceutical companies, it is quite extraordinary to see such a limitation imposed by a non-commercial regulatory agency. Further on we noticed that research access to data will be determined by an EMA panel that will assess each application on its own perception of the public health value of the proposed research. If such criteria are to be applied, it is appropriate that the review panel be independently constituted. We acknowledge that there may be legitimate reasons to restrict access in certain cases. We feel nonetheless that this selection procedure should be decided purely on scientific merit and therefore its decision-making should be independent of EMA. We further suggest, in the spirit of transparency, that the aims and objectives of projects given access and projects refused access should be stated. The EMA is a regulatory agency with a duty to safeguard health. We do not feel that	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		objective is best served by restrictive access to data. We urge the agency to remove such restrictions.	
378		This response to your consultation is sent in a personal capacity. I have no reason to doubt that Cochrane would support the following comments but it has not been possible to convene an appropriate forum in the consulting period. Cochrane strongly supports moves towards clinical trials transparency in order that health professionals and the public can make informed decisions in health care. Therefore there is much in your document that I would support. However, in common with the Alltrials group, of which Cochrane is a member, I am concerned that there are details within the proposal that may have a damaging effect, and place unreasonable limitations on scientific researchers. Specifically, following two conditions would seem to give the EMA inappropriate power to suppress material in an academic paper that it disagrees with or is inconvenient. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to censorship of scientific discussion and analysis of public health data" “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.”“A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” I also share the concerns expressed by the Alltrials coalition in relation to the work of the committee in determining who shall and shall not have access: “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” Again, this appears to give the Agency too broad powers. The panel should be independent both of EMA and manufacturers in my view and a more lenient standard should be applied – with the expectation that access will be given except in exceptional and specific cases where harm is likely.I support the Alltrials group in believing that research organisations who are given access to Eudravigilence data should be required to submit the results of their research for publication, and that healthcare professionals and the public should have access to	

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		serious adverse events data in additional formats in order to help them to make more use of the data.	
379		As a consideration, what feasible set(s) of examples could you explain to uphold your position on the proposed powers which cannot be first negotiated and discussed before being allowed to apply a proportional exemption. Furthermore, I would like to add that the principle of appeal should be by its very nature independent from the original bodies. This is the purpose within other legislation and regulatory bodies. It is fundamentally about the logic of error checking as it is about sufficient scrutiny. The underlying quality of good medicinal research is the diverse, systematic rigorous testing which takes place on the basis of ever growing updating data. And lack of data transparency does a great deal of hindrance to the usefulness of subsequent analysis and healthcare decision making in evidence based medicine. I urge you to reconsider any proposals in this manner and provide greater powers of scrutiny by other parties to. Finally, I look forward to corresponding with you on these matters in the near future.	
380	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	Principles of access for research organisations - I am very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data isgranted to research organisations. A.I object strongly to the following two conditions: “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data.Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses,for independent scientific scrutiny. Consequently, what is proposed is	

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		unworkable and these two principles should be removed. B. I am also concerned by the following principle: “An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, I believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: “Those given access to EudraVigilance data should make appropriate efforts to publish their research.”There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community.	
381		I strongly oppose the condition that would allow the EMA to block publication of analyses it disagrees with. I can see that it is tempting to try and control the way the data is represented, but this is not the way that science works. You have to let people say things that you might agree with and trust that the right answer will come to prominence in the end. Imagine for a moment that the leadership of the EMA changes and people who you disagree with come to power. What will you do? I hope this is not too late to be considered.	
382		Transparency of adverse drug reactions in Europe: Proactive public access to qualitative data is needed, pharmacovigilance data are not “trade secrets. Summary/Key points - In August 2014, the European Medicines Agency (EMA) organised a public consultation on the revision of its 2011 policy on the access to the European pharmacovigilance database EudraVigilance, which created the public interface adrreports.eu. - Reports of suspected adverse drug reactions are coded using standardised terminology and then registered in EudraVigilance as “Individual Case Safety Reports, ICSR”. In practice, however, this process can strip spontaneous reports of individual cases of clinical significance. That is why access to narrative summaries of individual cases needs to be provided along with quantitative data. - Unfortunately since 2012, the public interface Adrreports (www.adrreports.eu) has provided access to only a limited number of quantitative information, e.g. the number of suspected adverse reactions associated with a given substance, but it does not give access to a listing of case summaries (“Narrative Case Summary”). - According to Pierre Chirac, Medicines in Europe Forum coordinator: “In the EU, health professionals and patients,	

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		who are major contributors to the EudraVigilance database through the spontaneous reports they send to their national drug authorities, are paradoxically the actors who access the least information." - In its draft revision document, the EMA proposes to share more data with marketing authorisation holders (MAH), which makes sense since they are required to develop periodic benefit-risk evaluation reports about their drugs. Nevertheless, drug regulatory agencies have to closely monitor the MAH pharmacovigilance activities in order to avoid data being misinterpreted or withheld as recently happened on several occasions. - The EMA also proposes to give research organisations, on request, “access to ICSR data sets similar to those provided for MAHs in response to justified research requests”. However, the EMA sets up restrictive conditions for granting access to researchers, e.g. the signature of confidentiality agreements. The EMA also demands to “view any publication resulting from EudraVigilance data before submission (…). [and that] any issues raised by the Agency (…) must be addressed to the satisfaction of the Agency before submission for publication”. However, EMA’s central role does not give it the right to control how the data are used or to censor scientific discussion. - Another change of concern is that the description of access for each stakeholder now makes them responsible for applying “appropriate technical and organisational measures to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss”. Ancel.la Santos, Health Action International (HAI) Europe policy advisor, comments: - “There are standards in place for de-identifying personal data and additional measures can be explored for particular cases (rare diseases). But data protection cannot be used as a pretext to protect commercial interests. Pharmacovigilance data are not trade secrets, but information that is of the utmost relevance to protect public health.” - We encourage the EMA in its policy to support public health by: – proactively providing public access to useful qualitative data such as anonymised summaries of cases; – granting public access to consumption data of drugs in the EU; – providing access to all drug regulatory authorities’ assessment reports of MAH’s periodic benefit-risk evaluation reports (former Periodic safety update reports); – not forcing researchers to sign “confidentiality agreements”.	

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382		We welcome the opportunity to contribute to the European Medicines Agency (EMA) public consultation on the revision of its policy on the access to the European pharmacovigilance database EudraVigilance (1). This draft policy aims to update the previous EMA EudraVigilance access policy from 2011, which created the public interface adrreports.eu ([c]). Created in 2001, the EudraVigilance database is a central database holding reports on suspected adverse drug reactions in Europe ([d]). Until the 2010 EU pharmacovigilance legislation (directive 2010/84/EC and regulation (EC) 1235/2010), the data in EudraVigilance were submitted electronically by national medicines regulatory authorities on the basis on spontaneous reports from health professionals (and from patients in Member States already allowing patient reporting), and on the basis of reports submitted to medicines regulatory authorities by pharmaceutical companies. With the implementation of the 2010 pharmacovigilance legislation, the pharmaceutical companies are now allowed to submit data on their medicines directly in EudraVigilance (2). - EMA's question: As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? - Our answer: Spontaneous reports of suspected adverse drug reactions are registered in EudraVigilance as "Individual Case Safety Reports, ICSR". ICSR are the result of a coding of spontaneous reports using standardised terminology ([e]). In the registration process, one spontaneous report about a patient suffering several suspected adverse drug reaction will be coded into several ICSR, one for each suspected adverse reaction. In practice, the registration process can strip spontaneous reports of individual cases of clinical meaning, resulting in data being minimised or misinterpreted (i). That is why access to comprehensive summaries of individual cases needs to be provided along with quantitative data.	
382		Proactive disclosure of pharmacovigilance data: qualitative data is needed	

[c] Unfortunately, despite the short consultation period (4 August until 15 September 2014), the consultation document does not allow readers to identify clearly the changes proposed to the 2011 policy (no apparent modifications, even in the tables on pages 29 to 51). Holding a consultation in such a short timeline during summer recess is not consistent with the actual purpose of a consultation, which is to obtain an adequate and representative feedback from the public.

[d] "Taking into account the pharmacovigilance activities in the pre- and post- authorisation phase, EudraVigilance provides two reporting modules:
- The EudraVigilance Clinical Trial Module (EVCTM) to facilitate the electronic reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs) as required by Directive 2001/20/EC;
- and the EudraVigilance Post-Authorisation Module (EVPM) for post-authorisation Individual Case Safety Reports (ICSRs) as required by Regulation (EC) No 726/2004, Directive 2001/83/EC as amended." (ref. https://EudraVigilance.ema.europa.eu/human/index.asp)

[e] The coding of spontaneous reports is done using the Medical Dictionary for Regulatory Activities (MedRA) dictionary developed under the auspices of International Conference on Harmonisation (ICH).

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		According to the draft document, there will be “no changes in the EudraVigilance Access Policy (…) for (…) healthcare professionals, consumers and patients” who “maintain the possibility to search and screen ICSR data” using Adrreports. Adrreports (www.adrreports.eu) is the public interface of the EudraVigilance database set up by EMA’s 2011 access to EudraVigilance policy. Since May 2012 ([f]), Adrreports (www.adrreports.eu) provides access to only a limited amount of quantitative information and only for centrally approved medicines, e.g. the number of individual cases associated with a given substance. The database is also searchable by adverse reaction groups or for a selected adverse reaction (the adverse reactions are coded using the MedDRA dictionary). The number of individual cases is available by age group**,** sex**,** reporter group (e.g. health professional, patient, or MAH) and geographic origin**.** Since the registration process can strip spontaneous reports of individual cases of clinical meaning, comprehensive qualitative data are essential in order to better understand quantitative data. That is why the publicly accessible database of the Dutch pharmacovigilance centre, Lareb (www.lareb.nl), gives access to anonymised summaries of cases. Unfortunately, despite the work being done when ICSR are registered in EudraVigilance ([g]), the adrreports interface does not give health professionals and patients access to such a listing of summaries of cases. Health professionals and patients, who are major contributors to the EudraVigilance database by sending their spontaneous reports to their national drug authorities, are paradoxically denied access to any information about the context of occurrence of adverse reactions ([h]). There is no information either on the consumption data of a given drug in the EU or in the different EU Member States, making it impossible to have an idea of the incidence of a given adverse drug reaction associated with a given drug. This information is however easily available to the EMA since it is given by the pharmaceutical companies in their periodic benefit-risk evaluation reports (former periodic safety update reports, PSUR). And finally the Adrreports interface is not user friendly: • it is not compatible with several common internet navigators; • since the summer of 2014, it has been no longer possible to download and register	

[f] Adopted in 2004, regulation (EC) N°726/2004 already stated that “the Agency shall ensure that healthcare professionals and the public have appropriate levels of access to the EudraVigilance database”. However, until 2012 and the setting up of the interface adrreports.eu, ‘appropriate access’ meant no access at all.

[g] See the lines “ICH H - Narrative Case Summary and Further Information, including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant Information” and “Reporter’s comments” on page 50.

[h] Spontaneous reporting remains the main resource for bringing safety signals to light, despite the fact that adverse effects are vastly under-reported. This is because spontaneous reports are often very specific: a small series of properly documented cases can suffice to constitute a signal, and to enable health authorities to take whatever decisions are required to protect public health.

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		requests in pdf format, only as an Excel file; • it provides only cumulative data on the total number of adverse drug reactions being registered in the EudraVigilance database, without the possibility of identifying new cases. Our proposals for improvements through proactive disclosure of pharmacovigilance data include: ►Extend the possibility to search and screen Individual Case Safety Reports (ICSR): data should be extended to all medicinal products authorised in the EU, not only to centrally authorised medicines ([i]); when searching by brand names, the results should include the other brands for the same substance and same pharmaceutical form; ►Since EudraVigilance comprises a Clinical Trial Module (EVCTM), reports of suspected unexpected serious adverse reactions (SUSARs) should be included within the scope of the EudraVigilance access policy ([j]); ►Grant public access to duly anonymised "Narrative Case Summary" for each ICSR; ►Grant public access to consumption data of a given drug in the EU and in the different Member States, in order to give an estimate of the incidence of a given adverse drug reaction associated with a given drug; ►Redesign the Adrreports database to make it more user friendly (e.g. with a list of clickable "Narrative Case Summaries" made available for each request; with the official information about a medicine (packaging leaflet, SPC) being accessible by a simple click on the brand name of the medicine); ►For each substance, provide a link to drug regulatory authorities' assessment reports of the Periodic benefit-risk evaluation reports (former Periodic safety update reports) (e.g. link to be made to the registry to be set up in accordance to Regulation (EC) N°1235/2010, article 25a ([k])); ►Regarding proactive publication, if there are concerns about personal data protection for specific cases (rare diseases or very rare adverse drug reactions), the public (group II) as well as the other groups could be required to agree to a clause which states that they will comply with regulations on personal data protection and will not try to re-identify patients.	

[i] The extension of ADRreports to include non-centrally approved medicines was announced for Spring 2013. But in September 2014, it has still not been implemented.
[j] According to the draft revision document, "Access to reports of suspected unexpected serious adverse reactions (SUSARs) based on the provisions set out in Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC will be subject to a later consultation."
[k] "Article 25a: The Agency shall, in collaboration with the national competent authorities and the Commission, set up and maintain a repository for periodic safety update reports (hereinafter the 'repository') and the corresponding assessment reports (…)". (ref. Regulation (EC) No 726/2004).

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
382		More data sharing, but new worrying juridical data protection wording In its draft revision document, the EMA proposes several amendments which are welcomed to allow for more efficient pharmacovigilance: – Setting up proactive and regular data sharing with the World Health Organization (WHO) Uppsala Monitoring Centre and with other Medicine Regulatory Authorities; however, the "confidentiality agreements" of these institutions with the EMA (page 17) should not prevent them from making relevant information and analysis available to the public and to health professionals; – Increasing proactive access to extensive ICSR information to marketing authorisation holders (MAH). This proposal makes sense since MAH are required to develop the periodic benefit-risk evaluation reports about their own drugs ([i]); nevertheless, drug regulatory agencies have to take very seriously their responsibilities to check that MAH effectively report ADR to EudraVigilance and do not withhold the data ([ii],[iii]). Drug regulatory agencies must also control the interpretation of data by the MAH to avoid data being minimised (e.g. suicide attempts coded as "emotional liability") ([iv]); – Giving research organisations, on request, "access to ICSR data sets similar to those provided for MAHs in response to justified research requests". However, this access would be granted only under conditions which could threaten their independence (see below). Nevertheless, we identified two important reasons for concern: – creating confusion between the need to protect personal data and the consideration of pharmacovigilance data as "commercially confidential information" or even "trade secrets" in order to protect commercial interests; – setting up very restrictive conditions for granting access to researchers and over controlling the publication of results. "Protection of personal data": a pretext to justify opacity of pharmacovigilance data. According to the draft revision document, "The need to maintain the confidentiality of the identity of patients and reporters in accordance with EU data protection law is being further emphasised including the responsibility of concerned stakeholders to apply appropriate technical and organisational measures to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss (text integrated in the description of access for each stakeholder)" (page 5). This general statement raises serious concerns. In fact, the consultation takes place in a particular context that needs to be taken into account. After claiming that it would	

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		widely open up proactive access to clinical data in November 2012, it seems that the EMA gave in to pharmaceutical companies' pressure and watered down its draft policy on proactive access to clinical data ([m]). Moreover, in late November 2013, when both the European Parliament and the Council representing the 28 European Member States showed strong political support for transparency of clinical data during the new EU Regulation on clinical trials legislative process, the European Commission made public a new directive proposal "on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure". According to the trade association of the European pharmaceutical industry, clinical data would fall into the scope of this directive ([n]) ([v],[vi]). We strongly disagree: clinical data are not proprietary information. Restrictions on access to researchers and publication of results: patronizing is outdated and not acceptable. The parallel of EMA's general statement that there is a need "to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss" with the title of the new directive on trade secrets (read above) is even more disturbing when analysing what it means in practice for researchers. In fact, according to the EMA's draft revision documents, the "pre-requisites for granting access" to researcher organisations would encompass: – "Researches to sign confidentiality undertaking" (without stating whether such confidentiality undertaking would be signed with the EMA or with the marketing authorisation holder) (page 15); – "Researchers to sign agreement that EMA exercises the right of review for publications based on EudraVigilance data (…)" (page 15). Moreover, the EMA proposes that: – "The Agency has the right to view any publication resulting from EudraVigilance data before submission (…). [and that] Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication";	

[m] Made public in May 2014, the EMA revised draft policy on proactive access to clinical data forced data users to enter into legal agreements with pharmaceutical companies and allowed systematic censorship by pharmaceutical companies under the pretext of commercial confidentiality. Formal adoption of this controversial draft policy was delayed and should take place at a scheduled board meeting in October 2014 (ref. 14,15).

[n] As a result of the Transatlantic Trade and Investment Partnership (TTIP), this proposed directive includes a very broad definition of trade secrets. According to the trade association of the European pharmaceutical industry "*Almost every aspect of the drug development process involves the generation and application of substantial amounts of technical information and know-how, including the (…) clinical trials phase*." (ref.16). And according to an industry responsible, pharmacovigilance data are commercially confidential information (ref.17).

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		– "A confidentiality agreement must be signed by the party applying for extended data access for research purposes. Data may not be transferred to any third party" (page 23). Several of the EMA's requirements go too far and can be seen as an opportunity for censorship ([vii]). In fact, proportionality in ethics has to be taken into account ([viii]).“Unlikely to happen" risks need to be weighed against the current situation, where millions of otherwise avoidable adverse drug reactions are occurring, sometimes because the pharmaceutical industry routinely hides drug-induced harms (5to7,[o]). To claim that the disclosure of clinical trial data could lead to misinterpretation of data and to the dissemination of skewed information that would scare the public reflects an outdated paternalistic attitude. There is no example of misinterpretation of data and misuse from recent years (2010 to 2013) during which the European Medicines Agency has released clinical data to researchers on request without insisting on such restrictions. Moreover, the statement that "Data may not be transferred to any third party" forbids researchers to publish the raw data along with their paper, a practice increasingly growing in order to avoid fraud and allow other researchers and the scientific community to reanalyse data. Our proposals for greater disclosure of pharmacovigilance data on request include: ► Making clear that this policy can only apply without prejudice to the European Freedom of Information Regulation (Regulation (EC) N°1049/2001). European citizens, including researchers not wishing to sign confidentiality agreements, should still be able to access pharmacovigilance data using Regulation (EC) N°1049/2001 (page 8); ► Replacing the wording 'Research Organisations' by 'interested third parties making a research request justified on the grounds of public health' to ensure that healthcare professionals, students, public health organisations or patients/victims/consumer associations can qualify; ►No longer forcing researchers to sign "confidentiality agreements", to be replaced by an agreement including a clause stating that they will comply with regulations on personal data protection and will not seek to re-identify patients.	
382		To conclude - When medicines agencies publicly disclose important efficacy and safety information to potential users and the public at large, they fulfil their mandate to contribute to rational medicine use, and to safeguard and uphold public health. We therefore encourage the EMA to take into account our proposals, notably by: – proactively giving public access to useful qualitative data such as anonymised	

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		summaries of cases (a list of clickable “Narrative Case Summaries” should be made available for each request); – granting public access to consumption data of a given drug in the different EU Member States; – providing access to the drug regulatory authorities’ assessment reports of Periodic benefit-risk evaluation reports (former Periodic safety update reports, PSUR); – ending “confidentiality agreements”, to be replaced by an agreement including a clause stating that the persons accessing the data will comply with regulations on personal data protection and will not seek to re-identify patients.	
382	Page 5 and tables on pages 12 and 14 to 17	Comment: Pharmacovigilance data are scientific data and belong to the public; they are not a “trade secret”. Pharmacovigilance data are information of public interest, they are not “commercially confidential information”. Health professionals and patients who report adverse drug reactions (ADR) do so in order to advance science and to prevent other patients experience the same ADR where other treatment alternatives exist. Proposed changes: - delete the term information in the sentence: “The need to maintain the confidentiality of the identity of patients and reporters in accordance with EU data protection law is being further emphasised including the responsibility of concerned stakeholders to apply appropriate technical and organisational measures to protect ~~information and~~ personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss”. - on page 5 add a statement that: “In general, pharmacovigilance data should not be considered commercially confidential”.	delete the term information in the sentence: “The need to maintain the confidentiality of the identity of patients and reporters in accordance with EU data protection law is being further emphasised including the responsibility of concerned stakeholders to apply appropriate technical and organisational measures to protect ~~information and~~ personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss”. - on page 5 add a statement that: “In general, pharmacovigilance data should not be considered commercially confidential”.
382	All over the text	Comment: Healthcare professionals, students, public health organisations or patients/victims/consumer associations who wish to conduct research on pharmacovigilance data should be entitled to request data from the EMA. Proposed change: - Replace the wording ‘Research Organisations’ by “interested third parties making a research request justified by a public health reason” or add a definition of a “research organization” specifying that it comprises “healthcare professionals, students, public health organisations or patients/victims/consumer associations who wish to conduct research on pharmacovigilance data”.	- Replace the wording ‘Research Organisations’ by “interested third parties making a research request justified by a public health reason” - or add a definition of a “research organization” specifying that it comprises “healthcare professionals, students, public health organisations or patients/victims/consumer associations

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
			who wish to conduct research on pharmacovigilance data".
382	Page 8	Comment: European citizens, including researchers who do not wish to sign confidentiality agreements, should still be able to access pharmacovigilance data using Regulation (EC) N°1049/2001. Proposal for change: Make clear that this policy can only apply without prejudice to the European Freedom of Information Regulation (Regulation (EC) N°1049/2001).	Make clear that this policy can only apply without prejudice to the European Freedom of Information Regulation (Regulation (EC) N°1049/2001).
382	Page 15	Comment: The EMA is the institution collecting adverse drug reactions reports from all Member States, the final aim being to protect public health by early signal detection and large communication to the public and health professionals on suspected risks. This central position does not give the EMA the right to control how the data are used or to censor scientific discussion. In case of over- or under-interpretation of risk signals, scientific discussion and public debate will contribute to knowledge building. Moreover, public access to safety data should be rapid and not slowed down by the EMA. Proposed change: delete the following "Pre-requisites for granting access": ~~"•Researches to sign confidentiality undertaking~~ ~~• Researchers to sign agreement that EMA exercises the right of review for publications based on EudraVigilance data including a privacy check (possible re-identification of patients)"~~	delete the following "Pre-requisites for granting access": ~~"•Researches to sign confidentiality undertaking~~ ~~• Researchers to sign agreement that EMA exercises the right of review for publications based on EudraVigilance data including a privacy check (possible re-identification of patients)"~~
382	Pages 22 and 23 5.4. Access by Stakeholder Group -> 5.4.4. Group IV: Research Organisations	Comment: All along the consultation text, there is confusion between the need to protect personal data and the notion of protection of intellectual property. Referring to Regulation (EC) N° 1049/2001 would be clarifying (commercially confidential information is covered as an exception to the disclosure principle where there is no overriding public interest at stake). Proposed changes: ~~deletions~~ in bold, ital and crossed; additions in bold and ital • Data access should observe EU legislation on protection of personal data and ~~commercially confidential data~~ comply with Regulation (EC) N° 1049/2001. ~~• The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.~~ • A standard Agency disclaimer must be added to the manuscript to explain that the analysis of the data represent the view of the authors but not the position of the Agency which simply provided the data. ~~The Agency reserves the right to reword the~~	~~deletions~~ in bold, ital and crossed; additions in bold and ital • Data access should observe EU legislation on protection of personal data and ~~commercially confidential data~~ comply with Regulation (EC) N° 1049/2001. ~~• The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the~~

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		~~disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.~~ ~~• A confidentiality agreement must be signed by the party applying for extended data access for research purposes. Data may not be transferred to any third party.~~	~~Agency before submission for publication.~~ • A standard Agency disclaimer must be added to the manuscript to explain that the analysis of the data represent the view of the authors but not the position of the Agency which simply provided the data. ~~The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.~~ ~~• A confidentiality agreement must be signed by the party applying for extended data access for research purposes. Data may not be transferred to any third party.~~
382	Pages 30, 32, 36, 38, 39, 42, 43, 45, 47, 48, 49, 50, 51,	Complements to the answer to EMA's question: As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Comment: There is no reason to restrict access to stakeholder group II to several items of ICSR. Several databases worldwide give public access to such information (e.g. US Food and Drug Administration, Lareb in the NL, UK Drug Regulatory Agency MHRA, etc.) ([ix]). We therefore propose that these items are publicly disclosed. Proposed change: Change No to "Yes" for the following items of the ICSR: - Date of creation (Data element ICH C.1.2 on page 30) (to be able to identify new cases) - Case identifier(s) (Data element ICH C.1.9.1.r.2 on page 32) (to be able to identify if an individual case was registered under different ICSR, e.g. in case of several ADR occurring in a patient) - Gestation period when reaction/event was observed in the fetus (Data element ICH D.2.2.1a and 1b on page 36) - Body weight (kg) and height (cm) (Data element ICH D.3 and D.4 on page 36) - Date of death (Data element ICH D.9.1 on page 38) + Reported cause(s) of death	Change No to "Yes" for the following items of the ICSR: - Date of creation (Data element ICH C.1.2 on page 30) (to be able to identify new cases) - Case identifier(s) (Data element ICH C.1.9.1.r.2 on page 32) (to be able to identify if an individual case was registered under different ICSR, e.g. in case of several ADR occurring in a patient) - Gestation period when reaction/event was observed in the fetus (Data element ICH D.2.2.1a and 1b on page 36) - Body weight (kg) and height (cm) (Data element ICH D.3 and D.4 on page 36) - Date of death (Data element ICH D.9.1 on page 38) + Reported cause(s) of death (free text) (Data element ICH D.9.2.r.2 on page 39) + Autopsy-determined cause of

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		(free text) (Data element ICH D.9.2.r.2 on page 39) + Autopsy-determined cause of death (MedRA code) (data element ICH D.9.2.r.1b on page 39) - All items from the list classified under ICH E.i. Reaction(s)/event(s) on pages 42 to 44, especially: - Reaction/Event as reported by the primary source in native language (ICH E.i.1.1a) + Reaction/Event as reported by the primary source for translation (ICH E.i.1.2) - Term highlighted by the reporter (ICH E.i.3.1) - Date of start of Reaction/Event (ICH E.i.4) + Date of enf of Reaction/Event (ICH E.i.5) - Name part – scientific name + Trademark name + Strength + Form + Device name (ICH G.k.2.2 on page 45) - Route of administration (Data element G.k.4.r.10.1 on page 47) - Gestation Period at time of exposure (ICH G.k.6 on page 48) - Result of assessment (ICH G.k.9.i.2.r.3 on page 49) + EU Result of assessment (ICH G.k.9.i.2.r.3.EU.1 on page 49) - Case summary's and reporter's comments (Data element H.1 e H.2 on page 50) + Case summary's and reporter's comments in native language (Data element H.5.r.1a and H.5.r.1b on page 51) - Add the Consumption data	death (MedRA code) (data element ICH D.9.2.r.1b on page 39) - All items from the list classified under ICH E.i. Reaction(s)/event(s) on pages 42 to 44, especially: - Reaction/Event as reported by the primary source in native language (ICH E.i.1.1a) + Reaction/Event as reported by the primary source for translation (ICH E.i.1.2) - Term highlighted by the reporter (ICH E.i.3.1) - Date of start of Reaction/Event (ICH E.i.4) + Date of enf of Reaction/Event (ICH E.i.5) - Name part – scientific name + Trademark name + Strength + Form + Device name (ICH G.k.2.2 on page 45) - Route of administration (Data element G.k.4.r.10.1 on page 47) - Gestation Period at time of exposure (ICH G.k.6 on page 48) - Result of assessment (ICH G.k.9.i.2.r.3 on page 49) + EU Result of assessment (ICH G.k.9.i.2.r.3.EU.1 on page 49) - Case summary's and reporter's comments (Data element H.1 e H.2 on page 50) + Case summary's and reporter's comments in native language (Data element H.5.r.1a and H.5.r.1b on page 51) - Add the Consumption data
382		Short presentation of the signatory organisations Cochrane Adverse Effects Methods Group (AEMG). Registered with the Cochrane Collaboration in 2007, the Cochrane Adverse Effects Methods Group (AEMG) aims to	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		develop the methods for producing high quality systematic reviews and to advise the Cochrane Collaboration on how the validity and precision of systematic reviews can be improved. More info: aemg.cochrane.org; Contact: a.herxheimer@ntlworld.com HAI Europe. Health Action International (HAI) Europe is a non-profit, European network of consumers, public interest NGOs, health care providers, academics, media and individuals working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy. More info: www.haieurope.org; Contact: ancel.la@haieurope.org ISDB. The International Society of Drug Bulletins, founded in 1986, is a worldwide network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of the pharmaceutical industry. Currently ISDB has about 80 members representing 41 countries around the world. More info: www.isdbweb.org; Contact: press@isdbweb.org. MiEF. The Medicines in Europe Forum (MiEF) was launched in March 2002 and reaches 12 European Member States. It includes more than 70 member organisations representing the four key players on the health field, i.e. patient groups, family and consumer bodies, social security systems, and health professionals. Such a grouping is unique in the history of the European Union and is testament to the importance of European medicines policy. More info: english.prescrire.org; Contact: pierrechirac@aol.com.	
382		References 1. European Medicines Agency “Revision of EudraVigilance access policy for medicines for human use” Released 4 August 2014. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/08/WC500170699.pdf 2. ISDB & MIEF “Pharmacovigilance in Europe: the European Commission’s proposals endanger the population" Joint analysis; October 2009. 3. Prescrire Editorial Staff “Patient reporting improves pharmacovigilance" Prescrire International 2008; 17 (98): 241-242. 4. Prescrire Rédaction "Réorganisation de la pharmacovigilance européenne. Première partie: pharmacovigilance européenne: sous-traitance accrue aux firmes" *Rev Prescrire* 2014 ; **34** (369) : 536-544. 5. “GlaxoSmithKline to plead guilty and pay $3 billion to resolve fraud allegations and failure to report safety data". www.justice.gov accessed 30 July 2012: 3 pages. 6. “European Medicines Agency acts on deficiencies in Roche medicine-safety reporting" www.ema.europa.eu accesed 26 July 2012: 2 pages.	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		7. Healy D “Let them eat Prozac” New York: New York University Press, 2004. 8. The European Federation of Pharmaceutical Industries and Associations “EFPIA welcomes the Commission's Proposal on the protection of undisclosed know-how and business information ("Trade Secrets")” press release published on 28 November 2013. www.efpia.eu: 1 page. 9. European Commission (Directorate General Internal Market and Services) “Proposal for a Directive of the European Parliament and of the Council on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure COM(2013) 813 final - 2013/0402 (COD)” Brussels, 28.11.2013: 26 pages. 10. Kmietowicz Z “EMA’s proposal to vet drug research that uses its data is “outdated,” say critics” BMJ 2014 ; 349 (11 August 2014): 1 page. 11. Strech D et Littmann J “Lack of proportionality. Seven specifications of public interest that override post-approval commercial interests on limited access to clinical data” *Trials* 2012 ; **13** : 100. 12. Gøtzsche P “Deadly Medicines and Organised Crime: How Big Pharma Has Corrupted Health Care” ISBN: 9781846198847; Published: Aug 2013. 13. Prescrire Editorial Staff "Publicly accessible pharmacovigilance databases" Prescrire Int 2012; 21 (126): 99. 14. AIM, HAI, ISDB, MiEF, NCC"Backpedalling on EMA's "proactive publication of clinical-data" draft policy: Was it all just a window-dressing exercise? Who or what is the EMA afraid of?" Joint Press Release; 20 May 2014: 4 pages. 15. AIM, HAI Europe, ISDB, MiEF, NCC "EMA's new policy on access to clinical data: About to privatise pharmaceutical knowledge? The proof will be in the pudding (June 2014) Brussels, 24 June 2014. 16. AIM, HAI Europe, ISDB, MiEF, NCC, TACD, Wemos “EU Regulation on clinical trials: close to the finish line” press release Brussels, 17 March 2014: 3 pages. 17. “Neal Parker on AbbVie’s Mission to Discover New Diseases” transcript published on 13 September 2013 from a speech during a conference organized by EFPIA on 27 August 2013 in Brussels. Website davidhealy.org: 4 pages.	
383		I'm completly agree with the comments in the draft revision of EudraVigilance access policy for medicines for human use, from the AllTrials campaign. So I support it and endorse the comments below: http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
384		I support it and endorse the comments below:http://www.alltrials.net/wp-content/uploads/2014/09/AllTrials-Response-to-EudraVigilance-access-policy-consultation-EMA-759287-2009-rev1.pdf	
385		EAHP congratulates the EMA on its work in both constructing the present pan-European systems for ADR reporting, and the efforts made towards transparency to date. We trust efforts to continually improve transparency in relation to EMA activities will continue in the years ahead. Additional data outputs in www.adrreports.eu On page 2 of the consultation document the Agency asks a specific question to healthcare professional organisations: “would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal dataprotection?” EAHP considers this would be useful, particularly in relation to improving the context of the other available information. More generally there may some scope for cross reference between information on www.adrreports.eu. To take an example, the information field in www.adrreports.eu in relation to Corlentor does not contain any reference to the PRACdetermination of May 2014 to commence a review of this medicine1. Terms of access for research organisations. In relation to the terms of use of access for the research community, and some public debate that has taken place on the point2, EAHP can understand and sympathise with the perspectives of the differing commenting parties. There is a need for safeguards against misuse or misreporting of ADR data that could provoke undue public concern or distress about medicines. Conversely, EMA should not be, or be seen to be, a censoring body of independent research. EMA should also understand that there is the potential for its own conflicts of interest to have a bearing (consciously or unconsciously) in such decision making. A better approach therefore could be along the lines of “The Agency expects to respond positively to requests for research access. However, in cases where the Agency has cause to question the purposes of the research an ad hoc panel shall give consideration to the request. The panel shall include representation of the patient and healthcare professional interest.” Further information on the ability and methods for appealing a decision of the panel would alsobe welcome. EAHP can also appreciate the need for some review by the EMA of publications based on Eudravigilance information in order to insure against possible compromise of patient confidentiality. However the proposed policy may be more problematic in respect of the Agency wishing to have the right to amend ‘incorrect analyses’, ‘unsupported inferences’ and ‘misleading statements’. The policy (p23) might be better expressed therefore along the lines of: “Any issues	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		relating to the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication. Additionally, the Agency reserves the right to highlight what it considers to be incorrect analyses, problematic methodologies, unsupported inferences and misleading statements at any stage, and to make these public. Reasonable efforts should be made to alert the Agency to the date of publication." Improving awareness and communication of Eudravigilance. More generally, EAHP encourages the EMA to continue communication activities, in conjunction with the regulatory network, to improve awareness of the existence of Eudravigilance and www.adrreports.eu. Furthermore, it is encouraging to future reporting for healthcare professionals and patients to know that reports of adverse reactions are well recorded and made use of. EAHP therefore suggests for this purpose, and the purposes of awareness raising and organisational accountability, the EMA publish an 'annual Eudravigilance Report'. This should be written in layman friendly language and include information on: - the total number of reports being made to Eudravigilance each year, from which countries, and how this relates to previous years - levels to which the database is being accessed and checked, from which countries, by which groups, and how this relates to previous years - awareness levels of the database, how this compares to previous years, and actions undertaken, underway or to be taken to improve awareness - other developments in ADR reporting in Europe and globally, and - associated reflections and conclusions. This could be a helpful tool as well for continual improvement of systems. The report should be circulated to the European Parliament, European Commission, national medicines regulators, and members of EMA's healthcare professional and patient working parties. Transparency of the Pharmacoviglance Risk Assessment Committee EAHP expresses its support for the intention of further increasing the transparency of the Pharmacovigilance Risk Assessment Committee by publishing the agendas and minutes of its meetings. Some consideration might also be given to the feasibility and appropriateness of Web-streaming (live or post event) all or parts of its meetings, and permitting members of the public to register to attend and observe should they so wish to. Finally, as a small concluding point, EAHP draws the attention of the Agency to the need forattention to be given to how www.adrreports.eu performs in relation to search engine optimization as we note a low scoring for a number of search terms.	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
386		BEUC, the European Consumer Organization, welcomes the European Medicines Agency public consultation on the new draft EudraVigilance access policy[p] however we regret that the consultation was launched during the summer break and was open for only 6 weeks (4 August – 15 September). This is not in line with the European Commission public consultation guidelines that recommend a consultation period of 12 weeks[q] and prevents many interested parties to contribute to it. 1. General remarks Consumers are those who experience side effects and whose daily life is negatively affected by adverse drug reactions. Eudravigilance, as the central EU database of adverse drug reaction reports, and its public interface www.adrreports.eu, contain vital information about the safety of medicines for consumers, health care professionals, researchers, pharmaceutical companies and public health authorities. BEUC welcomes that, following the implementation of the new EU Pharmacovigilance Legislation (Directive 2010/84/EC and Regulation n. 1235/2010) the database now contains data based on reports coming not only from health care professionals and marketing authorizations holders, but also based on direct reports from consumers[r]. Pharmacovigilance data are scientific data about the safety of medicines on the market and they should not be considered "commercially confidential information". The draft should make a clear distinction between the protection of personal data and the protection of intellectual property rights. The draft should also clarify that it applies without prejudice the EU Regulation on access to documents n.1049/2001. 2. Response to EMA Question - EMA's question: As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? - BEUC response: Provided that personal data protection is fully ensured, healthcare professionals and the public should obtain access to additional data outputs from the European database of suspected adverse reactions including tabular presentations or outputs presented as individual cases. There is no reason to restrict access to stakeholder group II to several items of Individual Case Safety Reports (ICSR). Some regulators such as the MHRA in the UK and Lareb in the Netherlands already provide public access to this type of information. It would also be interesting to include more information about the method for the evaluation and	

[p] http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500170699&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc
[q] http://europa.eu/rapid/press-release_IP-12-1_en.htm?locale=en
[r] BEUC position on Pharmacovigilance, 2009.

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		the results of assessment. 3. Specific comments on the draft 3.1 Access for research organizations - “The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be addressed to the satisfaction of the Agency before submission for publication.” - “A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer.” BEUC considers that the Agency should not be entitle to censor the results of independent research and doesn’t support the above mentioned principles. Moreover we consider that the draft should include a more precise definition of “Research Organizations” to avoid too narrow interpretations. “An ad-hoc EMA panel will review requests for research access to data based on a research request. The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency.” BEUC considers that EMA discretion to refuse access is not justified and not in line with the EU Regulation on access to documents n. 1049/2001. The policy should specify who will be the members of the panel and the criteria for its composition. The criteria to refuse access, namely if the Agency is unconvinced of the public health value of the proposed research and if the Agency judges it is in conflict with the public health and legal responsibilities of the Agency, are too vague and are subject to interpretation. The criteria should be more concrete and objective. In order to increase accountability we recommend integrating some transparency provisions, such as the obligation to detail the reasons for a refusal and the publication on the Agency web site of all the requests received and the answers provided. 3.2 Access for health care professionals and the public - The access to information from the general public and health care professionals remains very limited. We therefore recommend making available also to the Group II (Health care professionals and public) the following information: - Date of most recent information (C.1.5); - Gestation period (D.2.2.1d); - Substance name (D.8.r.Eu.r.1);	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		- Substance strength (D.8.r.Eu.r.3a); - Scientific name, form, strength (G.K.2.2.EU 1-5); - Narratives or summaries : narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment; - Previous prescriptions: the information is necessary to identify possible interactions between treatments. It would also be useful to disclose to the general public consumption data in order to put the use of the medicine and the associated adverse events into context. Finally, we recommend to make the public interface of Eudravigilance, www.adrreports.eu more reader friendly and to organize awareness campaigns on the existence of the website in cooperation with stakeholders and with the Member States in the context of the public information campaigns on the importance of reporting side effects foreseen in the EU pharmacovigilance legislation.	
387		I'm concerned but not surprised that the EMA wants this but feel it should not be granted. We should have total transparency and publication of drug trial results with no group allowed to withhold information.	
388		The draft should allow all to read all what's written and is true,enough controlling the truth,do not allow the drafts to hide the truth on tests, it's criminal.	
389		• We have some concerns regarding access for research organizations. Since sensitive information about individual persons has to be protected, it can be questioned on what legal basis research organizations are given access to such information, almost to the same extent as member states. Article 24 of regulation 726/2004 does not provide for research organizations to have access to more information than health care professionals and the public. • It can also be questioned if there are legal grounds for the proposed pre-requisites mentioned in section 5.4.4 for giving research organizations access to information. Are those pre-requisites in line with regulation 1049/2001, according to which anyone requesting access to information does not have to state purpose, sign confidentiality undertaking or agree to have subsequent publications checked by EMA? Additionally, these conditions are described in a way that resembles censorship, which we don't support. • In what way will these pre-requisites guarantee that personal data does not be revealed by research organizations? Will EMA in any way enforce these conditions and take legal action in case of violation? • Regarding giving WHO UMC access to the information: It has to be ensured that information that can be traced back to individuals has enough protection and that	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		there is sufficient legal basis for giving access to such information to a non EEA party. The policy does not sufficiently explain the legislation that protects the information at the WHO UMC, which is not covered by EU legislation on personal data protection. The same concern applies to giving International Medicines Regulatory Authorities access to the information. • Definition of "sender" need to be clarified in the tables. • In particular the situation that the sender is both the reporter and the patient. It this situation the identity of the reporter (which is a patient) has to be confidential. A proposal is to add a column for this specific situation. • It is also questioned how and who will defined a researcher organization. • The process of provision of information to other authorities (including WHO) has to be more defined (Which authorities? Who decides the provision? When? Why?) • Because the differences in Privacy Law on a national level and different availability of national register it could still be possible to identify individual with this proposal. • If the MAH should have an opportunity to fulfill their PhV obligations on a substance level they have to gain access to data in order to identify duplicates not merely in published cases. But it should be balanced to keep the privacy data protection.	
390		Question by EMA: As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Response: We do not consider it as useful that "Healthcare professionals and the public" in general should be able to process queries and tabular listings from the EudraVigilance database. The processing and analysis of such queries requires a special knowledge and understanding in medical data management, biostatistics as well as epidemiology which cannot be expected from this group of users per se. The risk is that inappropriate conclusions are drawn. On the background of quality management principles which were introduced by the Guideline on Good Pharmacovigilance Practice, the minimum requirement is that the right of additional data output is limited to registered and appropriately trained users. Furthermore they should state beforehand what is the purpose of the data analysis and which methods will be used. Overall, the approach of the WHO Uppsala Monitoring Centre is preferred, meaning that the queries are performed by dedicated specialists only. Question by EMA: As regards stakeholder groups III. A "Marketing Authorisation Holders" do you consider the data set proposed in Annex 1 (Table column PV obligations – Level 2) as sufficient for a MAH to comply with the pharmacovigilance obligations as outlined in	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		Regulation (EC) 726/2004, Directive 2001/83/EC, the Commission Implementing Regulation (EU) 520/2012 and the Good Pharmacovigilance Practice Modules? Response: The question is very comprehensive as it relates to all pharmacovigilance obligations of the marketing authorisation holder. Unfortunately it is not possible within the relatively short period of time to analyse if the data access of level 2 allows to comply with the obligations in total. This will require an analysis of the single processes (PSUR, signal management, etc.). Therefore it should be possible to continuously amend level 2 information. Again, access should be limited to registered and trained users only. Furthermore they should state beforehand what is the purpose of the data analysis and which methods will be used. Comment: “This Access Policy will enter into force six months following the announcement by the Management Board of the Agency that based on an independent audit report, the EudraVigilance database has achieved full functionality.”	
390	Section 6	Proposed change (if any): Please add or reference the planned date of the independent audit, and of the availability of the audit report.	
391		I am writing in response to the planned review of rules regarding adverse events reporting. I am a practicing GP in England. As such I need to rely on the most up to date information. I understand that some of the data or analysis of them may be withheld of censored. I think an open culture would allow the EMA as well as independent researches access to data and the outcome would improve patient safety.	
392	Page 23: 5.4.4.1. Reports of suspected adverse reports in EVPM The Agency will have a standard timescale for response to requests for extended data.	This is a response to the consultation on the "Draft revision of EudraVigilance access policy for medicines for human use" from the AllTrials campaign. The AllTrials campaign was launched in January 2013 to call for all clinical trials to be registered and results reported. It is an initiative of Bad Science, BMJ, Centre for Evidence-based Medicine, Cochrane Collaboration, James Lind Initiative, PLOS and Sense About Science. It is supported by nearly 80,000 people and over 500 organisations including regulators; medical schools and universities; medical bodies and Royal Colleges; research funders and more than 200 patient groups from across the world. Principles of access for research organisations - We are very concerned by some of the principles in section 5.4.4.1. (page 23) under which access to the data is granted to research organisations. A. We object strongly to the following two conditions: • "The Agency has the right to view any publication resulting from EudraVigilance data before submission (maximum period for initial Agency review will be six weeks) including a privacy check as regards possible re-identification of patients. Any issues raised by the Agency concerning incorrect analyses, unsupported inferences, misleading statements or the protection of personal data must be	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		addressed to the satisfaction of the Agency before submission for publication." • "A standard Agency disclaimer must be added to the manuscript. The Agency reserves the right to reword the disclaimer to the manuscript in cases of unresolved disagreement over the interpretation of the data. The manuscript or its conclusions must not be disseminated in any way without the disclaimer." These principles would seem to give the EMA the right to supress anything in an academic paper that it disagrees with. This is a profoundly outdated world view. Simply because the EMA is the body collecting this public data from EU patients does not give it the right to control how it is used. This would amount to state censorship of scientific discussion and analysis of public health data. Furthermore, this means the EMA will require a significant team of statistical reviewers and may find itself embroiled in numerous longwinded disputes. Indeed, to come to the conclusion that analyses are flawed, will require the EMA to openly publish these analyses, for independent scientific scrutiny. Consequently, what is proposed is unworkable and these two principles should be removed. B. We are also concerned by the following principle: • "An ad-hoc EMA panel will review requests for research access to data based on a research request The Agency may refuse access to the data if the panel remains unconvinced of the public health value of the proposed research or judges it to conflict with the public health and legal responsibilities of the Agency." The panel that reviews research requests should be independent of the EMA to prevent conflicts of interest. It is possible that some analyses of these data may draw close attention to regulatory decisions made by the EMA itself, since these are often close calls. C. Finally, we believe the following principle could be strengthened to require research organisations to submit the results of their research for publication: • "Those given access to EudraVigilance data should make appropriate efforts to publish their research." There needs to be an expectation that access to these data for research purposes is granted on the expectation that the results of that research will be made available to the broader scientific community. Proactive publication of ICSR data - We support the EMA's aim of granting proactive access to more individual case safety report (ICSR) data. Data being published proactively should be up to date and not withheld for publication in batches. One improvement that openFDA introduced was immediate access to the most current data on the FDA Adverse Events Reporting System database. Immediate access to greater amounts of data will benefit patients, health workers, doctors, pharmacists, regulators and researchers. Restrictions on access - There is disparity in the access provided to the different stakeholder groups listed in Table 1 "Number of ICH E2B(R3) ICSR data elements" (page 11), which in our view is difficult to reconcile with principles of openness. The EMA should aim to provide	

Stake holder no.	General/Line no.	Stakeholder comments	Proposed changes by Stakeholder, if any
		access to as much information as possible. Providing access to more information about common adverse events for a treatment will not compromise patient confidentiality as the data will apply to a large number of individuals. The EMA can redact identifiable patient information from reports on rare side effects. We are concerned that neither healthcare professionals (Group II) nor research organisations (Group IV) will have access to case narratives or summaries (Annex 2 H.1 page 50 and H.5.r page 51). Researchers have told us that in their experience, these narratives can be very useful to understand the context of serious adverse events reported in the course of a treatment. Another restriction would mean that healthcare professionals would be unable to find out what drugs a patient had previously been prescribed (Annex 2 D.8.r page 37). This information is useful for healthcare professionals to be able to identify possible interactions between treatments. Additional question 1. As regards stakeholder group II "Healthcare professionals and the public" would you consider it useful to obtain additional data outputs from the European database of suspected adverse reactions (www.addrreports.eu) such as tabular presentations or outputs presented as individual cases whilst fully respecting personal data protection? Yes. We must ensure that healthcare professionals and the public have useful access to up-to-date information on serious adverse events contained within the database. Providing access to these data in additional formats will enable them to make better use of the data.	
393		Mi cuñado murio en un ensayo clinico de la Multinacional Astrazeneca el 20/04/2013 con la sustancia experimental SIFALIMUMAB, todavia hoy no sabemos nada del ¿porque? de su muerte, entrego la vida a la investigacion y firmo su sentencia de muerte, nos han negado todo derecho a informacion, tanto administracion autonomica como inclusive la AEPMS que estan al servicio del ciudadano....verguenza de pais...verguenza de AEMPS.....y la EMA nos desvia a la AEMPS....existe un seguro que cubre los daños producidos y se basan en decir que no hay relacion con el ensayo clinico....y mi hermana malviviendo, asi como mi sobrino con problemas psicologicos por haber perdido a su padre ¡¡¡NADIE NOS ESCUCHA!!!.. por culpa de la MENTIRA de la vida...pero vamos a los tribunales y ¡Ojala! que la justicia haga justicia...porque es la unica esperanza que nos queda....pero es que a pesar de que tenemos pruebas mas que evidentes estos laboratorios farmaceuticos tienen tanto poder que son capaces de callarle la boca a cualquiera....pero con nosotros le va a costar callarnos.....MENTIRA Y FALSEDAD es lo que existe	