8 July 2011
EMA/432253/2009
Patient Health Protection

Overview of comments received on draft EudraVigilance access policy and implemented amendments

Interested parties (organisations or individuals) that commented on the draft EudraVigilance Access Policy as released for public consultation from 22 December 2008 to 2 March 2009 include:

Stakeholder No.	Name of organisation or individual
1	AESGP- European Self-Medication Industry
2	AGEMED - Agency for Medicines and Medical Devices, Spain
3	AGES PharmMed, Austria
4	Danish Medicines Agency, Denmark
5	EFPIA – European Federation of Pharmaceutical Industries and Associations
6	EGA – European Generic Medicines Association
7	Federal Agency for Medicines and Health Products, Belgium
8	HAI – Health Action International
9	H. Lundbeck A/S, Denmark
10	INFARMED, Portugal
11	IOPI – International Patient organisation for Primary Immunodeficiencies
12	Johnson & Johnson, United Kingdom
13	Medicines Evaluation Board, Netherlands
14	Merck Serono, Spain
15	MHRA – Medicines and Healthcare products Regulatory Agency, United Kingdom
16	MPA, Sweden
17	National Institute of Pharmacy, Hungary
18	Novartis Pharma AG, Switzerland
19	OM Pharma, Switzerland
20	State Institute for Drug Control, Czech Republic
21	UEMO – European Union of General Practitioners

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Stakeholder No.	Name of organisation or individual
22	Wyeth Pharmaceuticals, United Kingdom

Table 1 General comments – overview

No.	Stake-holder No.	General Comment	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
1	20	We appreciate the innovative approach to EV Access Policy – especially in the field of healthcare professionals and general public as well as MAHs. We agree that particular accent should be placed on personal data protection (in the process of anonymisation of adverse reaction data) and high quality output should be ensured.	Acknowledged.
2	17	Please be informed that I have reviewed the draft proposal and I have no further comments.	Acknowledged.
3	16	We do agree with the general principles laid down in 3.1. The MPA are also satisfied with the way our access to EudraVigilance Data is described in 3.2.1.	Acknowledged.
4	10	INFARMED fully supports the need to establish a clear policy regarding the access by the various stakeholders to the information contained in EudraVigilance, in order to facilitate the conduct of pharmacovigilance by NCAs, MAHs and Sponsors of clinical trials.	Acknowledged.
5	15	The MHRA supports the delivery of this Access policy and has no objections to the level of data which is being proposed to the various stakeholder groups.	Acknowledged.
6	13	The Medicines Evaluation Board supports the draft EudraVigilance Access Policy in general, only some proposed arrangements of EudraVigilance could be elaborated more in detail or need some clarification. In line with the proposals in the consultation document, the MEB supports the improvement of readability of the Access Policy document, therefore it is suggested to include an overview table with the level of access grouped by stakeholder category (as published recently by Thomas Goedecke/Sabine Brosch/Peter Arlett in Regulatory Rapporteur, Vol 6, No 2,	A table providing an overview of access rights for all stakeholder categories has been included in the final policy.

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		February 2009).	
7	13	The document does not mention the possible access at the time of future enhancements of EVDAS (e.g. integration of Risk Management Plans). These future enhancements could be of importance in the monitoring of safety for the NCAs and should be accessible for the NCA as well (preferably without having to go through another consultation period).	The importance of access to the EU-RMP Annex 1 (electronic interface for EudraVigilance) is acknowledged taking into account that NCAs should have access to such core risk profiles for centrally authorised products. The access by NCAs to such information will be granted through EPITT. The detailed specifications related to the technical implementation of the Access Policy are being further elaborated by the EV-EWG taking into account the overall principles set out in the final Access Policy and future enhancements of EudraVigilance.
8	2	MAH access to EudraVigilance Data is well acknowledged as supported in Regulation and guidelines.	Acknowledged.
9	19	Usage of data by competitors: it seems important to include some dispositions in the system in order to avoid the usage of data, by healthcare professionals or MAH, in their promotional materials, specially the safety data on a competitor product (s).	A best practice guide on usage of data can be prepared based on the understanding that this would not be legally binding.
10	12	No concerns with the levels of access as defined.	Acknowledged.
11	12	Will levels of access be inclusive of lower Categories of access? In other words, will an MAH/sponsor with Access Category III be able to generate the searches/reports of Access Category II (aggregate data output)? We think this should be "yes".	Aggregated data and individual data elements in relation to the ICH E2B ICSR will be accessible to MAHs/Sponsors in the same way as for healthcare professionals (HCPs)/Public.
12	9	H. Lundbeck A/S welcomes the opportunity to review this draft policy document. We welcome this initiative and have no additional comments.	Acknowledged.
13	6	In general the EGA supports the EudraVigilance (EV) Access policy for medicines for human use to improve transparency regarding adverse reaction data for all stakeholders.	Acknowledged.

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		The EGA also suggests that access to EudraVigilance, as proposed, should be implemented during the course of 2009.	
14	5	EFPIA is very supportive of the general objectives of the EudraVigilance Access Policy, as a means of facilitating the conduct of Pharmacovigilance by National Competent Authorities (NCAs) and Marketing Authorization Holders (MAHs) and disseminating information on ADRs to HCPs, patients and consumers.	Acknowledged.
15	5	Consistent with the requirements for MAHs in measuring the effectiveness of additional risk minimization activities (including communication), EFPIA also considers it important that this transparency initiative should be followed by a measure to determine the effectiveness of communicating this information, impact on HCPs and General Public opinion and on Public Health improvement. It is believed that this feedback would also be made publicly available.	Such measures are not included in the EudraVigilance Access Policy as such but will be considered in the context of outcome research conducted by the European Medicines Agency.
16	5	It is understood that it is unrealistic to expect detailed information on the tools utilized for signal detection and data analysis in a guidance; however, EFPIA would appreciate if further clarification in future guidelines or points to consider documents could be made available.	The responsibilities for the monitoring the safety of medicinal products are laid down in Community legislation and guidelines (Volume 9A). A guideline on the use of statistical signal detection methods in the EudraVigilance data analysis system was already published by the European Medicines Agency (Doc. Ref. EMEA/106464/ 2006 rev. 1). Further guidance will be developed and training provided to facilitate the use of signal detection and data analysis tools in EudraVigilance by pharmaceutical industry.
17	5	Although the access to EudraVigilance is meant to allow for signal detection with medicinal products of one MAH would it be expected to run searches to see if medicinal product(s) of other MAHs is (are) also suspect and if so then report it to the Competent Authorities?	Since all NCAs have access to EudraVigilance, there is no need for an MAH to notify NCAs about reports in EVDAS from other MAHs, where their medicinal product (or active substance(s) of a medicinal product for which the company

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			holds a marketing authorisation in the EU) is also reported suspect/interacting.
18	5	Publication of numbers of occurrence of MedDRA Preferred Terms without medical assessment will lead to increased questions and inquiries of the media and the public to the Competent Authorities and the Marketing Authorisation Holders.	Acknowledged.
19	21	The European Union of General Practitioners (UEMO) agrees with the proposed draft on EudraVigilance access policy and has no further comments or suggestions.	Acknowledged.
20	8	Health Action International Europe welcomes the EMEA's decision to hold a consultation on the draft Eudra Vigilance Access Policy for medicines for human use. Giving stakeholders access to Adverse Drug Reaction (ADR) data is an important step. However, 'access' is not the end of the story and it is vital that the process of retrieval and format of information is suitable for those who wish to use the data. As it stands, there is no evidence that the EMEA or any other part of the EU has asked stakeholders, in particular health professionals, patients and consumers how they wish to use this information.	Following a detailed presentation of the draft access policy to Healthcare Professionals Organisations on 30/09/08 and to Patient and Consumer Organisations on 30/10/08 at the European Medicines Agency, consultation is continuing. Experts of those two groups will also be involved in the implementation phase of the Access Policy.
21	1	Despite the presence of some guidance, we fear that the publication of numbers of occurrence of MedDRA Preferred Terms without medical assessment and given out of context, will lead to increased questions and inquiries of media and public to the Competent Authorities and the Marketing Authorisation Holders.	Guidance will be prepared for patients/public on how to interpret the EudraVigilance adverse reaction data, which will be made accessible e.g. by explaining concepts of spontaneous reporting, principles of benefit/risk evaluation and decision making and the role of aggregated, spontaneous adverse reaction data in the context of an overall benefit/risk assessment.
22	1	Confidentiality of data: We wonder how data will be made anonymous for	Based on the recommendation of the European Data

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		access to the general public. If it's not the case, would the healthcare professionals and the general public only have access to Drug Analysis Print and not Individual Case Safety Reports (ICSRs)? Even though the intent is that only limited line listing data will be made available, we wonder whether HCPs will report if they believe that patients will be able to see their details in the database.	Protection Supervisor (EDPS), the European Medicines Agency has carefully assessed all the ICSR data elements for spontaneous reports to be disclosed taking into account the need to safeguard the identity of data subjects as defined in article 2 of Regulation (EC) No 45/2001. Annex 1 of the Access Policy summarises the ICH E2B data elements that can/cannot be disclosed based on this assessment.

Table 2 Specific comments on the text

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
1	3.1.2 – 89	6	Comments: Currently under access to EudraVigilance data we have: 3.1.2.1 Spontaneous reports and 3.1.2.2 Reports from interventional and non- interventional trials Rationale: Following the new legislative proposals on pharmacovigilance, the EMEA will be responsible for conducting literature searches for well established products. These Individual Case Safety Reports (ICSRs) should be added to the EV database and should be accessible to MAHs through the EVDAS. A more complete dataset is needed for these literature reports, including the narrative. Proposed change: We suggest adding an additional section entitled: '3.1.2.3 Reports from literature'. Marketing Authorisation Holders should have full access.	Not accepted. 1. Literature reports are not a report category per se in ICH E2B. Adverse reactions described in the literature refer either to spontaneous adverse drug reaction reports or reports from studies and are classified accordingly in E2B. 2. Access to the case narratives of ICSRs described in the world-wide literature could be considered in the context of the implementation of the new pharmacovigilance legislation once adopted.
2	3.1.2.1 – 93	22	Comments: What is the source of the spontaneous data? Will it be that which is submitted by National Competent Authorities and MAHs, and will it include non-healthcare confirmed reports? Is it from world-wide or EEA reports? Proposed change: Wyeth proposes that the source(s) of the spontaneous data be clarified.	Accepted. Spontaneous reports will be made available independent of the primary source qualification in accordance with ICH E2B A.2.1.4 'Qualification'.
3	3.1.2.1 – 101	15	Comments: It is proposed that NCAs access ICSR data via EudraVigilance Data Warehouse and Analysis System (EVDAS).	Not accepted. In line with Regulation 726/2004, Article 57(1)d NCAs have currently access to ICSR data via EVDAS.

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			Proposed change: We consider that it is necessary to have access to UK reports in the original XML format and would propose that all UK reports originating from industry that are not held initially by us are sent directly to our database via the Cyclone system.	The current legal framework does not foresee the 'sending' of reports from the EudraVigilance Gateway. Based on the current reporting rules as set out in Regulation 726/2004 and Directive 2001/83/EC as amended, it is not possible that UK reports originating from industry, that are not held initially by MHRA are sent directly to the MHRA database via the EudraVigilance Gateway. Reporting rules will be reconsidered in the frame of the implementation of new EC legislative proposal.
4	3.1.2.1 – 101 3.1.2.2 – 162	13	Comments: Since the roll out of EVDAS in July 2007, the NCAs have access. Nevertheless the MEB is convinced that access to NCAs might be provided via other mechanisms as well (taking into account the procedural and technical issues mentioned in section 4 of the consultation document). For instance export of 'cleaned data' from EVDAS to NCAs who would like to integrate the data into their own pharmacovigilance system, or who would like to extend their options for analysing data by using SAS. Proposed change: The MEB recommends that such options should be further explored by the EMEA.	Not accepted. See specific comment Nr. 3 for justification.
5	3.1.2.1 – 101	13	Comments: As a NCA, the MEB would like to receive a confirmation that not only access to EVDAS will be granted, but also to have permanent access to the transactional system (since this also	Accepted. Permanent access to the EudraVigilance transactional database is already provided to NCAs. Such access will be also maintained in future.

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			contains error reports).	
6	3.1.2.1 – 101 3.1.2.2 – 162	13	Comments: The consultation document clearly describes the routing of access for NCAs to specific data fields. The MEB underlines the general principle as put forward in the consultation. However, these access rights should also be 'extrapolated' to the queries. For example: NCAs have certain responsibilities in pharmacovigilance inspections and in order to do so they should have access to data and administrative data concerning the compliance. Currently the NCA has access to the relevant data fields for each individual report, regardless who might be the sender of the ICSR (which is in line with the Access Policy document). However, when using queries that have been designed to measure compliance NCAs currently only have access to their own data and not to data sent by MAH/Sponsors.	Accepted. NCAs can be provided with access to queries in EVDAS allowing for the monitoring of expedited reporting compliance of MAHs for non-EU cases (EU cases are currently sent through NCAs).
7	3.1.2.1 – 106	15	Comments: The proposal to provide online cumulative data at drug substance level mirrors the MHRA's approach with the provision of Drug Analysis Prints. However, it needs to be ensured data is fully validated and free of duplicates and that drug variants and synonyms are clearly linked to the active substance. Our many years of experience in making such cumulative data available has enabled us to understand the importance of how the data are presented and how it is necessary for detailed guidance to be provided so as to avoid misinterpretation as far as is possible.	Accepted. 1. The need for adequate quality of data in the context of the EudraVigilance Access Policy was raised by the European Medicines Agency at the level of the Heads of Medicines Agency in April 2008. Subsequently, a major tender to assist the EudraVigilance Data Quality Management was prepared by the European Medicines Agency. 2. Drug variants and synonyms are aspects that have been implemented in the EudraVigilance Medicinal Product Dictionary (EVMPD). 3. Detailed guidance on how to interpret the data made

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				publicly available will be prepared taking into account experience of NCAs that already implemented access to adverse reaction data at national level.
8	3.1.2.1 – 106	8	Comments: Main principles - what we need to know: the information should address the quality as well as the quantity of data. Some of the most common questions that are likely to be asked about a medicine are: What adverse effects might the medicine cause? How are they caused and how might they be prevented or mitigated? What is the severity, duration, reversibility etc. of those effects? In what circumstances do they occur? What might be the consequences for patients? At a minimum, the ADR data provided by the EMEA should be capable of responding to these issues. Simply offering access to tabulations of suspected but unverified ADR reports will do little to help anyone answer such questions.	Accepted. In general, patient leaflets provide guidance as regards to the most common questions. In addition, guidance will be prepared for patients on how to interpret the EudraVigilance adverse reaction data, which will be made accessible e.g. by explaining concepts of spontaneous reporting, principles of benefit/risk evaluation and decision making and the role of aggregated, spontaneous adverse reaction data in the context of an overall benefit/risk assessment.
9	3.1.2.1 – 106	8	Comments: Facilitating access: it is not clear from the text whether the database will be searchable but it is important that there are a variety of criteria to retrieve the data. Search criteria for the database should include: sex, age, product (brand and generic names), type of reaction, data reported. The database should also be constructed to enable searches on more than one criterion, e.g. age and type of reaction. Proposed change (if any):	Partly accepted. Search functions will be provided to healthcare professionals/public on the European Medicines Agency /EudraVigilance website. The need for queries based on more than one search criterion and the ease of retrieval of the results is acknowledged. As regards the potential usage of the published data (e.g. due to concerns of potential lawsuits), no specific

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			The database and format of information should be revised with the needs of stakeholders in mind. A disclaimer on the database would prevent restrictions on access due to fears about lawsuits. All information in the database should be easy to retrieve using a variety of search criteria in isolation and/or combination.	restrictions can be applied.
10	3.1.2.1 – 106	4	Comments: The Danish Medicines Agency finds that it is important to establish procedures involving Committee for Human Medicinal Products/Pharmacovigilance Working Party before EMEA is publishing reports on adverse reactions on the EudraVigilance website (for category II HCPs/Public).	Clarification: For access to HCPs/Public aggregated data will be made available without delay after completion of the data quality review to provide stakeholders with the necessary transparency on the data collected in EudraVigilance. Involvement of the Committee for Human Medicinal Products (CHMP) and/or the CHMP Pharmacovigilance Working Party (PhVWP) each time when new adverse reaction reports are received in EudraVigilance for all medicinal products authorised in the EU is not practical.
11	3.1.2.1 – 106	1	The initial implication is that access will include actual individual case reports. However, it then goes on to say 'the data will be presented as drug analysis prints' – and then Annex 1 more clearly explains the formats that the data will actually be presented in. It would be preferable to begin the section on Page 3 with something like: "Access will include collated data based on individual spontaneous reports" which, from our understanding of the rest of the document, would be more accurate.	Accepted: A statement has been introduced that explains that a restricted set of data elements as described in Annex 1 related to spontaneously reported cases taking into account the need to comply with Regulation (EC) No 45/2001 on personal data protection has been introduced. In addition, an explanation has been added on how the data can be accessed and the way data can be presented as a result of a specific query performed.
12	3.1.2.1 –	1	The intent of providing general guidance is good but we are	Clarification:

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	116		concerned that the public and particularly the media will not take this into account properly, even if it is clearly explained in 'lay' terms. We think that there is a high risk that access to the data even at the level of detail specified, will lead to over-reaction and misinterpretation, resulting in media-led "safety scares" etc. For example, the charts on pages 9-10 in Annex 1 might imply to a lay person that "Product X causes Event Y", e.g. myocardial infarction etc.	The concerns are noted. However, several NCAs have already started making adverse reaction data accessible for spontaneous reports and the European Medicines Agency will take their experience into account when implementing the Access Policy.
13	3.1.2.1 – 138	1	It reads that 'access will be granted in EVDAS to a defined set of data elements … excluding case narrative …": narratives are critical to have a good understanding of the case and often contain information regarding the suspect drug which can eliminate or implicate a company product. There may also be information which is critical and does not fit into any of the other boxes.	Clarification; Taking into account the need to comply with Regulation (EC) No 45/2001 on personal data protection, case narratives can currently not be disclosed. Once the revised legal framework based on the two legislature proposals of the European Commission will come into force, the EudraVigilance Access Policy will be reviewed. In this context, the Agency will consider if access to MAHs can be granted for a wider ICSR data set related to those medicinal products/active substances, for which they hold a marketing authorisation in the EEA. This relates in particular to expected changes of the adverse reaction reporting rules and revised obligations in the conduct of pharmacovigilance as well as the implementation of the new ICSR and IDMP ISO standards once finalised.
14	3.1.2.1 – 147	1	It is stated "The data will be made accessible online …which will allow for the use of data analysis and signal detection tools by the MAHs": this raises the question as to whether there will be an expectation or onus on the MAHs to carry out	Clarification; Based on current pharmaceutical legislation, the Agency has to comply with the provisions laid down in article 26, paragraph (3) and article 57, paragraph (1)(d) of

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			signal detection using EudraVigilance data as well as their own database? This would mean significant additional work for companies. If MAHs can only see the DAPs and no narratives (see previous point), the data will have limited if any value for signal detection. Changes in frequencies of an event may be a signal, but it is the detailed investigation of these cases that confirms (or otherwise) that there is a new safety concern. ➔ Clarity should be provided regarding MAH and CA roles in performing signal detection activities via EudraVigilance. ➔ As full access to the data will be restricted, the signal detection and data analysis process should be a joint activity between the CAs and MAHs i.e. MAH should if required be allowed to request for EMEA to perform in depth reviews on data if the MAH suspects a signal from one of its products.	Regulation (EC) No 726/2004. The obligations as regards marketing authorisation holders in relation to pharmacovigilance and signal detection are set out in Regulation (EC) No 726/2004 and Directive 2001/83/EC as amended as well as Volume 9A. EudraVigilance should be regarded as an additional source of information to support the pharmacovigilance activities of the MAH.
15	3.1.2.1 – 106	15	Comments: Follow up Access: It needs to be considered how the Agency will respond to further detailed requests for information from patients and HCPs following review of the cumulative data including requests for access / provision of data for research purposes. This area does not appear to be covered in the access policy.	Clarification: The Access Policy considers proactive and reactive information disclosure as complementary i.e. the maximum possible information is proactively made available sparing the need for additional requests by stakeholders. As part of its proactive information policy, the Agency will also provide additional explanations to facilitate the understanding of the data that are made accessible. As regards requests for information, the European Medicines Agency applies the 'Rules for the implementation of Regulation (EC) 1049/2001 on access to EMEA documents'

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				(Doc. Ref. EMEA/MB/203359/2006 Rev 1). The European Medicines Agency has also included aspects related to access for research purposes
16	3.1.2.1 – 112	20	Comments: It would be useful to specify what time period is meant by the term regular interval of EVDAS drug analysis publishing (should publicly accessible data be published e.g. monthly or in three months periods?).	Accepted. The data will be made available without delay after completion of the data quality review and management process to ensure that reliable data are being disclosed.
17	3.1.2.1 – 112	6	Comments: The periodicity of the drug analysis prints should be better defined; the wording 'at regular intervals' is too vague (eg, it could be weekly, monthly, etc). Proposed change: The data will be presented as drug analysis prints generated by EVDAS and will be published on the EudraVigilance website ~~at regular intervals~~ *every three months* without delay after completion of the data quality review, in accordance with the access policy as defined in chapter 3.2.	Partially accepted. The data will be made available without delay after completion of the data quality review and management process to ensure that reliable data are being disclosed.
18	3.1.2.1 – 116	19	Comments: The Access to General Public: this access is questionable, particularly the way the information will be understood or interpreted by individual patients. Proposed change: We do think that this access should be restricted, for example to registered Group of patients or Patients associations.	Not accepted. The European Medicines Agency cannot restrict access to certain stakeholder groups but must comply with the provisions laid down in Article 57(1)d of Regulation (EC) 726/2004.
19	3.1.2.1 – 116	14	Comments: I fully agree with the proposal to accompany drug analysis	Accepted. These aspects have been taken into account in the final

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			prints with a general guidance on data interpretation and particularly on causality assessment. These explanations should be worded very carefully to avoid patient concerns and potential legal suits due to EudraVigilance reports of "adverse reactions" which have not been confirmed as causally associated with the product and therefore do not appear in the product information (SPC /package leaflet).	EudraVigilance Access Policy. The guidance will be developed with input from the EudraVigilance Expert Working Group.
20	3.1.2.1 – 116	5	Comments: EFPIA is very supportive of the general objectives of the EudraVigilance Access Policy, as a means of facilitating the conduct of Pharmacovigilance by National Competent Authorities (NCAs) and Marketing Authorization Holders (MAHs) and disseminating information on ADRs to HCPs, patients and consumers. The proposal to include contextual statements, which place the data into perspective is particularly welcome and we would urge the EMEA to ensure that this is very prominently presented in order to avoid inappropriate interpretation of the data and facilitate a better understanding of the clear limitations of spontaneous data sources.	Accepted. These aspects will be taken into account in the implementation of the final EudraVigilance Access Policy. The 'contextual statements' will be developed with input from the EudraVigilance Expert Working Group.
21	3.1.2.1 – 116	6	Comments: It is paramount that the information provided to the general public is clear. Nevertheless, if questions arise from the information provided via EV, the public should be instructed to consult their healthcare professionals.	Accepted. These aspects will be taken into account as part of the implementation of the final EudraVigilance Access Policy.
22	3.1.2.1 – 116	18	Comments: We fully support the concept of providing an accompanying explanation and list of caveats with drug safety prints for	Accepted. These aspects will be taken into account as part of the implementation of the final EudraVigilance Access Policy.

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			consumers. The wording of such disclaimers is critical to putting the information into appropriate context for a lay audience with diverse backgrounds and levels of education. Indeed, failing to do so may induce patients or caregivers to make incorrect treatment decisions, such as discontinuing medication, without consulting their physicians. We strongly encourage the agency to consider the following actions. Review language used by health authorities that have already opened their databases to the public (in particular MHRA, Health Canada, and the U.S. FDA) and adopt the best elements of each. Release the EMEA explanatory statement for consultation or, at minimum, perform comprehension testing with consumers. If the bullets presented on page 3 (of the draft EudraVigilance Access Policy) are meant to be examples of what consumers will read, they should be re-considered, as the language is too technical for the average person and tells them little about how the information should be used. Along with the explanatory statement, it would be useful to provide consumers with generic contextual examples of drug print use. For instance, a drug analysis print that lists 60 myocardial infarctions with an arthritis drug could review some of the other risk factors that may have contributed to the total, such as the age and general health of the patient population. Factors that can affect reporting rates in a voluntary reporting system should be listed, e.g. widespread media coverage of	Guidance will be developed by the EudraVigilance Expert Working Group considering the approach of those NCAs that already provide public access to adverse reaction data. Consultation will take place on the guidance for healthcare professionals and consumers at the level of the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Group (HCPWG) established at the level of the European Medicines Agency. Examples can be included as considered necessary by both committees. This will be taken into account in the preparation of the guidance that will be provided to patients and healthcare professionals.

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			an ADR with one drug might lead to increased reporting for the entire class. Consumers should have the opportunity to read a brief summary of the overall ADR reporting system so that they understand how and why reports are made and how the agency uses spontaneous ADR information. Prominently list the general risks (e.g. hospitalization, death) of discontinuing or changing one's medication without first consulting a health professional. The importance of this warning can not be overstated.	This will be taken into account as part of the implementation of the EudraVigilance Access Policy. This will be taken into account as part of the implementation of the EudraVigilance Access Policy.
23	3.1.2.1 – 116	6	Comments: The general public should be reminded that they should consult their physician or pharmacist when there are questions on the nature of adverse events of medicines that they or their relatives are taking. Proposed change: The general guidance should also contain the following reminder: "When an adverse reaction is identified, the patient is advised to contact his/her local physician or pharmacist for further guidance and answers to questions".	Accepted. This will be taken into account as part of the implementation of the EudraVigilance Access Policy. As part of the guidance to be developed the strengths and weaknesses of aggregated adverse reaction data will be explained to permit for adequate interpretation of the data (explain e.g. concepts of spontaneous reporting, principles of benefit/risk evaluation and decision making). Guidance will include general aspects such as advice to consult healthcare professionals before taking e.g. a decision on changing the course of treatment based on published adverse reaction data and will explain potential risks to discontinue or change ongoing medication without prior consultation with treating physician.
24	3.1.2.1 – 116	5	Comments: Although reference is made to 'general guidance', the current	Accepted. These aspects will be taken into account in the final

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			text does not fully address the critical need for data to be released in context i.e. raw numbers without clear and explicit guidance that is understandable to the audience may lead readers to be alarmed and confused. This step towards enabling a reader to comprehend the concept of balance of benefit and risk is of particular importance. In order to provide further context and clarity for interpretation of the data, it is suggested to add some text as shown in the next columns. Proposed change: Suggest some additional points to consider (into the guidance document). The drug analysis prints will be published with a general guidance on the nature and their interpretation of the data. Such guidance will include general explanations addressing the following key elements: Adverse reaction reports are only a subset of data being dealt with in the frame of pharmacovigilance to safeguard public health. A proper evaluation may require additional measures to assess the safety of medicines e.g., the conduct of post-authorisation studies. It is impossible to compare the risks of different medicinal products by comparing the numbers presented in drug analysis prints. A more detailed evaluation of adverse reaction data is mainly performed on case series taking into account other pharmacovigilance information available (e.g. sales and	EudraVigilance Access Policy. The guidance will be developed with the EudraVigilance Expert Working Group. See also specific comment Nr. 17.

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
			prescription data by subgroups or pharmacoepidemiological data) and has to be balanced with the drug benefit." Individual causality assessments of adverse reaction reports are not always reliable as the degree of causality often depends on the quality of information supporting a causal association. A routine evaluation of adverse reaction data is foreseen in the legislation in the frame of the EU risk management strategy as well as part of the regular preparation of periodic safety update reports (PSURs). Potential safety issues that may arise in the frame of such evaluation are addressed in form of regulatory actions, which are subsequently communicated to the stakeholders concerned (e.g., changes in the Summary of Product Characteristic (SPC); Dear Doctor Letter). Patients experiencing AEs which they are suspecting to be related to a specific medical product are strongly recommended to contact their HCP before taking any action.	
25	3.1.2.1 – 116	5	Comments: Referring to "The drug analysis prints will be published with a general guidance...": The information in the mentioned general guidance is not complete and adequate for the interpretation of the data. Datasets may include duplicates from several sources which cannot be distinguished by data quality reviews. Total number of reports may greatly differ between compounds of a same class or between originator and generic products depending on the market presence of each product, its stage of life cycle and other factors.	Accepted. The need for validation of ICSR quality including detection and management of duplicates is well recognised and will be addressed as part of a tender to support the EudraVigilance Data Quality Management activities. The guidance aspects will be taken into account as part of the implementation of the EudraVigilance Access Policy.

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
26	3.1.2.1 – 116	5	Comments: It is critically important for the whole concept that the key elements that are specified under the bullet points are addressed clearly and unequivocally. The difference between the definitions of adverse drug reactions in section 4.8 of the SmPC and the derived UPL and the adverse drug reactions listed in the prints should be explained. It is very confusing (and will be even more so to the public) that both documents refer to 'adverse drug reactions'-, while the definitions are different [with reference to an already available example of output: the MHRA listings include products for which at least one suspected Adverse Drug Reaction (ADR) report has been received that specifies that product as a 'suspected drug' (i.e. suspected causal association with the reaction). This is not the definition we use for classifying an ADR for the SmPC]. The format in which the info is made available is of vital importance and should involve industry as a stakeholder when this is being developed in detail. Proposed change: In order to avoid misunderstandings it is suggested to use "suspected adverse drug reactions" throughout the document released to the public.	Accepted. These aspects have been taken into account in the final EudraVigilance Access Policy.
27	3.1.2.1 – 116 Annex 1 - 384	8	Comments: Analysis, not just access: people need to understand the reactions, and this requires clear and detailed descriptions – at least the free text of the reports – not just the use of standardised technical Medical Dictionary for Regulatory Activities (MedDRA) terms, which were developed for quite a	Not accepted. According to the provisions laid down in article 26, paragraph (3) and article 57, paragraph (1)(d) of Regulation (EC) No 726/2004, the Agency should grant 'appropriate levels' of access to EudraVigilance to the stakeholders mentioned in article 57, paragraph (1)(d) (i.e.

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			different purpose. Regrettably, the EMEA has not shown much interest in analysing the adverse effects and it has not contributed to their investigation. Proposed change: A detailed description and analysis of individual reports should be available to facilitate investigation and the EMEA should play the leading role in facilitating this. The EMEA should take the lead in providing clear and detailed descriptions of the reports.	healthcare professionals, marketing authorisation holders (MAHs) and the general public) while personal data protection should be guaranteed. The data are made accessible based on internationally agreed formats and terminologies (i.e. ICH E2B reporting format for Individual Case Safety Reports and ICH M1, the Medical Dictionary for Regulatory Activities (MedDRA)). The roles and responsibilities for reviewing and assessing suspected adverse reactions are clearly defined in Community legislation and are based on a variety of data not restricted to spontaneous reports. The European Medicines Agency is routinely analysing all available pharmacovigilance data in collaboration with the European Regulatory Network and regulatory actions (e.g. updates of the SPC) are taken based on thorough assessment which are communicated to all stakeholders accordingly.
28	3.1.2.1 – 126	5	Comments: Under "individual causality assessments of adverse reaction reports are not always reliable as…", it should point out the limitations of the spontaneous reports. Proposed change: Suggest adding: "Spontaneous reports often lack key information to exclude potential confounding factors and other aetiologies."	Accepted. These aspects will be taken into account in the development of the guidance on the interpretation of the data to be made accessible in the context of the EudraVigilance Access Policy.
29	3.1.2.1 – 129	5	Comments: EFPIA fully supports the concept of providing an	Accepted. These aspects will be taken into account as part of the

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
			accompanying explanation and list of caveats with drug safety prints for consumers. The wording of such disclaimers is critical to put the information into appropriate context for a lay audience with diverse backgrounds and levels of education. Indeed, failing to do so may induce patients or caregivers to make incorrect treatment decisions, such as discontinuing medication, without consulting their physicians. Proposed change: We strongly encourage the Agency to consider the following actions: Review language used by health authorities that have already opened their databases to the public (in particular MHRA, Health Canada, and the U.S. FDA) and adopt the best elements of each. Release the EMEA explanatory statement for consultation or, at minimum, perform comprehension testing with consumers. If the bullets presented on page 3 are meant to be examples of what consumers will read, they should be re-considered, as the language is too technical for the average person and tells them little about how the information should be used. Along with the explanatory statement, it would be useful to provide consumers with generic contextual examples of drug print use. For instance, a drug analysis print that lists 60 myocardial infarctions with an arthritis drug could review some of the other risk factors that may have contributed to the total, such as the age and general health of the patient population. Factors that can affect reporting rates in a voluntary reporting	implementation of the final EudraVigilance Access Policy and the development of the specific guidance on the interpretation of the data by the EudraVigilance Expert Working Group. See specific comments Nr. 22 and 23.

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			system should be listed, e.g. widespread media coverage of an ADR with one drug might lead to increased reporting for the entire class. Consumers should have the opportunity to read a brief summary of the overall ADR reporting system so that they understand how and why reports are made and how the agency uses spontaneous ADR information. Prominently list the general risks (e.g. hospitalisation, death) of discontinuing or changing one's medication without first consulting a health professional. The importance of this warning can not be overstated.	
30	3.1.2.1 – 138	2	We are missing in the document a clear statement regarding EV-DAS queries output, whether it would be as a printout or downloading files with clear specifications of downloadable fields.	Accepted. This is further clarified in the final EudraVigilance Access Policy. EVDAS query results will be downloadable and printable including all data fields as provided in the query result. Detailed specifications related to the technical implementation of the Access Policy are being further elaborated by the EV-EWG taking into account the overall principles set out in the Access Policy.
31	3.1.2.1 - 138	2	Comments: Having understood that MAH will not have access to narrative fields, it is not clear whether MAH will access other data as PRR. Some contradictory information is released regarding MAH access to data fields.	Accepted. Taking into account the need to comply with Regulation (EC) No 45/2001 on personal data protection, case narratives can currently not be disclosed. Once the revised legal framework based on the two legislature proposals of the European Commission will come into force, the EudraVigilance Access Policy will be reviewed.

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
				In this context, the Agency will consider if access to MAHs can be granted for a wider ICSR data set related to those medicinal products/active substances, for which they hold a marketing authorisation in the EEA. This relates in particular to expected changes of the adverse reaction reporting rules and revised obligations in the conduct of pharmacovigilance as well as the implementation of the new ISO ICSR and IDMP standards once finalised. MAHs will have access to all signal detection and data analysis functionalities in EVDAS.
32	3.1.2.1 – 138	15	Comments: We note your proposals for MAH access to individual cases for products for which they are responsible. Will this replace the obligation on NCAs to provide similar data within 15 days?	Clarification: In line with current Community legislation, the NCAs' obligation to inform the MAH about suspected serious adverse reactions reported to them by healthcare professionals is maintained. This is to allow MAHs to comply with their international pharmacovigilance obligations e.g. to notify other regulatory authorities which do not have access to EudraVigilance (e.g. FDA, PMDA etc) and prepare aggregated reports (e.g. PSURs). These aspects may change in the context of. the legislature proposals aimed at amending the current legal framework adopted by the European Commission in December 2008.
33	3.1.2.1 – 138	18	Comments: Please verify that all MAHs will have access to the entire database, not just reports for their own products. This is	Accepted. MAHs will have access to all spontaneously reported ICSRs with access to subsets of ICSR data fields taking into

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			implied but not explicitly stated. If a MAH discovers an ADR in EudraVigilance that is not in its own safety database (e.g. a report made by a physician directly to a health authority), there should be a process for the MAH to retrieve the entire case, including the narrative, with any personal identifiers redacted. Please describe if such a process exists and how it can be accessed by MAHs.	account the need to comply with personal data protection requirements as set out in Regulation (EC) No 45/2001. Sender-based access to ICSRs for non-interventional trials as currently implemented will be maintained. Sender-based access to ICSRs will be extended to interventional trials. The obligation of NCAs to inform MAHs about suspected serious adverse reactions that have initially been reported to them by healthcare professionals remains in line with the requirements set out in current Community legislation. If a MAH discovers a spontaneous report in EudraVigilance that is not in its own database, functionalities will be provided in EudraVigilance that will allow the MAH to retrieve an electronic copy of the report with the data elements as outlined in Annex 1.
34	3.1.2.1 - 139	15	Comments: Additionally it is important to understand the full range of products and substances licensed to each MAH so that cases for generics and multi constituent products in particular are available to all licence holders.	Accepted. Access to the EudraVigilance Medicinal Product Dictionary for authorised medicinal products will be granted to allow for adequate search and query functionalities by all stakeholders.
35	3.1.2.1 – 141	12	Comments: Marketing Authorisations Holders: "Access will be granted…excluding case narrative…" Proposed change (if any): Allow visibility into case narrative for better use of data.	Not accepted. To provide access to case narratives is not possible due to the need to comply with EU data protection requirements as defined in Regulation (EC) No 45/2001. Once the revised legal framework based on the two legislature proposals of the European Commission will come into force, the EudraVigilance Access Policy will be reviewed. In this context, the Agency will consider if access to MAHs

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				can be granted for a wider ICSR data set related to those medicinal products/active substances, for which they hold a marketing authorisation in the EEA. This relates in particular to expected changes of the adverse reaction reporting rules and revised obligations in the conduct of pharmacovigilance as well as the implementation of the new ISO IDMP standard once finalised.
36	3.1.2.1 – 147	18	Comments: This section implies that it is the responsibility of each MAH's QPPV or designee to conduct signal detection in EudraVigilance. Please confirm if this is the intent and provide specific details on the agency's expectations for methodology, periodicity, notification to the authorities, and other elements of the process. We believe that expecting each MAH to replicate the agency's ongoing signal detection activities is an ineffective and burdensome duplication of resources.	Clarification: The roles and responsibilities related to pharmacovigilance are defined in the current Community legislation and further detailed in Volume 9A. EudraVigilance should be regarded as an additional source of information to support the pharmacovigilance activities of the MAH. The EC legislative proposal for pharmacovigilance and amendment of Regulation 726/2004, Article 24, paragraph (2) foresees that the EudraVigilance database shall also be accessible to marketing authorisation holders to the extent necessary for them to comply with their pharmacovigilance obligations. The tasks and responsibilities of involved parties (Member State, Agency, marketing authorisation holders) will be clarified as part of Good Vigilance Practice guidance.
37	3.1.2.1 – 147	5	Comments: As Access Category III, industry would have access to a very robust selection of data elements for spontaneous cases	Clarification: Access will be provided to MAHs in EVDAS to a well defined data set related to spontaneous ICSRs as outlined in Annex

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
			(much more than our Freedom of Information access to FDA AERS data) making it theoretically more useful with regard to signal detection and evaluation. However the meaning of "The data would be made accessible on-line via EVDAS" is unclear. Will marketing authorization holders be down-loading it to work with their own signal detection tools or do they work in the EVDAS environment with their tools?	1– taking into account the need to guarantee personal data protection in line with Regulation (EC) No 45/2001. This will include the use of signal detection and analysis tools integrated in EVDAS. Results can be downloaded and printed.
38	3.1.2.1 – 147	5	Comments: Relating to the statement "…for the use of data analysis and signal detection tools...", will the same signal detection tools be used by all stakeholders?	Clarification: The signal detection and analysis tools will be identical for NCAs, marketing authorisation holders, sponsors and research organisations. Differences apply only to the data set that will be accessible.
39	3.1.2.2 – 168 3.2.2.1 – 272	8	Comments: A lack of comprehensive data: it is unacceptable that access to safety data generated in interventional and non-interventional trials will not be available to healthcare professionals and the general public. HAI strongly opposes this provision as it further entrenches the idea that it is acceptable to withhold certain data generated in clinical trials. This data is vital for interpreting safety issues that occur once a medicine is on the market. We request that the EMEA reconsider the inclusion of this provision. Proposed change: All safety data generated in interventional and non-interventional trials should also be made available to healthcare professionals and the general public.	Not accepted. According to Directive 2001/20/EC Article 17 paragraph 3(a), suspected unexpected serious adverse reactions related to Investigational Medicinal Products (IMPs) are only accessible to the competent authorities of the Member States and the European Commission. This is also in line with the current policies applied and implemented by NCAs.
40	3.1.2.2 –	4	Comments:	Accepted.

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
	175		Article 57 (2) or Regulation (EC) No 726/2004 foresees that references to data on clinical trials currently being carried out or already completed which are contained in the EudraCT database provided for in Article 11, paragraph (1) and (4) of Directive 2001/20/EC, may be accessible to the public. According to EMEA's draft EudraVigilance Access Policy this is addressed in a Commission guideline published for "public consultation on the data fields contained in the clinical trials database to be included in the EudraPharm database on medicinal products and made public". Proposed change: EMEA should be aware that the Commission has published the official guideline (2008/C 168/02) on July 3rd 2008.	The reference is no longer included in the final EudraVigilance Access Policy.
41	3.1.2.2 – 183	5	Comments: It is not acceptable that MAHs or sponsors of a study to have such limited or no access. There might be cases where co-suspect medications were reported, or where information from studies is presented (Investigator Initiated Studies, Comparator Compound) where the sponsor and the MAH are different organisations. Proposed change: Under the aspect of an intensive exchange of information in the EU PhV System the sponsor or the MAH should have at minimum the right to download any information where one of their compounds are reported as co-suspect medication in order to complete their internal PhV data.	Not accepted. According to Directive 2001/20/EC Article 17 paragraph 3(a), suspected unexpected serious adverse reactions related to Investigational Medicinal Products (IMPs) are only accessible to the competent authorities of the Member States and the European Commission. Sender-based access to ICSRs for non-interventional trials as currently implemented will be maintained. Sender-based access to ICSRs will be extended to interventional trials. Sponsors will obtain access to a well defined data set (annex 1) for spontaneous reports. Sponsors should share ICSRs for all other report types with those companies, where co-suspect medication is involved ('courtesy cases').
42	3.1.2.2 - 198	5	Comments: Non-interventional study cases are transmitted to	Not accepted. See specific comment Nr. 41 for justification.

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
			EudraVigilance (EVPM) by the National Competent Authority. MAHs and Sponsors should be allowed, in order to be able to "undertake in the monitoring of the patients' safety during the conduct of the trials", to access ICSRs occurred in any trials for which they are the Sponsors or for which at least one of the IMP(s) is a product they are the holder of a MA. Proposed change: The mentioned sentence should be changed to: "*Therefore it is proposed that for Marketing Authorisation Holders and Sponsors access to EudraVigilance data will be provided which is restricted to those individual cases related to interventional and non-interventional trials ~~that they have transmitted electronically to EydraVigilanc.~~ for which they are the Sponsor or for which at least one of the IMP(s) is a product they are the holder of a MA"*	
43	3.1.2.2 – 198	2	Comments: According to the first paragraph "MAH and sponsors will have access to the full information on the ICSR for those individual cases related to interventional and non-interventional trials that they have been transmitted electronically to EudraVigilance". Comment: How is the ownership of the case assigned? Will the MAH/Sponsor have access to an ICSR sent by the MAH/Sponsor to NCA, and then NCA re-submitting the case to EudraVigilance? Proposed change: In our opinion, a MAH/Sponsor should only have full access to ICSRs where they have been the "sender (A.3.1)" and not to	Clarification. MAHs/Sponsors will only have full access to ICSRs, where they have been the direct sender (ICH E2B (R3) A.3.1) of the reports to EudraVigilance. They will not have access to the ICSRs of interventional and non-interventional studies, where they have been retransmitted by other organisations to EudraVigilance. They will have access to a restricted data set for spontaneous reports taking into account the need to comply with Regulation (EC) No 45/2001.

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
			the NCA's re-submitted case.	
44	3.1.2.2 – 198	22	Comments: ICSRs occurring in non-interventional trials in the EEA are reported to the NCA of the Member State where the reaction occurs in accordance with Article 104 of Directive 2001/83/EC. The same directive requires the NCA to transmit the ICSR to EudraVigilance. The MAH/sponsor will therefore not be the owner of this information in EudraVigilance. As described in the draft policy, the MAH will therefore be denied access to EEA ICSRs relating to non-interventional studies submitted to the NCAs. Proposed change: Wyeth proposes that the MAH be given access to information on all non-interventional studies for all authorized medicinal products submitted to the EVMPD by the MAH.	Not accepted. According to Directive 2001/20/EC Article 17 paragraph 3(a), suspected unexpected serious adverse reactions related to Investigational Medicinal Products (IMPs) are only accessible to the competent authorities of the Member States and the European Commission. Sender-based access to ICSRs for non-interventional studies as currently implemented, will be maintained. Sender-based access to ICSRs will be extended to interventional trials. Sponsors will obtain access to a well defined data set (annex 1) for spontaneous reports.
45	3.1.2.2 – 206	5	Comments: Will the same dataset be used by national competent authorities and marketing authorisation holders? Signal detection should be applied on the same version of dataset even though the two datasets have different number of variables.	Accepted. MAHs will have access to all spontaneously reported ICSRs (like NCAs) with access to a well defined subset of ICSR data fields (annex 1) taking into account the need to comply with personal data protection requirements as set out in Regulation (EC) No 45/2001.
46	3.1.3 – 210	20	Comments: Our priority is to protect personal data of patients as well as reporters. We make the report anonymous from the patient's side and blinded from the side of reporter in case we have to resend the report to MAH. Rules regarding anonymisation of data are laid down in the	Accepted. In response to the final Opinion of the EDPS dated 7 September 2009 on "a Notification for Prior Checking regarding the data processing operations of EudraVigilance" further guidance on personal data protection in the context of pharmacovigilance will be developed.

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
			revised version of Vol 9A. Further discussion and possible changes in this field should take place as soon as possible and – in our opinion – before approval and implementation of EV Access Policy. Results of this discussion should be formulated very clearly, published and put in EV access approach.	
47	3.1.3 – 210	15	Comments: We agree that all data provision needs to be in anonymised form and would recommend that the access policy is explicit in providing for the anonymity of reporters as well as the patients.	Accepted. The need for the protection of the identity of data subjects in line with Regulation (EC) No 45/2001 has been respected in the Access Policy.
48	3.1.3 – 210	13	Comments: The MEB appreciates that the EMEA seeks to establish common rules in the area of pharmacovigilance and safety monitoring in clinical trials regarding personal data protection, more specifically via the collaboration with International Pharmaceutical Privacy Consortium and the Article 29 Working Party. Any harmonisation resulting from this should be taken into account when implementing the Access Policy.	Accepted. See specific comment Nr. 46.
49	3.1.3 – 210	8	Comments: The role of regulation: elaborate regulation of access to largely unhelpful or useless data misses the point and in no way satisfies the aims of openness, transparency and accountability. The concern surrounding personal data protection is understandable from a legal perspective but does not inherently interfere with the provision of ADR data. It is possible to achieve a balance between data protection	Not accepted. No restrictions can be applied on the usage of data e.g. due to fears for potential lawsuits by patients. However, as part of the overall user guidance to be developed by the EudraVigilance Expert Working Group, the limitations of aggregated, spontaneous adverse reaction data in the context of an overall benefit/risk assessment will be addressed.

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
			and providing useful and transparent data on adverse drug reactions. Most people who suffer and ADR want others to benefit by helping to prevent similar events. Proposed change: Lawsuits against clinicians, pharmaceutical companies, or the state could be precluded with a disclaimer that "EudraVigilance data cannot be used as the basis of litigation."	A best practice guide on usage of data can be prepared based on the understanding that this would not be legally binding. As regards personal data protection, please refer to specific comment Nr. 46.
50	3.1.3 – 210	15	Comments: We understand that the issues surrounding the release of more than just aggregated ADR data and data ownership with regard to ICSRs held within EudraVigilance are being addressed by discussions with the European Commission and/or European Data Protection supervisor. These discussions and the commitment to confidentiality of the ICSR data is critically important and we have to be sure that safeguards on access to the data do not conflict or compromise those put in place in the Member States.	Accepted. See specific comment Nr. 46.
51	3.1.3 – 211	5	Comments: The definition of data which fall under data privacy legislation does not include the reporter's information. The reporter section could include patient information in case of consumer reports or where the reporting health care professional is also the patient. Proposed change: The presentation of data from EudraVigilance by the EVDAS system should not display any data which may be used to identify the patient or the reporter of the information.	Accepted. See specific comment Nr. 46.

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
52	3.1.3 – 213	10	Comments: We also have some concerns regarding the protection of personal data. Although it is recognised by the EudraVigilance Expert Working Group that this issue must be addressed in the implementation of the access policy, and that "discussions on the detailed practicalities of data anonymisation with regard to the reporting of suspected adverse reaction should be initiated with the European Commission and/or the European Data Protection Supervisor as soon as possible", it is not clear how or when this personal data protection will be achieved. It is also important to bear in mind that, in line with we have already had the opportunity to express in the NUI circulated by the EMEA regarding this subject, although a given field concerning the patient (for example the age) does not by itself identify him/her, that information taken together with other patient information (sex, weight, height, medical or past drug history) may in fact identify the patient. Proposed change: As such, and because there still is no clear EU guidance regarding personal data protection, we feel that before a EudraVigilance access policy is implemented it must be clearly defined how this issues will be addressed when disclosing the information contained in EudraVigilance to the stakeholders.	Accepted. See specific comment Nr. 4.
53	3.1.3 – 213	4	Comments: The Danish Medicines Agency finds that the draft is in line with legislation and the objective to provide the stakeholders with information on adverse reactions. However, it is very	Accepted. See specific comment Nr. 46.

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
			important to develop good search facilities in order to achieve the objective while at the same time to be to secure protection of personal data. The Danish Medicines Agency has notices that it follows from the draft EudraVigilance Policy that the discussions on the detailed practicalities of data anonymisation with regard to the reporting of adverse reactions should be initiated with the European Commission and/or the European Data Protection Supervisor as soon as possible.	
54	3.1.3 – 218	5	Comments: 'Cause of death' is listed as data that would be removed. This however may be important in signal evaluation. If initials, names, addresses, case narratives, dates of birth, etc are not visible, is seeing the cause of death really a risk?	Accepted. See specific comment Nr. 46 and annex 1 of the Access Policy, which explains the approach applied to safeguard the identity of individuals in relation to ICSRs.
55	3.2.1.1 – 241	5	Comments: Where regional PV centres will be allowed full access at the discretion of a competent authority, it is essential they are fully aware of EU Requirements and process. These centres should work with the local agency, with any clarifications or follow-up being sought via the local agency to the applicable Rapporteur or RMS rather than directly to the MAH(s).	Accepted. NCAs decide on access of regional pharmacovigilance centres to EudraVigilance as was reflected in the draft EudraVigilance Access Policy.
56	3.2.2 – 261	16	Comments: When it comes to Health Care Professionals (3.2.2) we would like to stress the important part they play in the operation of a successful pharmacovigilance system. It should be considered if not Health Care Professionals should have access to more specific data and possibilities to search for data in a more fine-tuned way than described in the draft	Not accepted. Taking into account the need to comply with Regulation (EC) No 45/2001, a subset of data for spontaneously reported ICSRs will be made accessible in the same way for healthcare professionals, patients and consumers as well as marketing authorisation holders. Query functionalities will be provided with various output

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			policy.	options e.g. aggregated data or as report forms.
57	3.2.2.1 – 266	22	Comments: The information appears too complex. There is a risk of the patient arriving at wrong conclusions on the safety of their medicine based on the information in drug analysis prints, and leading to failure to take medication. Additionally, will the drug analysis print and the general guidance be available in EEA languages? Proposed change: Wyeth proposes that a Patient Information Leaflet is more informative to the patient on the benefits and risks of taking their medicines.	Not accepted. Guidance will be provided to healthcare professionals and the public explaining the information made publicly available (explaining e.g. concepts of spontaneous reporting, principles of benefit/risk evaluation and decision making). Access to Patient Information Leaflets is provided for centrally authorised medicinal products at the European Medicines Agency website and reference will be included in the general guidance for patients and healthcare professionals to always consult their healthcare professionals before changing or stopping their medication. The publication of data in all EEA languages is currently not feasible. This can only be addressed once the international standardisation work on the identification of medicinal products (ICH M5/ISO IDMP)/Individual Case Safety Report (ICSR) will be completed and fully implemented.
58	3.2.2.1 – 269	2	Comments: With regard to "data quality review" (to be performed by EMEA): what is the target time for this review? How often will Data Analysis Print for Health Professionals and consumers be updated?	Clarification. The data quality management in EudraVigilance will be performed on continuous basis. Data will be made available in real time after completion of the data quality review of all newly received ICSRs.
59	3.2.3 – 276	12	Comments: As written, the MAH/Sponsor access is very limited (2 roles) and very specific. The QPPV should have a very flexible and	Accepted. Access rights will be provided to a maximum of 5 pharmacovigilance/data analysis experts per MAH/Sponsor

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			simple way of delegating access rights to multiple MAH/sponsor staff, with regular checking that the delegates are still correct. The details of this may not belong in a policy, but a statement to the effect that flexible and simplified delegation of access will be available to the QPPV and EV deputy definitely does belong in the policy.	at headquarter level; the experts may reside within or outside the EU; the EU-QQPV/Responsible Person for EV of the MAH/Sponsor will nominate the experts in line with the EudraVigilance Registration Process and will be responsible for updating the user registration for their organisation accordingly.
60	3.2.3 – 276	5	Comments: EFPIA appreciates that, with respect to MAH access to EudraVigilance, it is possible for the EU QPPV to delegate access responsibility. It is important for the Policy to clarify that it is acceptable to delegate accessing EDVAS to "individual users" who are not located in EEA. For many companies whose corporate headquarters reside outside the EEA, the company expertise for signal detection may be located there and not in Europe. Therefore, in order to avoid unnecessary redeployment of resources and restructuring of departments, again for no obvious public health benefit, it is important that delegation to personnel outside Europe is permitted. For many large companies, it would be very beneficial to have more than two people with access to EudraVigilance since the group that performs case entry may be different than the group that performs signal detection.	Accepted. See specific comment Nr. 59.
61	3.2.3 – 276	2	Comments: We express our concern to give MAH unrestricted access to such data: We are concerned by the fact that MAH can access information about any medicinal product (except free text fields) according to page 6/17 section 3.2.3. In this case, a	Not Accepted. See specific comment Nr. 49 for justification.

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			clear policy on data usage should be in place. Proposed change: We would recommend including specific restrictions on MAH's data usage for inappropriate aims, such as obtaining safety profiles for competitors' drugs with marketing purposes. It would be outrageous to compare safety profiles of similar medicines to obtain safety conclusions. We would propose to prepare in parallel a draft document on Data Usage Policy to ensure a proper use of information by MAH, with clear limitations to data use and data spreading (internally or externally).	
62	3.2.3.1 – 277	7	Comments: Access category IIIA (access to EVPM for MAHs and sponsors of CT in the EEA) Proposed change: In order to avoid promotional use of the data we wonder if it could be possible to limit the access to the active substances and not to provide the trade names of the medicinal products includes in EVPM. Furthermore, it should be useful to ask all MAHs and sponsors to undertake to not use the information from EVPM for promotional or commercial purposes.	Not Accepted. See specific comment Nr. 49 for justification.
63	3.2.3.1 – 277	5	Comments: Adverse reactions arising from non-interventional trials_are processed and assessed according to the same criteria as adverse reactions reported spontaneously by Healthcare Professionals. As such, they are transmitted to EudraVigilance EVPM. As stated under Section 3.1.2.2 (last sentence):	Partially Accepted. MAHs will have access to all spontaneous ICSRs with access to subset of ICSR data fields taking into account the need to comply with personal data protection requirements as set out in Regulation (EC) No 45/2001. Sender-based access to ICSRs for non-interventional trials as currently implemented will be maintained. Sender-based

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			"Therefore it is proposed that for Marketing Authorisation Holders and Sponsors access to EudraVigilance data will be provided which is restricted to those individual cases related to interventional and non-interventional trials that they have transmitted electronically to EudraVigilance. Access will be granted to the full information available in the ICSRs." Apart from non-interventional trials, MAHs should have restricted access to full information also for all the other individual cases regarding their medicinal products, also in case they are transmitted to EudraVigilance through the concerned National Competent Authority (e.g. Italian Agency.) Proposed change: In order to be consistent with Section 3.1.2.2 and to allow MAHs to have restricted access to full information regarding all their reports, Section 3.2.3.1 Access Category III A: EVPM should be modified as follows: "Authorised personnel of the MAH have access to a subset of the ICSR data fields in EVDAS, which have been reported electronically to EudraVigilance Human – EVPM in accordance with the Community legislation. This includes information on spontaneous reports and all AMPs stored in the EVMPD. The subset of data elements is described in Annex 2. In addition, Marketing Authorisation Holders and Sponsors have restricted access to full information for individual cases related to non-interventional trials and spontaneous reports that they have transmitted electronically to EudraVigilance,	access to ICSRs will be extended to interventional trials. According to Directive 2001/20/EC Article 17 paragraph 3(a), suspected unexpected serious adverse reactions related to Investigational Medicinal Products (IMPs) are only accessible to the competent authorities of the Member States and the European Commission. This is also in line with the current policies applied and implemented by NCAs.

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
			directly or through their concerned National Competent Authority. "	
64	3.2.3.1 - 281	2	Comments: In section 3.2.3.1 it is stated that the MAHs can access all spontaneous ICSRs. In 3.1.2.2 it is stated that MAH/Sponsors will have access to EudraVigilance data restricted to those individual cases related to interventional and non-interventional trials that they have transmitted electronically to EudraVigilance. In 3.2.3.1 Access Category IIIA: EVPM, It is stated that authorised personnel of MAH will have access to spontaneous reports. According to Access Category IIIA:EV-PM. Will MAHs have access to non-interventional trials reports available in EVPM? Proposed change: If yes, then 3.2.3.1 should be amended to include access to non-interventional trials reports that they have submitted electronically to EV-PM.	Accepted. See specific comment Nr. 63.
65	3.2.3.1 – 281	3	Comments: Pharmacovigilance responsibilities of MAHs refer to products for which they actually hold marketing authorisations. Information about competitors is not absolutely necessary for the evaluation of the risk-benefit ratio for specific products and might easily be used for promotional purposes. Proposed change: Access for MAHs should in consequence be limited to ICSRs involving products, which contain active substances (or combinations) for which they hold marketing authorisation. Necessity of confidentiality agreements for MAHs should be	Partially accepted. MAHs will be provided with access to medicinal product information (ICH E2B(R2) B.4.k.2.2 active substance) as reported and as recoded. For centrally authorised medicinal products, information reported in ICH E2B(R2) B.4.k.2.1 (medicinal product name) will be also provided. Please refer to Annex 1 for further details. The same information will be made available to healthcare professionals and the general public. No reference can be included as regards the potential usage of the published data (e.g. restrictions of access due to

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			made absolutely clear.	fears for potential lawsuits by patients). However, as part of the overall user guidance, the limitations of aggregated, spontaneous adverse reaction data in the context of an overall benefit/risk assessment will be addressed. A best practice guide on usage of data can be prepared based on the understanding that this would not be legally binding.
66	3.2.3.1 – 286 3.2.3.2 – 308	14	Comments: Both sections 3.2.3.1 and 3.2.3.2 (Access for MAHs to EVPM and EVCTM, respectively) state that the authorised personnel with access to ICSRs in EVDAS will be only the Qualified Person Responsible for Pharmacovigilance (QPPV) and the appointed EudraVigilance Deputy. In my opinion, this is not sufficient particularly for companies with a large portfolio whose QPPV may delegate data mining / signal detection activities to other functions. Proposed change: Therefore, I think it should be possible for the QPPV to grant EVDAS ICSR access to additional users, just by defining in EudraVigilance the access rights of each user.	Accepted. See specific comment Nr. 59.
67	3.2.3.1 – 286 3.2.3.2 – 308	22	Comments: The Trusted Deputy is the person to whom the Qualified Person has delegated the functions related to registration of new users with EudraVigilance. However, this person may not be involved in pharmacovigilance activities that utilize the	Accepted. See specific comment Nr. 59.

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			data made accessible in the EVDAS. Proposed change: Either, in addition to the Trusted Deputy for registration of users, additional 'Trusted Deputies' be created to whom the QPPV delegates access to the EVDAS, and who have either scientific or medical expertise, to be designated as: - Trusted Deputy for EudraVigilance Data Analysis, or - Trusted Deputy for EudraVigilance signal detection Or, all personnel of the company, upon registration in EudraVigilance at headquarter level, be designated as authorized personnel for access to EVDAS.	
68	3.2.3.1 – 286 3.2.3.2 – 308	5	Comments: MAH access to EVPM could be read as being restricted to only the QPPV and deputy at the European Company headquarters. This is highly impractical for many MAH since it is not always these individuals in a company who actually carry out signal detection, nor are they always based in the EU (particularly for non EU companies). It is essential that in addition to the registered EU-based QPPV and deputy, other pre registered (named) individuals in a company should be allowed access (and for example the persons locally responsible for pharmacovigilance) and without the requirement that these individuals are based in the EU. In addition, is the EMEA considering any simplification of the registration process?	Accepted. See specific comment Nr. 59. The registration process is conducted in line with the European Medicines Agency security policies to avoid unauthorised access to EudraVigilance.
69	3.2.3.1 – 286	6	Comments: Other authorised personnel might have access to EV, such as	Accepted. See specific comment Nr. 59.

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
	3.2.3.2 – 311		the local Qualified Person Responsible for Pharmacovigilance (QPPV), when required. The access to EV is defined by each MAH, so we should consider the possibility of recognising other authorised personnel other than the QPPV or his/her Deputy. We suggest amending accordingly. Proposed change: In this context, authorised personnel is interpreted as The Qualified Person for Pharmacovigilance as defined in Regulation (EC) N° 726/2004, Article 23 and in Directive 2001/83/EC, Article 103 and The appointed "EudraVigilance Deput*ies*" at the EU company headquarters' level as defined in the frame of the EudraVigilance registration process and Other pharmacovigilance personnel, according to the stakeholder policy as defined in the framework of the EudraVigilance registration process (e.g. local QPPV).	
70	3.2.3.2 – 299	3	Comments: Granting of access to sponsors is highly appreciated as it will strengthen the possibility for early signal detection in clinical trials.	Acknowledged.
71	4 – 325	5	Comments: Could you please clarify the timing of the roll out in the second phase, will access to the MAH be provided at the same time as access to the Healthcare Professional and the Public?	Accepted. The Access Policy will be implemented in a stepwise approach as outlined in the EudraVigilance Access Policy, chapter 6.
72	4 – 334	20	Comments: From our point of view it is very important to ensure high quality of data to obtain reasonable data output from the	Accepted. A cross reference to the EudraVigilance Business Rules in the latest version has been included in the final

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			database. In order to make the requirements for data quality clear it may be useful to add reference to new version of Business Rules – EudraVigilance Human Version 7.1 Processing of Safety Messages and Individual Case Safety Reports (ICSRs) here. This could improve communication between the EMEA and EV users and help increase the data quality of reports.	EudraVigilance Access Policy.
73	4 – 338	22	Comments: According to EV 7 Guidelines, error reports are maintained until the sender provides the corrected reports. Wyeth feels that the exclusion of error reports is justified in order to ensure high quality and correct output of the data, however, ICSRs classified as 'error reports' in EudraVigilance may be in the company's database as valid ICSRs. This will result in discrepancies between data used for signaling in EudraVigilance and that used in the company database. Proposed change: Wyeth proposes that in section 4 – 'procedural issues that need to be implemented', management of 'Error reports' be added to ensure all error reports are notified to senders for correction.	Partially accepted. Safety messages are acknowledged by the European Medicines Agency with an acknowledgement message, which contains for each ISCR a validation outcome i.e. if the ICSR is valid or if the ICSR is erroneous and needs to be retransmitted. An explanation on the classification of reports in EudraVigilance has been added in chapter 5.3.3
74	4 – 338	5	Comments: Much emphasis on 2 areas - duplicate detection and medicinal product information - in order to ensure high quality and correct output of the data. Both of these areas are quite challenging for industry as well and it takes a long time to improve processes and data quality. Is there a timeframe associated with sorting out the	Clarification: This will be addressed by the European Medicines Agency as part of the EudraVigilance Data Quality Management tender,.A contract for a third party to support the data quality management in EudraVigilance was signed in August 2010.

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
			procedural and technical issues stated in this section?	
75	4 – 342 4 – 354	5	Comments: Please clarify in the policy who will be responsible for the duplicate detection & management of ICSRs.	Accepted. See specific comment Nr. 74.
76	4 – 347	5	Comments: Please clarify whether this is implying that full population of EVMPD from MAH is required or that EMEA has task to update EVMPD. Will this now expedite the mandatory population of the EVMPD? Is there any specific impact on biotech products?	Clarification: Based on current guidance (Volume 9A, part III) and according to the European Commission's legislature proposal (Article 57, paragraph 2(b)) the submission of medicinal product information to the European Medicines Agency is through the MAH.
77	4 – 351	5	Comments: Please provide clarification on the availability of automatic and manual recoding: Is this for the MAH or related to EMEA? It doesn't seem feasible for the MAH to do this.	Accepted. See specific comment Nr. 74.
78	Annex 1 – 355	5	Comments: As the proposal for new legislation with regards to pharmacovigilance provides for the reporting of non-serious cases into the EudraVigilance database the presentation of data should distinguish this information with an appropriate explanation.	Accepted. There will be functionalities that allow flagging cases as serious and non-serious.
79	Annex 1 – 363	5	Comments: These are only examples and do not show what actually will be provided to the MAH or the public.	Acknowledged.
80	Annex 1 – 365	5	Comments: According to Annex I, the published information includes PRODUCT. We assume this means the brand name. We do not believe that specifying the brand name with each listing	Partially accepted. The medicinal product name will not be disclosed with the exception of centrally authorised medicinal products. Please refer to annex 1 for further information.

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			has added value and it may add to the confusion if there are differences between the EVMP output differs from section 4.8 for the Product. See also previous comment. Proposed change: The EVPM output table should specify active substance but not the brand name.	
81	Annex 1 – 365	5	Comments: Will the information with regards to active substances from biosimilars be different from the originals?	Clarification. Differentiation of biosimilars and the originals will initially only be possible at the level of the invented name. The differentiation at substance level can only be addressed once the international standardisation work on the identification of medicinal products (ICH M5/ISO IDMP)/ISO ICSR will be completed and fully implemented.
82	Annex 1 – 369	5	Comments: "Only the valid reports with the most recent information are counted…" The meaning of „valid" needs further clarification. Does this mean „HCP confirmed" reports? Proposed change (if any): Nevertheless the presentation of data should distinguish between reports that are HCP confirmed and those that are consumer reports which are not HCP confirmed.	Accepted. Category II (HCPs/Public) aggregated data will initially only include medically confirmed cases in line with the expedited, electronic adverse reaction reporting requirements set out in Community legislation and Volume 9A. Once the new EC legislature proposal will come into force, the data could be published taking into account the following two categories: medically confirmed by healthcare professionals all others (non-medically confirmed) A chapter has also been included on report classifications.
83	Annex 1 – 373	5	Comments: The likelihood of misinterpreting the data is potentially high if only the absolute numbers of AEs are given for a drug in one	Accepted. As part of the guidance to be developed the strengths and weaknesses of aggregated adverse reaction data will be

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			time period. Proposed change: Can other relevant material be provided as reference?	explained to permit for adequate interpretation of the data (explain e.g. concepts of spontaneous reporting, principles of benefit/risk evaluation and decision making). This will include interpretation of absolute numbers of adverse reactions.
84	Annex 1 – 379	13	Comments: Data elements EVPM access category II, the MEB has a question for clarification, namely the examples provided show the number of reactions. Proposed change: Would it be possible to display also the number of cases?	Accepted. It is also possible to show the number of cases, which is reflected in Annex I.1.
85	Annex 1 – 379 Annex 1 – 384	5	Comments: A number of examples of possible data output are listed but it is not clear whether: 1) the person accessing the database can choose which output he/she would like to see 2) how for example age and gender will be accounted for in the examples a and b Proposed change: This should be more clearly specified to avoid surprises.	Accepted. Refer to Annex 1 and 2 of the draft policy were examples of data outputs that can be provided. Category II (HCPs/Public) aggregated data output will be further elaborated in consultation with the Patients' and Consumers' Working Party and Health Care Professional Working Group.
86	Annex 1 – 392	5	Comments: We suggest changing the title of the third column from "Total" to "Total ADR number".	Accepted.
87	Annex 1 – 439	2	Comments: The age groups must match ICH E11 Note for Guidance on the Clinical Investigation of the Medicinal Products in the Paediatric Population (CPMP/ICH/2711/99). Proposed change:	Accepted. The ICH E11 guideline will be used as the reference.

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			According to it, the age groups are: Term newborn infants (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) Elderly (more than 65 years)	
88	Annex 2 – 457 Annex 2 – 498	22	Comments: Annex 2, which lists accessible data elements, does not include study fields. If MAH/Sponsor has access to data from interventional and non-interventional studies that they have submitted to EudraVigilance, accessible data elements need to include those that relate to reports from studies. Proposed change: Wyeth proposes the following data elements be added in Annex 2 and referenced in Section 3.2.3.2: 1.1 A.1 Identification of the case safety report A.1.4 Type of report - Spontaneous report - Reports from Study A.2.3 Study identification A.2.3.0 Study registration number A.2.3.1 Study name A.2.3.2 Sponsor study number A.2.3.3 Study type in which the reaction(s)/event(s) were observed – Clinical trials – Individual patient use (e.g.,”compassionate use” or named	Clarification. For spontaneous reports the data elements that are disclosed are summarised in Annex 1. For interventional and non-interventional clinical trials, sender based access will be provided, which will allow full access to all the ICSRs data fields.

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			patient basis) – Other studies (e.g., pharmacoepidemiology, pharmacoeconomics, intensive monitoring)	
89	Annex 2 – 492	3	Comments: Information contained in data field "A.2.1.4 Qualification" is not necessary for the conduct of risk-benefit analysis or identification of duplicate reports. The information "lawyer" might allow to draw conclusions about ongoing lawsuits concerning competitor products. Proposed change: Information should consequently be limited in order to allow differentiation between "medically confirmed" or "not medically confirmed" ICSRs only.	Not accepted. The data field 'A.2.1.4 Qualification' will be maintained as this element is required for case management and pharmacovigilance purposes. Spontaneous reports will currently only include medically confirmed cases in line with the expedited, electronic adverse reaction reporting requirements set out in Community legislation and Volume 9A. Once the EC legislature proposal on pharmacovigilance will come into force, the data will be published taking into account the following two categories: medically confirmed by healthcare professionals all others (non-medically confirmed)
90	Annex 2 – 508	3	Comments: Distribution of information contained in data field "A.3.1.2 Sender Identifier" might allow to draw conclusion about CROs commissioned by competitors and is not necessary for the conduct of risk-benefit analysis or identification of duplicate reports. Proposed change: Information displayed should be limited to data field "3.1.1 Type".	Accepted. The data field A.3.1.2 Sender Identifier will not be disclosed (please see Annex 1).
91	Annex 2 – 577	6	Comments: The MAH's causality assessment should at least be provided,	Not accepted. The ICH E2B(R2) data field B.5.4 'Sender's comments'

No.	Paragraph - Line No. of draft policy	Stake-holder No.	Comment and rationale; proposed changes	Outcome of review of comments and proposed amendments to the draft EudraVigilance Access Policy
			as this data is not confidential and attributes a different importance to the case, especially for unexpected events. We suggest adding a new field B.4.k.18 to B.4 Drug (s) information Proposed change (if any): B.4.k.18. Relatedness of drug to reaction/event from the perspective of the Marketing Authorisation Holder	includes a free text field for sender's causality assessment which could make reference to personal data. Therefore and in compliance with Regulation (EC) No 45/2001 this information can not be disclosed.
92	Annex 2 – 583	10	Comments: However, we (INFRAMED) would like to express our concerns regarding the access by MAH foreseen in the EV Access Policy currently under public consultation. In fact, in what concerns the Post Marketing module of EudraVigilance, MAHs will have access to a subset of the ICSR data fields in EVDAS that include field B.4.k.2.1 (Proprietary medicinal product name, as reported by the sender and as recoded by the EMEA). Although we acknowledge the importance of being as most transparent with the stakeholders as possible in line with the EU Transparency Initiative, we are concerned that that information might be used for marketing purposes given the fact that, based on the adverse drug reaction data contained in EudraVigilance, MAHs may tend to use that information to persuade prescribers to use their medicinal product instead of the competitor medicines, when more ADR cases have been reported to EudraVigilance for the competitors. As it is known, the fact that more ADR cases have been reported with a given medicinal product does not necessarily mean that that medicine is less safe than others (for example, it may only be due to the fact that the MAH of that medicine	Not accepted. See specific comment Nr 65 for justification.

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			has a more effective pharmacovigilance system in place), and as such that information by itself should not be used as an argument to support the better safety of a given medicine when compared to its competitors. Proposed change: As such, we feel that the proprietary medicinal product name of the suspect/interacting medicines in each ICSR should not be accessible by MAHs due to the risk of misuse of that information for marketing purposes.	
93	Annex 2 – 625	2	Comments: We wonder what could be the reason to get access to those additional not E2B fields as for example "Internal EMEA field Message Official Receive Date".	Clarification: This is to show the status of the information i.e. when this information was made available to the European Medicines Agency in EudraVigilance.
94	Annex 2 – 625	6	Comments: Duplicate cases are not deleted from EV so, when evaluating a case, it should be immediate information if it is a duplicate. We suggest adding an additional option under 'Case Classification'. Proposed change: Case Classification (e.g. Initial, Follow-up, Report Nullification, Duplicate Report)	Accepted. The implementation of the EudraVigilance Access Policy will be based on 'cleaned' data excluding, where possible duplicate reports. A chapter on case classification has been added including the concept of Master case, where duplicates have been confirmed and managed.