03 December 2018
EMA/768660/2018

Overview of comments received on European Medicines Agency policy on access to documents

Policy 0043 (EMA/729522/2016)

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

Stakeholder no.	Name of organisation or individual
1	Bundesverband der Arzneimittel-Hersteller e.V.
2	CPME - Standing Committee of European Doctors
3	European Federation of Pharmaceutical Industries and Associations (EFPIA)
4	Duke Clinical Research Institute
5	German Environment Agency (UBA)
6	Groupe-LFB, France
7	Health Action International (HAI)
8	Health Care Without Harm (HCWH) Europe
9	Hellenic Cancer Federation – ELL.O.K
10	IFAH-Europe and HealthforAnimals
11	Institut für Qualität und Wirtschaftlichkeit/ Institute for Quality and Efficiency in Health Care (IQWiG)
12	The International Society of Drug Bulletins (ISDB)
13	Dr. Juergen O. Kirchner
14	NoGracias
15	The Nordic Cochrane Centre
16	Medicines for Europe

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Stakeholder no.	Name of organisation or individual
17	Medicines Evaluation Board, NL
18	Oekotoxzentrum, Switzerland
19	Prescrire
20	SEC Associates, Inc
21	Mr. Paul Ulrich

1. General comments – overview

Stakeholder no.	General comment (if any)	Outcome (if applicable)
21	The updated access to documents web page http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/document_listing/document_listing_000312.jsp&mid=WC0b01ac0580999a9c says Revised policy on access to documents (new) EMA is revising its policy on access to documents. The revised policy extends the policy's scope to corporate documents and includes information on access rules to these documents. It also updates information on the table on access rules to documents on human and veterinary medicines. EMA published the revised draft policy on 15 February 2017 for a 3-month public consultation. Please submit comments using the form provided to atdpolicy@ema.europa.eu until 16 May 2017: But the news announcement http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/02/news_detail_002697.jsp&mid=WC0b01ac058004d5c1 was issued today, 17 Feb 2017, and gives until 18 May 2017 for the consultation.	N/A
3	EFPIA welcomes the opportunity to comment on the revised access to documents policy and the associated output documents. As a general observation, it is noted that the scope and principles of policy 0043 and the rules (arrangements) for implementation of Regulation (EC) No 1049/2001 on access to EMA documents remain largely unchanged. Specific comments are provided below on the new text highlighted by the EMA but also on other sections that merit	This statement is noted and the individual comments are addressed below. EMA is the Data Controller under Policy 0043.

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	reconsideration since the guideline was first published in 2014. In relation to industry experience with policy 0043, the key concerns for EFPIA continue to be: • Level of protection afforded to private interests – both CCI (commercially confidential information) and PPD (personal protected data). • Large volume of requests with insufficient advanced notification or processing time with the associated risk of not fully redacting PPD. • PPD in third-party documents not being properly redacted by the EMA before being disclosed to the requestor. • Not routinely consulting third-parties before disclosing documents created by them (Article 4, Regulation EC 1049/2001) • Clarity around the meaning of CCI and who decides whether something is CCI. • Clarity of who the Data Controller under Policy 0043 is. • Short timelines for sponsor/MAH consultation (currently 5 days) which in most cases is extremely disruptive for operations. The relevant section of Policy 043 states “no shorter than five working days.” A pragmatic and realistic approach to timelines is needed. Our other concerns with the EMA draft revised guideline include: • Reclassification of certain documents (Orphan designations and Paediatric Investigation Plans; see below) • An apparent shift in the decision-making regarding exceptions to disclosure, by repeatedly emphasising the role of the EMA ([EMA]	

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	determines that in the 'Arrangements Section'.) Currently, the absence of these words suggest that the decision-making process is more collegial. We are concerned that this amendment reflects an intent on the part of the EMA to consult less with third-parties before disclosing documents created by those third-parties. If that is the intent, EFPIA is opposed to this. We recommend that a decision as to whether disclosure would b likely to undermine the protection of commercial interests is taken with the originator of the document. If the originator already consulted during a previous request, the originator should in any event be informed of the new request. Specifically on Orphan Designation and Paediatric Investigation Plan: • As one of our major observations, EFPIA is surprised with the EMA proposed classification changes to Orphan designation and Paediatric Investigation Plan in the "Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use". The proposed changes were not mentioned in the press release on the revised Policy 0043 published on the EMA website on the 17 of February 2017 (http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/02/news_detail_002697.jsp&mid=WC0b01ac058004d5c1). It is not so much a question of what as of when. At the time of decision the two documents are still of strategic value for the development activities to be conducted. We argue that the currently available information on the EMA website i.e., Public summary of opinion on Orphan Designation and European Medicines Agency	

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	Decision on PIP is sufficient to meet the needs of the public. In addition, if our understanding of the Output table is correct, the disclosure changes regarding orphan designations and paediatric data early in development is in direct conflict with other sections in the draft revised Policy 0043 guideline. The guideline states that “In practice this means for documents related to medicinal products that these will be considered as non-releasable prior to the availability of the Commission Decision granting, refusing or varying the marketing authorisation for the particular medicinal product, or prior to the receipt of the withdrawal letter submitted by the pharmaceutical company.” (Lines 123-126). It is further stated that “In case of an assessment made by those EMA scientific committees, where the assessment is part of an ongoing marketing authorisation application or variation, this assessment is considered non-releasable until the availability of the Commission Decision on the granting or refusal on, or the variation to the marketing authorisation, or the receipt of the withdrawal letter submitted by the pharmaceutical company” (Lines 129 – 133). We strongly believe that the proposed changes concerning Orphan designations and PIPs, are harmful, will lead to unnecessary disclosure of commercially confidential information (CCI) and disincentivise innovation.	
3	To be able to submit the EFPIA response on the above consultation on revised policy on access documents please inform us on the exact deadline for submission - 16 or 18 May? We noticed the two dates are mentioned on the EMA website (see attached)(SCREENSHOT OF WEBSITE)	The public consultation period was from 17 February 2017 to 18 May 2017. EFPIA's submission has been received and is included in these stakeholder comments.

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9	Openness and transparency are paramount values enshrined in the TEU1 and in the TFEU2 as they contribute to strengthen the principles of democracy and good administration. The Hellenic Cancer Federation welcomes the mention of openness and transparency values, at the beginning of the policy document, as they should govern the activities of all EU agencies, given that they are fundamental EU values.	The comment is noted.
6	LFB does not have any comment on this proposal	The comment is noted.

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Line 119-121	4	Line 119-121: Clarify if disclosure preparatory documents, i.e. working documents, internal notes, and documents containing opinions for internal use or related to preliminary consultations within EMA are excluded from disclosure at any time or if they are excluded only until final decision is issued. If appropriate to reflect intent, suggest adding “final” before “documents” on lines 123 and 127.	EMA agrees with the proposal to clarify the language used in lines 123 and 127. In this regard, reference to "documents" will be preceded by the term "preparatory."
Lines 284-287	4	Lines 284-287: The EMA Policy on disclosing non-final documents is further confused in this paragraph. Lines 118-120 of the Policy states that “EMA shall only release final documents once the concerned procedure has been finalized. This will exclude from disclosure preparatory documents,…”. Although this statement is confused by the lack of specificity through the use of the term, “documents” in the next following paragraph with no reference to final and/or non-final documents, there is no indication in the main body of the Policy that a process exists whereby non-final documents may be released.	EMA agrees with the proposal to clarify the language used in lines 284 and 286. In this regard, reference to "documents" will be preceded by the term "preparatory."
Lines 289-290	4	Lines 289-290: The phrase “unless it has already been determined that the document shall or shall not be disclosed” presumes that EMA will always have sufficient understanding of the nature of the commercial information to make a determination regarding disclosure undermining commercial interests, legal proceedings or investigations and	EMA does not agree with your proposal. It is noted that the concerned language of the policy reflects the wording of Article 4(4) of Regulation (EC) No 1049/2001. The Agency is, therefore, required to observe the applicable legislation.

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		audits. While this presumption is clearly the intent of the policy, from a non-government entities prospective, this presumption is troubling, particularly as it is coupled with a standard of “obviousness” that its quite subjective, even to an individual level Delete the phrase “unless it has already been determined that the document shall or shall not be disclosed.”	
Lines 343-344	4	Lines 343-344 The use of a standard of obviousness seems very subjective regarding releasing third party documents without consultation. If obviousness is a sufficiently objective standard why does it not apply to the release off documents originating from a member state? Aren’t governments to be held to the highest level of transparency?	Regulation (EC) No 1049/2001, Article 4 (4) states that the institution shall consult the third party (document owner) with a view to assessing whether an exemption under paragraph 1 or 2 of the same Article is applicable, unless it is clear that the document shall or shall not be disclosed. The policy follows the applicable legislation. Under Article 4 (5), a Member State may request the institution not to disclose a document originating from that Member State without its prior agreement. Hence a Member State shall be consulted. Lines 343 to 344 of the policy reflect the wording of Article 4(4) of Regulation (EC) No 1049/2001. As the legislation has not changed in this regard, the Agency is not in a position to assess further your proposal.
Lines 57-59	13	The term "document" needs to be defined more detailed as most documents are existing only digitally in data bases. For instance requests regarding data from EMA databases like EudraVigilance should be defined to be documents. This is very important in terms of the time span from submission to answer: If document derived from EudraVigilance is defined to be a document according to this policy, the maximum time span is 15 working days, but if it is defined to be	The term "document" as provided within the meaning of Article 3(a) of Regulation (EC) No 1049/2001 has been interpreted by the Court of Justice of the European Union. It, therefore, falls outside the remit of the Agency to pronounce on the scope of the term "document."

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		a request for information it can last 2 months. In daily practice this can mean that the answer to a request for a summary of adverse event reports can last two months, however the request for the reports as such has to be answered within 15 working days (real case from daily practice).	
Lines 69-94	13	Especially if legal aspects, e.g. reporting to OLAF, are concerned there might be a legitimate interest of the requester for an early answer.	The Agency strives to provide a response to requests for access to documents as soon as possible. Indeed requesters are welcome to highlight any reason which they believe the Agency should take into account when processing said requests. However, the Regulation EC (No) 1049/2001 does not state that priority must be given to some requests over others. The Agency cannot therefore include this point in its policy as it may be regarded as discriminatory.
Lines 151-159	13	Measurement of performance parameters are needed to be defined in terms of time needed for answers in order to identify needs for improvements in terms of head count or technical equipment.	The Agency has a system in place that allows for the monitoring of deadlines and information on compliance with the legal deadlines is published in the Agency's Annual Activity Report (available at: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2017/07/WC500230378.pdf). The current reporting does not distinguish between different groups of requesters as all requests are processed in the same way. The Agency is therefore not considering, at this stage, to expand on the reporting done to include the average time needed to release a document from date of submission and per type of requester. This would require substantial additional resources to gather, extract and organise that

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			information.
Lines 49-50	13	The proactive disclosure of EMA documents needs to be regulated and supervised - see comments below.	The Agency has already produced a guide on the different types of information it currently publishes, as well as publication times (available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000169.jsp&mid=WC0b01ac0580a45420). The Agency welcomes feedback on how said information can be organised. Currently all information related to one product can be found under that product on the website of EMA. This seems to be easier for stakeholders than a list of documents published. In addition, all documents pertaining to scientific committees are also published under their relevant pages and linked to the product pages when applicable.
Line 74	13	According to practical experience EMA documents are often not published within the predefined time frames. Best examples might be the PRAC minutes: Art 12 of the PRAC rules state: "Agendas and minutes of each of the above mentioned Committees and CMDh should be made available to each other on a monthly basis" However, at least the minutes for the PRAC meeting March 2017 were not adopted during the following PRAC meeting in April 2017 due to "time constraints" (official statement of the EMA). However, this prevents the timely information of the other committees about PRAC activities. Further Art 16 2. of the PRAC rules states: Agendas and adopted minutes of the PRAC meetings shall be made publicly available at pre-defined monthly time points. However, these time	The topic of proactive publication of documents by the Agency is out of the scope of this policy. Information on what documents are published and when can be found in our webpage (available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000169.jsp&mid=WC0b01ac0580a45420).

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		points are not published (or not existing?) and thus, the compliance of the PRAC with this rule is questionable. Additionally the "Q&A on signal management" states: "All PRAC recommend actions are further reflected in the meeting minutes, which are published a few days after their adoption at the following PRAC meeting". However, the truth is far away from this assumptions. Not only that minutes are not always adopted in the following PRAC meeting, also the time span from adoption to publication has not to be counted in days but in months, see e.g. the following PRAC meeting minutes: Nov/Dec 2016 adopted 09 Jan 2017, published 10 Apr 2017 (3 months). Oct 2016 adopted 28 Nov 2016, published 22 Feb 2017 (3 months). Sep 2016 adopted 24 Oct 2016, published 21 Feb 2017 (4 months).	
Line 74	13	On 26 Apr 2017 it turned out that the SOP/EMA/0041 "Access to Documents" disappeared from the EMA website and was not traceable anymore, neither by the IT- nor by the ASK-EMA department and also not by the "Head of Access to Documents". However, this SOP is mentioned in terms of differentiation by other SOPs, eg. SOP/EMA/0019 and was valid at least in the past.	SOP/EMA/0041 was declared obsolete and therefore removed from the webpage as it was no longer applicable. The document is available and has been provided by means of an access to documents request. It may, however, be highlighted that the Agency is not considering to maintain obsolete SOPs in its public webpage as it could lead to confusion and also make the webpage more difficult to navigate due to the large number of documents.
87-94	13	ASK-EMA rejected to deliver a document within the period of 15 working days because of "current high volume of requests". However, this cannot be a	The resources made available to the Documents Access and Publication Service take account of the Agency's overall priorities, other responsibilities and the posts approved by the

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		legitimate reason as this does not concern only single requests, but indicates a systematic failure in terms of administrative conduct.	Budgetary Authority. The Agency would like to note, however, that, when dealing with requests, most specifically multiple and repeated requests, it will apply the principle of proportionality in order to avoid that performance of core tasks assigned to EMA is jeopardised
151-159	13	Measurement of performance parameters need to cover also cases of non-compliance with applicable time-frames.	The Agency has a system in place that allows for the monitoring of deadlines and information on compliance with the legal deadlines is published in the Agency's Annual Activity Report (available at: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2017/07/WC500230378.pdf). The current reporting does not distinguish between different groups of requesters as all requests are processed in the same way. The Agency is therefore not considering, at this stage, to expand on the reporting done to include the number of cases when the deadline has been extended and per type of requester. This would require substantial additional resources to gather, extract and organise that information.
160 -176	13	The current design of the two "Output Tables" regarding access to Documents is hindering the use of the information given as no links are provided for documents available on the EMA website or to any detailed list of releasable documents (e.g. invalid SOPs). If something is published on the EMA website the content must be accessible without any barriers. Further, releasable documents need to be listed in a way which makes those detectable (e.g.	In accordance with Article 12(1) of Regulation (EC) No 1049/2001 documents shall as far as possible be directly accessible to the public in electronic form or through a register in accordance with the rules of the institution concerned. The Agency maintains a number of electronic document databases and information systems that are available to the public. These databases and systems reflect the various roles and obligations of the Agency in relation to protection of public health and regulation of medicinal

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		SOP/EMA/0041 "Access to Documents" simply disappeared from the EMA website).	products in the EU. This electronic access is part of a two-fold approach of direct access, proactive publication of material on the Agency's website or under Policy 0070 clinical data publication and in combination with access to document requests. The Agency considers that the various electronic document databases and systems currently made publicly available by the Agency enable effectively the citizens to exercise the rights given to them by Regulation (EC) No 1049/2001, as required by Article 73 of Regulation (EC) No 726/2004 and Articles 2(4) and 11 of Regulation (EC) 1049/2001 and therefore, there is no need to provide additional links in the output tables.
234-236 305-310	13	According to own experience with the EMA access to document procedure it appears to be crucial to improve internal capacities in order to handle the requests "promptly" as required by the policy. Requests for documents related to pharmaceutical drugs are regularly connected to product safety aspects. Thus, the time to releasing a requested document has much more significance as in other contexts. In order to handle the resulting need for timely access to documents, it is required to establish a sufficient management of personnel resources.	The resources made available to the Documents Access and Publication Service take account of the Agency's overall priorities, other responsibilities and the posts approved by the Budgetary Authority.
305-308	13	Unfortunately the text of the request is not confirmed in the automated acknowledgement.	The acknowledgement of receipt is an automated message from the system used for the submission and processing of queries made to the Agency, sent shortly after receiving the query. The Agency already includes the text of the question raised to the Agency with every response or decision letter released.

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			Therefore, the Agency believes it is unnecessary to modify the IT system given that the query raised is always included in the reply.
Lines 75-78	11	IQWiG appreciates the opportunity to comment on EMA's policy on access to documents (Policy 0043). IQWiG generally supports EMA's approach to transparency. EMA's recent initiatives including Policy 0070 make the agency the most transparent regulatory body worldwide. Given the relevance of information on methods and results from studies in human subjects for public health, from IQWiG's point of view, this study information can generally not be considered commercial confidential information.	The Agency proactively publishes clinical study reports in line with Policy 0070, EMA policy on publication of clinical data for medicinal products for human and veterinary use (2/10/2014). The issue of commercial confidential information is clarified in the joint HMA/EMA recommendations on transparency (EMA/484118/2010) that is available on the EMA website. In this document, regarding commercial confidential information, in view of the lack of a legal definition and for the purpose of harmonisation 'commercial confidential information' shall mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information. As common principle, it was agreed by the competent national authorities of all EU Member States (including Germany) that information that is already in the public domain cannot be regarded as commercially confidential.
Lines 92-94	11	Given the resources needed to prepare requested documents for transfer to the requestor and considering the public interest in transparency of study information, the documents should not only be provided to the requestor but should be made publicly available on EMA's clinical data website on which also documents according to Policy 0070 are published.	Policy 0070 and the implementation of Regulation (EC) No 1049/2001 relating to access to documents have different purposes. The clinical study reports now published under Policy 0070 follow this policy and are published on a publically available website where personal data must be duly protected and commercial confidential information respected. The Agency is committed to a policy of transparency and a large range of material is published for public information on its website.

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Lines 150-159	11	IQWiG supports transparency on the number of requests by type of requestor	The number of requests by type of requestor can be found at the EMA annual reports which are publicly available. Please see: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000208.jsp&mid=WC0b01ac058002933a
Lines 192-193	11	IQWiG does not agree that third-party documents should be classified as non-releasable by default. Certain types of documents (e.g. Clinical Study reports according to ICH E3) should be considered releasable by default. According to REGULATION (EU) No 536/2014 “clinical study report should not be considered commercially confidential a once a marketing authorisation has been granted, the procedure for granting the marketing authorisation has been completed, the application for marketing authorisation has been withdrawn.”	The Agency does not agree with your proposal comment. First, it is noted that lines 192 to 193 of the policy reflect the wording of Article 4(4) of Regulation (EC) No 1049/2001. The Agency is, therefore, subject to the legal requirement to consult with third parties, unless it is clear that the document shall or shall not be disclosed. As the legislation has not changed in this regard, the Agency is not in a position to derogate from the application of this provision. Second, recital 68 of Regulation (EU) No 536/ 2014 imparts the intention of a general principle concerning the nature of the information contained within a clinical study report. This principle is, however, not absolute. In this regard, the Regulation also recognises that all or certain data contained within clinical study reports, which are submitted to the EU database may not be subject to disclosure. This exception is provided in accordance with Article 81(4)(b) of the Regulation (EU) No 536/2014.
Lines 194-195	11	IQWiG supports the need for a dedicated internal entity at EMA to operate the transparency measures. This entity should be provided with the required resources.	The comment is noted. The resources made available to the Documents Access and Publication Service take account of the Agency's overall priorities, other responsibilities and the posts approved by the Budgetary Authority.

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60-61	21	Although the definition of Third Party is in line with Regulation (EC) 1049/2001 it is strange to consider the Member States and EU institutions and bodies as third party as the regulation is about public access to EU documents.	The policy is in line with Regulation (EC) No 1049/2001 and applies the definition of "third party" therein.
123-133	21	If the EU and the EMA really want to be transparent they should not release the documents related to marketing authorization of medical products of the EMA to the Commission after the decision but before the decision.	In accordance with the first subparagraph of Article 4(3) of Regulation (EC) No 1049/2001, access to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure. The Agency's approach to scientific decision-making follows the legislation in place. Such documents are published or released under access to document requests following completion of the decision-making phase.
192-193	21	By classifying third party documents by default as non-releasable there is no proactive disclosure by the EMA but the public must make each time a specific request for a document (reactive disclosure). Certain types of third party documents should be proactive disclosed by the EMA (according to the specific principles).	In accordance with the first subparagraph of Article 4(3) of Regulation 1049/2001, access to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure. The Agency's approach to scientific decision making follows the provisions of the legislation. Such documents are published or released under access to document requests following the decision. Since October 2016, EMA proactively publishes clinical data submitted by pharmaceutical companies to support their

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			regulatory applications for human medicines under the centralised procedure. The public can access these clinical data on the dedicated website: clinicaldata.ema.europa.eu.
274-362	21	The paragraphs differ in some aspects (the highlights) from the Regulation (EC) 1049/2001. The arrangements should correctly paraphrase the regulation.	Articles 4, 6, 7 and 8 of Regulation (EC) No 1049/2001 are reproduced in this part of the policy for completeness of information for the reader regarding exceptions, requests for access, handling of initial applications and handling of confirmatory applications. The term 'EMA' has been substituted for that of institution. In addition, some specific Treaty provisions have been added for accuracy instead of the term 'relevant'. In the case of confirmatory applications who takes the decision has been stated. The policy substantially reproduces the text of the legislation with the changes identified above and with the aim of ease of readability for the reader.
	13	In regard to my requests for documents submitted to the EMA during the last two weeks I observed the following: 1. I requested documents which I need for submissions to OLAF, to the German financial supervision authority BAFIN and to public prosecutors. Background: There are good reasons for suspecting preferential treatment of Marketing Authorisation Holders (MAHs), non-compliance with stock market rules by MAHs and severe threats to public health with probably a considerable number of unnecessary deaths (see Executive Summary attached). Because of the urgency of the matter I requested priority according to "EMEA/MB/203359/2006 Rev 1 Adopted" where is	1. Regulation (EC) No 1049/2001 does not allow the Agency to prioritise one request or requester over others as it would be discriminatory. 2. This has already been replied to in our responses on the same comment submitted by you above. The Agency measures compliance with the legal deadlines established in the Regulation (EC) No 1049/2001. 3. The term "document" as provided within the meaning of Article 3(a) of Regulation (EC) No 1049/2001 has been interpreted by the Court of Justice of the European Union. It, therefore, falls outside the remit of the Agency to pronounce on the scope of the term "document."

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		stated:"An application for access to a document shall be handled promptly." However, my appeal was rejected indirectly by stating that I shall get the documents within the timeframe of 15 working day which will possibly be expanded by additional 15 working days. Thus, my suggestion is to open a regular way to appeal for prioritization if a good reason is given. Further, if such an appeal would be rejected, this needs to be justified and there should be a legal remedy as well. 2. There should be a measurement of the time needed for handing over the documents. My impression is that the 15 days are utilized too often. Such a measurement should include: Working days needed from confirmation to handing over the requested document. Separately the same for prioritized requests. If the average period for the handling of requests appears to be to long, the reason needs to be investigated and a solution should be considered. 3. There should be a clear definition of "Document": I requested a document which contains one figure from Eurdravigilance: How many of distinct reports of adverse events are contained in the database?	

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		However, this could be interpreted as a question instead of being a document and this would make out of 15 working days a two months period. In the case given there would be a stupid but probably effective way to maintain the 15 working days period: To request all the single reports as those are definitely documents .... Thus, what I suggest is to define data from EMA databases as documents as the database as such fulfils major criteria for being a document as such.	
	13	For an issue submitted to OLAF I urgently need to look at the SOP/EMA/0041 "Access to documents". However, it is not detectable at the EMA website - although mentioned in other SOPs, e.g. SOP/EMA/0019 Please, can you help me to get access to this SOP?	This document has been provided to the requester.
Line 39	3	The EMA uses the word “corporate” document but does not define the word.	The Agency considers that "corporate" documents are all documents that are not included and/or related to medicinal products. Given the diverse nature of the documents (reporting, budget, financial accounts, procurement,…), the Agency cannot provide an exhaustive list of what would be included under this category.
Lines 44-45	3	Whilst the aim of policy 0043 is to ensure the widest possible access to the documents the EMA produces, receives or has in its possession and to ensure that it effectively meet its obligations under Regulation (EC) No 1049/2001, the “right of access” to EMA documents	EMA considers it important to highlight that it is subject to the obligation to pursue the objectives of Policy 0043 in accordance with Article 16 of Regulation (EC) No 1049/2001. For the purpose of ensuring clarity, the policy will be revised to incorporate explicit reference to this provision.

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		(subject to certain exceptions) does not confer a “a right to reproduce” or “right to publish” EMA documents on requestors (or third-parties).	
Lines 53-55	3	The long sentence is ambiguous. If it means that EMA security-sensitive information is out of scope, the guidance should simply state this.	EMA has an internal classification system for its internal purposes such as security to ensure due confidentiality of sensitive documents, e.g. in the legal area. Access to databases is likewise managed under internal policies that ensure the integrity of the data and to secure it against external threats. This internal classification system is part of the governance of the Agency and is in order to distinguish access rights for staff compared to any contractor working at the Agency. Notwithstanding the internal classification policy, the access to document's legislation and the rights of citizens to make access to document's requests continues to apply and overrides any internal classification policy.
Line 59	3	The term “within the EMA sphere of responsibility” is ambiguous	This section of the policy contains definitions. The definition of "document" reflects the definition provided in accordance with Article 3 (a) of Regulation (EC) No 1049/2001 (substitution of '"EMA"' for that of '"institution"). The Agency applies in the policy the definition in line with the applicable legislation.
Lines 60-61	3	Access to documents generated by companies and submitted to the Agency is frequently requested. By consequence, the fact that sponsors and Marketing Authorisation Holders are key third-parties must be explicit.	This section of the policy contains definitions. The definition of "third party" reflects the definition provided in accordance with Article 3(b) of Regulation (EC) No 1049/2001 (substitution of '"EU or non EU-institutions"' for that of '"other Community or non-Community"'). The Agency applies the definition in the policy in line with the applicable legislation. The definition of the term ' "any natural or legal person"' includes everyone and therefore covers sponsors and Market

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			Authorisation Holders.
Lines 84-86; 134-136; 279; 282; 287	3	The term overriding public interest gives considerable leeway for interpretation by the EMA. The interest of transparency in general cannot in itself be sufficient in a situation where precisely, transparency has to be weighed against other interests. There has to be a more specific justification why disclosure is deemed to take precedence.	The Agency would like to highlight that the scope and content of the concept of "overriding public interest" has been defined in the case law of the Court of Justice of the European Union. It, therefore, falls outside the remit of the Agency to pronounce further on the scope of the term "overriding public interest".
Lines 87-94	3	It is stated that "… EMA will also apply the principle of proportionality in order to avoid that performance of core tasks assigned to EMA is jeopardised. […] EMA will liaise with the applicant in order to seek agreement on a fair and reasonable solution whenever the request addresses a long list of documents...". It would be fair and reasonable to have a reciprocal principle for MAHs in terms reviewing documents (as third-party authors) prior to disclosure. Last, we understand that when several requests are submitted in parallel by a requestor, EMA only processes one request at a time.	The Agency consults regarding third-party documents with the relevant owner(s). In the consultation letter, the Agency provides the scope of the (clarified) request along with a list of the (identified) requested documents. If the request concerns several documents and the Agency has to examine each document individually to ensure that no private or public interests are being compromised, the Agency consults on sets of documents at certain intervals and documents are sent for consultation in batches in line with the principle of proportionality. Usually, the third party is given five working days to provide their comments and only in exceptional cases further to communication with the third party an extension of this deadline is considered in view of the short overall deadline for the processing of ATD requests in accordance with the Regulation whereby a reply is provided within 15 working days (extended by a further 15 working days in exceptional circumstances in accordance with the Regulation). Third parties may liaise with the Agency on a case-by-case basis in order to seek an agreement on a reasonable and

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			timely feasible consultation of the requested documents (e.g. batch release). The Policy is revised accordingly. As per the current EMA practice, EMA liaises with the applicant to indicate a degree of priority when making multiple requests. Also, when an applicant requests access to a third-party document(s), EMA will always inform the originator, even if the requested document(s) have already been disclosed to other applicant(s) in a prior request. If there is more than one requester for a given document, the originator is informed of this. Regarding advance information about requests temporarily put on hold, we will review the feasibility of this proposal considering the Agency's Access to Documents Service workload and the specifications of the IT tool used by the access to documents service. The Policy is revised accordingly to address the above practice: "Applicants are advised to indicate a degree of priority when making multiple requests. Furthermore, third parties may liaise with the Agency on a case-by-case basis in order to seek an agreement on a reasonable and timely feasible consultation of the requested documents (e.g. batch release)".
Line 105	3	It is unclear when this updated draft policy 0043 document will become effective and implemented. The	The revised policy was adopted by the EMA Management Board on 04 October 2018. When the new Regulation (EC) No

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		implementation of Regulation (EC) No. 2016/679 will only be effective from 25 May 2018 onwards. If 45/2001 is still applicable would possibly be relevant to just include both.	2016/679 and the regulation replacing Regulation (EC) No 45/2001 becomes effective, the relevant references will be updated.
Lines 112-116	3	EFPIA is concerned by a proposed extended access to COMP summary reports and Paediatric Investigational Plans (PIPs).	The reply to this comment is set out in the Output table responses.
Line 121	3	Preliminary PRAC/CHMP Rapporteur assessment reports are considered as preparatory documents and therefore should not be disclosed (incl. D80 and D150 assessment reports in initial MAA review).	In accordance with Article 4(3) first paragraph of Regulation (EC) No 1049/2001, in case of an assessment made by EMA scientific committees, where the assessment is part of an ongoing marketing authorisation application or variation, this assessment is considered non-releasable until the availability of the Commission Decision on the granting or refusal on, or the variation to the marketing authorisation, or the receipt of the withdrawal letter submitted by the pharmaceutical company, unless there is an overriding public interest in disclosure. EMA scientific committees assessment reports are releasable, once a Commission Decision on granting or refusing the MA/variation, or upon finalisation of the procedure related to the annual decision of the Commission, or upon availability of the Committee opinion if there is no subsequent Commission Decision, or Committee conclusion if there is no subsequent Committee opinion or company's letter notifying the withdrawal.
Lines 139-141	3	There is an ambiguity regarding information of the originator when several applicants are requesting several times the same document(s)	As per the current EMA practice, when an applicant requests access to a third-party document(s), EMA will always inform the originator, even if the requested document(s) have

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			already been disclosed to other applicant(s) in a prior request. If there is more than one requester for a given document, the originator is informed of this.
Lines 157-159	3	The wording leaves a doubt whether requestor affiliations will be revealed or not. It is further not clear whether the Agency refers to the "Organisation/employer" field or to the "Who you are" field of the request form	The beneficiaries of the requested documents will be asked to provide their affiliation (e.g., academia, patients, industry etc). This information is made public and the number of requests by type of requestor can be found at the publicly available EMA annual reports. Regarding identity of the requester the identity of natural persons submitting requests for access to documents cannot be released to the third-party originator of the document or made publicly available by EMA.
Line 173	3	The output table is considered as a living document.	The output tables have been revised following the Agency's experience of implementing Regulation (EC) No 1049/2001 and its commitment to transparency. Further revision of the output tables will be undertaken as this experience evolves over time. These documents are, therefore, considered as living documents. It is not possible to establish a fixed timetable for the revision of the output tables as the evolution of access to documents does not have a regular timetable. Future changes to the output tables will be announced in advance. Consultation would be undertaken at the relevant advance time point.
Lines 192-193	3	Third party documents are considered non-releasable by default but the list of third parties is long. Secondly, the experience of EFPIA member companies is that the principles for CCI and PPD have not been	The definition of "third party" which is provided in Section 3 of the policy reflects the definition provided in accordance with Article 3(b) of Regulation (EC) No 1049/2001. Policy 0070 - clinical data publication is handled by the Documents Access and Publication Service. An important distinction regarding

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		applied consistently to Policy 0043 and Policy 0070. It is not clear whether the two policies will be handled by the same or separate groups within the Agency.	Policy 0070 is that the clinical data published under this policy are published on a publically available website. Under an access to document request the requestor only receives the information. The standard applicable to personal data must take into account this crucial difference that must be more rigorous for publication on a public website in order to obviate the possibility of personal identification using alternative sources of information available on the internet. Regarding commercial confidential information (CCI), the same standard is applicable. There may be differences that arise due to the time difference between the publication of clinical data under Policy 0070 and an access to document request that is made much later. It is likely that with the passage of time more information will have entered the public domain such that with a later access to document request the volume of CCI may have lessened. Both under Policy 0070 and Policy 0043 the document owner is involved regarding the applicable redaction.
Lines 198-202	3	It is suggested that the EMA in exceptional cases may consider holding such information subject to ongoing foreign marketing authorisation applications. In particular, documents containing interim results could be classified as not accessible. If EMA received documents from an ongoing active blinded randomized trial even as part of an authorisation application, these data should be considered to be “non-releasable” until such time as that studies' end of trial notification has been submitted in the EU or until it is considered by the	In accordance with Article 4(4) of Regulation (EC) No 1049/2001 and the established EMA access to documents procedure, when the applicant requests access to a third-party document, EMA will consult the third party concerned prior to taking any decision on disclosure. The third party is provided with a “Justification Table” and asked to provide the Agency with a detailed justification as to how the disclosure of (parts of) document(s) would undermine the protection of the interests concerned. Further to an individual and specific assessment of third party's comments in relation to the information contained in

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		third party that ongoing activities are finalized. Under the current policy 043, even if a sponsor could consult with EMA to withhold or modify the release per policy 070 there could be a chance that a policy 043 request could be made. In such a circumstance the sponsor would need to redact such documents to protect treatment assignment and this could be impossible and could jeopardise the scientific integrity of that trial. As an example for further international trends in the area, Health Canada's proposal for public release of clinical information in drug submissions and medical device applications clearly states that "clinical study reports, overviews, and summaries will cease to be CCI unless data contains information on secondary or exploratory end points which may constitute a component of an on-going development programme. The term "completed clinical trials" for drugs and "completed clinical studies" for medical devices is meant to exclude interim clinical study results. The disclosure of clinical results prior to the completion of the study may risk jeopardizing the completion or integrity of the study by un-blinding a blinded study.	the document, the Agency provides in the Justification Table a rationale of its assessment to partially accept or reject the third party's proposed redactions. This approach also applies for information regarding interim data for ongoing clinical trials. Based on justification, EMA will assess the release or non-release of such data.
Lines 198-206	13	EFPIA acknowledges the approach. However, when the EMA are reviewing the 'justification table for redactions' it would be helpful if the integrity of the table (as commented on by the MAH) could be maintained with the EMA providing their comments against each individual line item submitted by the MAH. This would make it easier to understand what is, and what is not, accepted as CCI (and the reasons	In accordance with Article 4(4) of Regulation (EC) No 1049/2001 and the established EMA access to documents procedure, when the applicant requests access to a third-party document, EMA will consult the third party concerned prior to taking any decision on disclosure. The third party is provided with a "Justification Table" and asked to provide the Agency with a detailed justification as to how the disclosure of (parts of) document(s) would undermine the protection of the

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		why). This in view of preparing for any future Policy 043 requests.	interests concerned. Further to an individual and specific assessment of third party's comments in relation to the information contained in the document, the Agency provides in the Justification Table a rationale to partially accept or reject the third party's proposed redactions. The Justification Table is then annexed to the EMA's decision letter to disclose documents. In this decision letter, EMA indicates examples of the accepted proposed redaction. In case the Agency agrees with (some of) the third party's proposed redactions in an access to documents request does not automatically mean that it will be accepted in future requests. This is mainly due to the fact that each document subject to an access to document request is assessed on its own merit and in light of the circumstances of the given moment. This is regardless of what information has been accepted / rejected in previous requests. Information that was previously considered to be commercially confidential may no longer be considered such in light of new developments, change of circumstances, new publications or EMA becoming aware of new elements affecting the assessment. Regarding the comment on "Dialogue with the EMA" please note that the Agency implements its decision no sooner than 10 working days after the document(s) concerned has been sent to the third party, in accordance with section 5.7 of the Annex to the revised EMA policy of access to documents (previous Article 8(7) of the Agency rules). At this stage of the process the third party cannot submit any further redaction-related comments.

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			This is because a) Regulation (EC) No 1049/2001 sets out strict deadlines for the assessment and responses to requests for access to documents which cannot be extended outside the limits set out in this legislation; b) the necessary timeframe has been allocated at the consultation phase for the third party to provide a detailed justification regarding their proposed redactions. Should the third party wishes to avail themselves of the remedies available under Union law against this decision, the third party can bring a complaint before the European Ombudsman, pursuant to Article 228 of the Treaty on the Functioning of the European Union (TFEU). Alternatively, the third party can institute legal proceedings before the General Court of the European Union in accordance with Article 263 of the TFEU.
Lines 203-205	3	In the 'Summary report of the webinar on the implementation of Policy 070 and revised external guidance to industry' (dated 16 February 2017) it is stated that "the methodology followed to identify possible CCI (…) is exactly the same". This being the case, it would be inconsequential, undermine Policy 070 and impose an unreasonable workload on sponsors, to require the MAH to redact the same document twice. A document disclosed on the EMA website should be released unchanged, in case of an Access to Documents request. Admittedly, the release of information under Policy 0043 would not be conditioned by the 'Terms of Use'. Furthermore, it seems the spirit of the paragraph 4.4 and the	In case of an access to documents request (in accordance with policy 0043) of a document already disclosed under policy 0070, the Agency advises the requester to visit the Clinical data publication website where the document requested has been published. This decision is in line with the principle set out in our Policy on access to documents (available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/11/WC500099473.pdf) which states that the Agency will apply the principle of proportionality in order to avoid the core business tasks of the Agency and its performance being jeopardised by the administrative workload related to activities within Regulation (EC) No

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		introduced concept of “two-fold approach” to implementation of public access would rather warrant to refer a policy 43 applicant to policy 70 EMA clinical data platform in case the requested document was already proactively disclosed.	1049/2001. The context of the publication of clinical data for medicinal products for human use under Policy 0070 is therefore different from that under Regulation (EC) No 1049/2001 on access to documents and the level of anonymisation that Marketing Authorisation Applicant/Holder will take to reduce the risk of re-identification to an acceptable level may not be comparable as alternative methodologies to anonymise documents will be available to MAA/Hs (e.g. generalisation, randomization etc.) and not to EMA. Taking the above into account, EMA will always anonymise documents before disclosure under Regulation (EC) No 1049/2001.
Lines 274; 281; 285-286; 288-289	3	New highlighted text in the annex to policy 0043 (“it determines that”; “determines that”; “has already been determined”) has the effect of shifting the decision-making authority on what constitutes “commercial interests of a natural or legal person” (exclusively) to the EMA. The inference is that the EMA intends to consult less with relevant third-parties. The EMA is not best positioned to determine what constitutes a “commercial interest” and “shall” (Article 4, Regulation EC 1049/2001) consult with the relevant third-party when there is any doubt. Furthermore, the EMA is unlikely to know if the documents inadvertently reveal the identities of individual company staff.	In the annex of the policy, Section 1 to which these comments relate correspond directly to the relevant provisions of Article 4 of Regulation (EC) No 1049/2001 and are reflected for completeness of information for the reader. As a general principle, therefore, the Agency does consult with third parties regarding access to document requests and there is no change to this approach which is in line with the applicable legislation.
Lines 274-	3	We suggest adding here a short statement on the need to protect data on interim results and ongoing studies	In accordance with Article 4(4) of Regulation (EC) No 1049/2001 and the established EMA access to documents

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278		(see comment on line 123).	procedure, when the applicant requests access to a third-party document, EMA will consult the third party concerned prior to taking any decision on disclosure. The third party is provided with a “Justification Table” and asked to provide the Agency with a detailed justification as to how the disclosure of (parts of) document(s) would undermine the protection of the interests concerned. Further to an individual and specific assessment of third party's comments in relation to the information contained in the document, the Agency provides in the Justification Table a rationale of its assessment to partially accept or reject the third party's proposed redactions. This approach also applies for information regarding interim data for ongoing clinical trials. Based on justification, EMA will assess the release or non-release of such data.
Lines 288-290	3	As currently written, the guideline could be viewed as suggesting that EMA need not consult with a third party prior to disclosure if EMA has already made up its mind about whether a document is releasable. EMA should consult with the third party to assess whether an exception to disclosure applies unless EMA has already previously consulted with the third party to determine whether the document shall be disclosed. In the latter, the EMA shall nevertheless inform the third party that a new request was made.	This text reflects the wording provided in Article 4(4) of Regulation (EC) No 1049/2001. The Agency does inform the third party that an access to document's request has been submitted and does consult the third party prior to taking a decision on the release or not of the requested material. Where an access to document's request has previously been submitted for the same document(s) and the consultation had previously been undertaken a further consultation may not be required.
Lines 304-318 Lines 319-	3	Regulation EC 1049/2001 states that the EMA should within 15 days of registering a request, either grant access to “the document” or, in written state the	We cannot define a “large” request by specifying the number of document(s) requested or the number of pages concerned. In reality, it is case-by-case exercise which depends on the

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333 Lines 348-352		reasons for not doing so. We understand that the reality is that many requests are not for a single document but for large or large and multiple documents. This may not have been foreseen when the original Rules for Implementation were drafted. In the light of the practical experience, the revision is an opportunity to revisit the unrealistically short durations defined in the original Policy 0043 guidance document. We request that timely alignment on expectations with the third-party takes place to avoid overburdening requests for both sides. Moreover, please consider that 15 day extensions could be usefully applied also in cases of high complexity of the subject-matter or other complex circumstances (in case of licensing agreements, co-development, etc.) where there are several stakeholders involved and not simply due to the size of the documents requested. A public status table for Policy 0043 requests would facilitate the workload planning management for MAHs but also make the process more clear and understandable for the general public, patients and academia.	nature and type of the requested data contained in the relevant document(s). In addition, a “large” request may apply to documents where the third party provided during the consultation phase with lots of comments. The Agency has to perform an individual and specific assessment of each and every of the comments received in relation to the information contained in the document in order to ensure that no private or public interests are being compromised in accordance to the provisions of Article 4 of Regulation (EC) No 1049/2001 (the Regulation). In case of a “large” request, the Agency considers to consult on sets of document(s) at certain intervals and document(s) are sent for consultation in batches in line with the principle of proportionality. Usually, the third party is given five working days to provide their comments and only in exceptional cases (further to communication with the third party) an extension of this deadline is considered in view of the short overall deadline for the processing of access to documents requests in accordance with the Regulation whereby a reply is provided within 15 working days. Therefore, an automatic 15 day extension cannot be applied. The Agency systematically asks requestors to indicate priority when making multiple requests. Regarding the proposal for the EMA to publish on regular basis a table with the number of pending requests, the company impacted and the estimated timeline for processing,

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			we will review the feasibility of this proposal considering the Agency's Access to Documents Service workload and the specifications of the IT tool used by the access to documents service
Lines 335-336	3	It would be useful to clarify that these exceptions relate to article 3 of the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMA documents (can create confusion with article 4 of the same regulation).	The Agency believes that the language is clear in light of the fact that the text referred to is provided within the annex to the policy, which explicitly makes reference to the Rules for the implementation of Regulation (EC) No 1049/2001. It follows, therefore, that these rules reflect the relevant provisions of Article 4 of Regulation (EC) No 1049/2001 that addresses exceptions.
Line 340-342	3	The originator should always be informed, see our previous comments. We would appreciate further clarification on what EMA considers as something “disclosed either by its author or under Regulation (EC) No 1049/2001 341 or similar provisions”, especially in cases where disclosure has taken place with some redaction already but in different jurisdictions. Imagining a document has been released previously (e.g. a protocol with redactions disclosed as per FDAAA final rule) in the US, the EMA should in any case consult with the sponsor to ensure redaction according to current EU requirements is done adequately.	The Agency will inform the third party owner of the document of the third party request. In addition, the Agency consults the third party owner regarding an access to document request for an originator's document. Where the author of the document has already disclosed it e.g. through publication or on a public website, the document in question has now entered the public domain and consultation of the third-party author is not required. The Agency recognises that the exceptions to the application of this general principle are few. For this reason, it always aims to find/consult the current third party owner of a document that is subject to an access to document's request.
Lines 343-347	3	Examples of which documents might be released without consultation with the sponsor would be helpful. Similarly, examples of documents provided by the Member States.	Documents which might be released without consultation with the sponsor are for instance documents that have already been released under Regulation (EC) No 1049/2001 (in the frame of a previous access to documents request). In this

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			case the originator will be informed of the request and the release of the relevant document(s). The Agency will implement its decision no sooner than 10 working days after the document(s) concerned has been sent to the originator. Another example are documents that have already been disclosed and can be found in the public domain. In this case, the request is handled as request for information (RFI). Documents originating from a Member State are for instance CMDh documents (please see HMA website: http://www.hma.eu/humanmedicines.html).
Lines 353-355	3	We propose that a more formal appeals process is put in place. At present, an MAH who opposes disclosure has to start court proceedings in order to try and prevent disclosure. It may be more helpful and cost-effective to have an appeal hearing where the MAH can be assured of the opportunity to make oral representations to better explain why disclosure should be denied.	Regulation (EC) No 1049/2001 provides very well defined timeframes regarding access to documents and EMA should provide a reply to the requester within a period of 15 working days which in exceptional circumstances may be extended to a further 15 working days. Introduction of a formal "appeal hearing" procedure may compromise these legally enforceable timelines. Furthermore, the third party consultation phase provides the appropriate step in the procedure whereby the third party is invited to consider any information in the document(s) concerned to fall under any of the exceptions of Article 4 of the Regulation and provide the Agency with a detailed justification for each and every element requested for redaction and how disclosure would undermine the protection of the interests concerned.
Lines 361-362	3	The copyright policy referred to covers documents under EMA copyright. The guidance should spell out that third-party documents, or parts thereof, may be	The policy will be updated to incorporate reference to Article 16 of Regulation (EC) No 1049/2001. In this regard, it will be clarified that public access to a document will be treated in

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		protected under third-party copyright.	accordance with the aforementioned provision.
Footnote on Page 3 of 11, Lines 92, 94, 110, 138, 299, 300, 303, 306, 309, 311, 315, 317, 325, 329, 332, 338, 357	3	The definition of “applicant” in the context of this policy can be misleading with the other text within the updated draft policy document (and also the changes proposed here by the industry group).	This change is accepted and the policy will be updated to replace 'applicant' with 'requester'.
Lines 09-10	7, 12,14,15,19	General comments: As recalled in the proposed revised Policy 0043, openness and transparency are fundamental European Union values. In this regard, all efforts by the European Medicines Agency (EMA) to stick to these values are welcome. For the purpose of enhancing transparency, we invite the EMA to set up and maintain a comprehensive public register of all documents it holds. As pointed out by the European Ombudsman, “the aim of a public register is to enable the public to gain detailed and up-to-date knowledge of the documents, or at least the type of documents, that an institution holds. This knowledge facilitates members of the public to exercise their fundamental right to request access to	In accordance with Article 12(1) of Regulation (EC) No 1049/2001 documents shall as far as possible be directly accessible to the public in electronic form or through a register in accordance with the rules of the institution concerned. The Agency maintains a number of electronic document databases and information systems that are available to the public. These databases and systems reflect the various roles and obligations of the Agency in relation to protection of public health and regulation of medicinal products in the EU. This electronic access is part of a two-fold approach of direct access, proactive publication of material on the Agency's website or under Policy 0070 clinical data publication and in combination with access to document requests. Within the context of EMA's work a single register would not address all the elements of 'document' as defined in accordance with Regulation (EC) No 1049/2001. The Agency considers that the various electronic document

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		documents."	databases and systems currently made publicly available by the Agency enable effectively the citizens to exercise the rights given to them by Regulation (EC) No 1049/2001, as required by Article 73 of Regulation (EC) No 726/2004.
Lines 43 – 55	7,12, 14,15,19	At line 51, it is noted that the consultation on EMA's access to documents policy excludes requests for information from the scope of this policy because they are handled in accordance with the EMA Code of Conduct. However, later in the document, aspects relating to requests for information are outlined. This is confusing and should be clarified. In addition, in the EMA Code of Conduct (dated 16 June, 2016), clear, specific rules for dealing with requests for information are not included. The Code mainly deals with conflict of interest rules.	Request for information" shall mean external requests requiring an answer from the Agency and not falling within the scope of "Access to documents". These requests shall be handled in accordance with the EMA Code of Good Administrative Behaviour (and not EMA Code of Conduct). The Policy 0043 will be revised accordingly. Please see EMA Code of Good Administrative Behaviour : http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/09/WC500150730.pdf Aspects relating to requests for information are outlined only on Lines 26 and 51 of the revised Policy 0043. Therefore, your comment that "... later in the document, aspects relating to requests for information are outlined " is not clear. The SOP/EMA/0019" Handling of requests for information" provides the procedure for the handling of requests for information received by the Agency.
Lines 53 - 55	7,12, 14,15,19	The proposed revised Policy 0043 states that the EMA can manage access to its databases according to separate procedures and criteria. It would be very helpful, and contribute to a better understanding of EMA's transparency policy, if all rules outlining EMA's policy on access to documents are	Policy 0043 sets out the Agency's approach to access to documents under the provisions of Regulation (EC) No 1049/2001. These rules govern documents that are not automatically published and can be released on request, that are subject to third party consultation and may be subject to some redaction.

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		made available in the same location on its website. All documents that contain important information on medicines development, and assessment of medicines before and after marketing authorisations (quality, safety, efficacy), either proactively disclosed, being subject to a request for access, or being included in an EMA database (such as EudraVigilance), should be addressed in a comprehensive EMA policy on access to information and documents. To facilitate public access, EMA must clearly indicate which rules and procedures apply regarding access to documents and information included in different databases. EMA's webpage to request a document is insufficient. It does not allow the inclusion of attachments. The webpage to introduce complaints to the European Ombudsman permits the inclusion of attachments. EMA should take the necessary steps to allow inclusions of attachments.	All other material on the Agency's website is proactively published and is publically available, e.g. agenda and minutes of meetings. No access to document request need be made in order to access this material. The What's new part of the website as well as Press releases allows visitors to the website to identify new material of interest to them.
lines 75 - 78	7,12, 14,15,19	General principles: The EMA policy on access to documents must, above all, emphasise the importance of public access to regulatory and corporate documents held by EMA, and adhere to the overriding public interest that justifies the disclosure of documents. It currently focuses too much on clarifying the conditions for non-disclosure (e.g., protection of commercially confidential information).	EMA complies fully with Regulation (EC) No 1049/2001. It is committed to transparency as can bee seen by the expanding number of documents and other material that is published publically on its website. In addition, EMA has implemented Policy 0070 - clinical data publication and has been publishing clinical data in line with this policy since October 2016. As regards access to documents, it is relevant to set out in Policy 0043 the conditions that apply to access to document requests. The Agency's responsibilities pertain to the regulation of human and veterinary medicinal products whereby the updated access to documents policy supports

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			this access upon request.
Lines 81 - 83	7,12, 14,15,19	Pharmaceutical company redactions of patient numbers in clinical study reports is a common occurrence. For independent researchers, this makes it impossible to study serious harms because one cannot link information in various parts of the documents. Such redactions should not be allowed.	EMA does not accept your proposal to publish patient numbers derived from clinical study reports. The redaction of patient numbers is required in accordance with applicable EU legislation in order to ensure that the privacy and integrity of the concerned data subjects is not undermined.
Lines 84 - 86	7,12, 14,15,19		It is not accepted to alter the wording from 'may' to 'must' since Article 4 of Regulation (EC) No 1049/2001 provides that access to a document shall be refused where disclosure would undermine the protection of the public interest as regards: public security, defence and military matters, international relations, the financial, monetary or economic policy of the EU or a Member State; privacy and the integrity of the individual in particular in accordance with EU legislation regarding the protection of personal data.
Lines 87 - 94	7,12, 14,15,19	Criteria of proportionality: From the latest data made available by EMA on requests for access to documents (relating to 2016 and published a few days ago) it appears that 55% of all requests originate from the pharmaceutical industry. Requests from academia and research institutions only account for 8%. Due to the fast-growing number of requests submitted to EMA, research institutions and civil society organisations, such as Prescrire, have experienced increasing delays and difficulties with their own requests. EMA should increase resources to deal with	Point (1) The resources made available to the Documents and Publication Access Service take into account the Agency's responsibilities, priorities and the posts authorised by the Budgetary Authority. Point (2) Once an Access to Documents (ATD) is received an ATD Coordinator is assigned and will contact the requester to clarify/coordinate the request. The ATD coordinator assists the requester aiming to identify the documents that would satisfy the request and to provide

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		access to document requests. Requests by independent researchers are particularly relevant from a public health perspective and should be handled in a timely manner. Transparency should be the norm, rather than the exception, and clinical data should belong to the public. This data is particularly important for protecting public health because it allows for independent analysis, including comparative effectiveness reviews, which enhance knowledge about the real effects of medicines. Granting public access to detailed clinical data, including raw data, is crucial to minimise dangerous practices of reporting bias, which overrates the benefit of a drug while underestimating its harm. The European Ombudsman's investigations on access to medicine documents held by the EMA indicate that full Clinical Study Reports and trial protocols cannot be classified as trade secrets, commercially confidential, and/or intellectual property data. Their disclosure does not undermine commercial interests.	guidance on the timelines of the procedure. "A Guide on access to unpublished documents-Access to unpublished documents" (EMA/304162/2014, 26 August 2014) is available at the EMA website and provides detailed procedural guidance to requesters. Point (3) In line with the legally defined framework, EMA is not in a position to implement at present time such an initiative.
Lines 92 - 94	7,12, 14,15,19	Previous EMA complaints about the large number of requests for documents received from Prescrire are unwarranted. A significant number of requests for documents could be avoided if the EMA regularly updated European Public Assessment Reports (EPARs), particularly when new information is available. In addition, packaging mock-ups being dated could be made available online in a new section document of the EPAR, similar to what is done in the United States	It is not proposed to alter the policy. Documents may contain personal data or commercial confidential information that should be redacted. Other information about authorised medicinal products is revised and published in line with the outcome of the related regulatory procedures.

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		Food and Drug Administration (FDA) and the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA).	
Lines 97 - 105	7,12, 14,15,19	Specific interests: Information shared between EMA and non-EU regulatory agencies (e.g., FDA), should always be released if there is an overriding public interest in disclosure. This prevents the creation of a 'safe harbour' for protection of information deemed commercially confidential by another agency that has a narrower approach to data disclosure. To comprehensively assess a marketing authorisation, the EMA should always request all necessary data directly from the relevant company, even if the data has already been obtained from other sources. This helps ensure that such information remains available for public access under existing EU regulations and EMA policies that govern access to clinical data, rather than fall under the safe harbour of confidentiality agreements signed between EMA and regulators outside the EU.	It is not proposed to revise the policy. Article 4.1 (a) of Regulation (EC) No 1049/2001 provides the legal basis' upon which a document may be refused. In this regard, a request for access to a document shared between EMA and other EU and non-EU regulatory bodies has to be assessed in line with the provisions of Regulation (EC) No 1049/2001. Disclosure may, therefore, only be granted if the exception relating to the existence of an "overriding public interest" is fulfilled in accordance with Article 4(2) or Article(3) of Regulation (EC) No 1049/2001.
Lines 112 - 116	7,12, 14,15,19	Commercially confidential information: The proposed definition of "commercially confidential information" is too broad. We urge EMA to consider our proposed definition in the right column. As previously mentioned, the European Ombudsman's	The issue of commercial confidential information is clarified in the joint HMA/EMA recommendations on transparency (EMA/484118/2010) that is available on the EMA website. In this document, regarding commercial confidential information, in view of the lack of a legal definition and for the purpose of harmonisation, "commercial confidential information" shall

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		investigations into access to medicines documents demonstrated that neither the examined Clinical Study Reports, nor trial protocols, contained information that could be classified as trade secrets, commercially confidential and/or intellectual property data. The Ombudsman also indicated that their disclosure could not undermine commercial interests.	mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information. This definition was agreed with the competent national authorities of all EU Member States. The Agency is, therefore, not in a position to give broader expression to the concept of "commercially confidential information."
Lines 118 - 136	7,12, 14,15,19	Protection of internal deliberations: In the absence of a decision from the European Commission (or a recommendation from Committee for Medicinal Products for Human Use [CHMP] or Coordination Group for Mutual Recognition and Decentralised Procedures - Human [CMDh]) to grant or refuse variations to marketing authorisations, the EMA considers internal documents as non-releasable. Based on our experience with this policy, however, information included in the Periodic Safety Updated Reports (PSURs), for example, is at least 18 months old when made available. It therefore becomes of lesser interest because it is outdated. Any delay in access to information or data (e.g., adverse effects) represents a risk to patients. This is particularly the case considering the lengthy time frame for the PSUR production and decisions about the subsequent marketing authorisation variations. The adverse drug reaction reports webpage is not user-friendly and, therefore, uninformative.	A public alert campaign is outside the scope of the policy on access to documents. Other regulatory mechanisms are used in such cases.

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		In addition, regarding the increased priority that EMA gives to scientific advice (including PRIME), it is of utmost importance to ensure that information on advice received by companies is made publicly available in a comprehensive and timely manner. This is crucial to enhance public scrutiny and trust. We argue that, ideally, detailed reports of scientific advice provided by regulators to pharmaceutical companies during drug development should be published at the time of the decision on trials, or no later than 12 months following the end of trials. At the very least, we require that the EMA establish a timeline that indicates at which point in time detailed reports on scientific advice will be made publicly available. The EMA should also consider the possibility that a sponsor, which has received scientific advice from tis Agency, does not submit in the end an application for marketing authorisation to the EMA (but through authorisation procedures other than the centralised one) or not at all. If a drug development programme is discontinued for some reason (e.g., safety issues), it would be relevant from a public health perspective to have public access to study reports, including information related to scientific advice.	
Lines 137 - 149	7,12, 14,15,19	Third party consultation: EMA's consultation with or information of third parties regarding the access to a third-party document is a source of delay. It alerts the company which might immediately submit a complaint to the Court of Justice	EMA does not accept your proposal. This comment is out of the scope of Policy 0043. In accordance with Article 4(4) of Regulation (EC) No 1049/2001 as regards third party documents, the Agency is subject to the obligation to consult the third party with a view to assessing whether an exception is applicable unless it is clear that the document shall or shall

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		of the EU to withhold access to the specific document. The cumbersome process for accessing documents prepared by third parties deprives the public of rapid access to comprehensive and exploitable data, notably about adverse drug reactions. In addition, in the past, the name of the requesting party has been disclosed to the company. This might lead the company pressure the requesting party. EMA should take steps to prevent this practice. The general public may find it enlightening and informative if the EMA released information on the occasions and circumstances in which pharmaceutical companies may directly or indirectly influence EMA activities (e.g., early scientific advice, pilot projects).	not be disclosed.
Line 169	7,12, 14,15,19	Output of the policy: The EMA says that the output tables should be considered “living’’ documents that will be updated on a continuous basis. We believe it is crucial that the general public receives detailed information on the legal and practical impact of any changes in those tables, particularly regarding the inclusion of additional documents and changes in the publication status of the documents (e.g., releasable or non-releasable, proactively available or on request, redacted on the grounds of confidentiality). In particular, for the sake of transparency, we need further explanations from the EMA on the legal and practical impact of the change of concepts, particularly	The output tables have been revised following the Agency's experience of implementing Regulation (EC) No 1049/2001 and its commitment to transparency. Further revision of the output tables will be undertaken as this experience evolves. These documents are, therefore, considered as living documents. Future changes to the output tables will be announced in advance. Consultation would be undertaken at the relevant advance time point. The output tables set out clearly documents that are releasable, that are public, at what point are published on the Agency's website or can be requested in line with Policy 0043. Non-releasable documents are those that cannot be released in line with policy 0043 and Regulation (EC) No 1049/2001. It is considered that the terms 'releasable' or 'non-releasable' are clearer in the context of the Agency's policy on access to

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		the move from “public” or “confidential” towards “releasable” or “non-releasable”. In our view, a document should always be considered releasable, even if some parts have been redacted for commercial confidentiality.	documents and make it more transparent as to the documents that can be requested and will be released.
Lines 173 - 176	7,12, 14,15,19	It is proposed that both output tables must be considered “living” documents and be updated on a continuous basis by taking into account, for example, the legal interpretation given by the Court of Justice of the EU. While acknowledging that the EMA has done significant steps in the implementation of the right of access to clinical data in recent years, we are aware of situations in which access was unjustifiably denied. For example, prior to the adoption of this access to documents policy, the EMA illegally refused to grant Prescrire access to PSURs. Following Prescrire’s complaint to the European Ombudsman, the EMA was obliged to send them. Prescrire’s experience showed cases of various types of documents being denied as ongoing appeals were lodged with the Court of Justice of the EU. The organisation also experienced delays in response and data delivery. The signatories of this response are aware that the EMA is again being sued by some pharmaceutical companies. While wishing an outcome that upholds data transparency as the default position, we call upon	The output tables have been revised following the Agency's experience of implementing Regulation (EC) No 1049/2001 and its commitment to transparency. Further revision of the output tables will be undertaken as this experience evolves. These documents are, therefore, considered as living documents. Future changes to the output tables will be announced in advance. Consultation would be undertaken at the relevant advance time point. Moreover, it is highlighted that the Agency is subject to the obligation to await the outcome of those proceedings before the Court of Justice of the European Union.

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		EMA to ensure a smooth application of its access to documents policy during the course of these proceedings.	
Lines 192 - 193	7,12, 14,15,19	As previously mentioned, EMA's consultation with or information of third parties regarding the access to a third-party document is a source of delay. The cumbersome process for accessing documents prepared by third parties deprives the public of rapid access to comprehensive and exploitable data, which contributes to the prevention of medication errors.	In accordance with Article 4(4) of Regulation (EC) No 1049/2001, as regards third party documents, the Agency shall consult the third party with a view to assessing whether an exception is applicable unless it is clear that the document shall or shall not be disclosed.
Lines 206 – 236 216 - 218 219 – 220 225 - 228	7,12, 14,15,19	Implementing the policy: The proactive and timely disclosure without delay of EMA documents on its website is welcomed and necessary for transparency, independent research and, ultimately, to improve public health and patient safety. We fully support the proactive publication of clinical data (EMA policy/0070). At the same time, we would appreciate clarification from EMA regarding its statements that it may establish other rules regarding publication of documents. We hope that any future initiatives will aim at further expanding public access to EMA documents and clinical data. It is important to stress that Clinical Study Reports and Clinical Overview Documents are key components of marketing authorisation procedures. These data are, in essence, regulatory data, created for public interest use. When Clinical Study Reports are received at EMA,	In accordance with Article 12 of Regulation (EC) No 1049/2001 documents shall as far as possible be directly accessible to the public in electronic form or through a register in accordance with the rules of the institution concerned. The Agency maintains a number of electronic document databases and information systems that are available to the public. These databases and systems reflect the various roles and obligations of the Agency in relation to protection of public health and regulation of medicinal products in the EU. This electronic access is part of a two-fold approach of direct access, proactive publication of material on the Agency's website, access to information through structured databases or under Policy 0070 - clinical data publication and in addition access to document requests. Within the context of EMA's work a register would not address all the elements of '"document"' as defined within the meaning of Article 3(a) of Regulation (EC) No 1049/2001. The Agency considers that the various electronic document databases and systems currently made publicly available by

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		they become a “document held by the Agency” and Regulation (EC) N°1049/2001 applies. In addition, the Clinical Trials Regulation imposes online access to these reports. The recent decision by the Court of Justice of the EU to temporarily uphold the suspension of the release of a clinical study report is very worrying because it completely ignores current policy. A positive outcome, in which the Courts uphold data transparency as the default position, are needed. In the meantime, EMA should ensure a smooth application of its access to documents policies. The EMA should clarify its statement that it might establish other rules regarding the publication of documents in order to ensure an appropriate level of transparency. Any future initiative should aim to enhance public access to corporate documents and information on medicines (including clinical data). As stated in the consultation document, EMA makes various electronic document databases and systems publicly available under Regulation N° 726/2004 and Regulation N° 1049/2001. However, the EMA’s “ADRreports.eu” portal, derived from EudraVigilance, is not user-friendly. Details to notifications are not made available even if they are included in EudraVigilance. Without changes, and better access to detailed information, the current system prevents analysis and understanding of public data and, therefore, hinders patient safety. We would appreciate further access to more detailed information from EMA, which is required	the Agency enable effectively the citizens to exercise the rights given to them by Regulation (EC) 1049/2001, as required by Article 73 of Regulation (EC) 726/2004 and Articles 2(4) and 11 of Regulation (EC) 1049/2001. Legal action taken by document owners is the right of those parties and the outcome of these legal actions is awaited. The Agency robustly defends proportional and reasonable public access to information in such cases and has been successful in defending these principles. Policy 0070, clinical data publication, was established in accordance with Article 80 of Regulation (EC) No 726/2004. Further transparency initiatives may be taken in the future that will be subject to the consent of the European Commission and the approval of the Management Board.

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		for independent research organisations' analyses.	
Line 257	7,12, 14,15,19	ANNEX - Arrangements for policy implementing: 1. Exceptions The access to documents policy should, above all, emphasise the importance of public access to corporate and regulatory documents, as well as access to clinical data. In line with Regulation 1049/2001, we call upon the EMA to truly deal with considerations on confidentiality as an exception. The EMA's definition on commercially confidential information is too broad and needs to be narrowed in scope. In addition, the EMA must uphold the principle of overriding public interest in disclosure. We consider that data sharing between EMA and other regulatory agencies (including non-EU regulators) can be of added value; however, it will be counter-productive if this is done at the expenses of data transparency. Information in the public interest must be disclosed. In the context of the ongoing legal proceedings at the Court of Justice of the EU, we strongly encourage the EMA to maintain a smooth functioning and policy regarding access to documents.	It is not proposed to revise the policy in this regard, as it is in line with the prevailing legislation. Article 4.1 (a) of Regulation (EC) No 1049/2001 provides the legal basis' upon which access to a document shall be refused. It is also highlighted that a request of access to a document which contains information relating to other regulatory bodies has to be assessed in line with the provisions of Regulation (EC) No 1049/2001. Disclosure may, therefore, only be granted if the exception relating to the existence of an "overriding public interest" is fulfilled in accordance with Article 4(2) or Article(3) of Regulation (EC) No 1049/2001. The HMA/EMA recommendations on transparency of November 2010, EMA/484118/2010, which are published on the EMA website set out the principles regarding commercial confidential information. In view of the lack of a legal definition and for the purposes of harmonisation '"commercial confidential information"' shall mean any information which is not in the public domain or publically available and where disclosure may undermine the economic interest or competitive position of the owner of the information. This definition was agreed by the competent national authorities of all EU Member States. The Agency is, therefore, not in a position to give broader expression to the concept of "commercially confidential information."
Line 284-287	7,12, 14,15,19	There is no reason for EMA to keep opinions for internal use and preliminary consultations away from public scrutiny, particularly when it has made a decision based on those documents. These documents	EMA would like to highlight that lines 284 to 287 of the revised policy reflect the wording provided in the second subparagraph of Article 4(3) of Regulation (EC) No 1049/2001. The Agency is, therefore, required to observe the

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		should not be automatically classified as “non-releasable’’, especially when the decision-making process is over.	applicable legislation.
Lines 304 - 318	7,12, 14,15,19	Handling of initial applications: Based on our experience with requests for documents, the EMA rarely meets its deadline to reply.	In most of the cases EMA meets the legal deadlines regarding the process of access to documents. A statistical percentage of responses to ATD requests provided within set timelines in 2015 (94%), 2016 (target) (90%) and 2016 (result) (97%) is provided in the publicly available EMA Annual Activity Report: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2017/07/WC500230378.pdf The process of access to documents is explained in the “Guide on access to unpublished documents-Access to unpublished documents” (EMA/304162/2014, 26 August 2014) which is publicly available at the EMA website and provides detailed procedural guidance to requesters. As explained in the above mentioned Guide, EMA will do its best to process an access to documents request on time. If the requester is not satisfied with the decision of the Agency, they may ask the Agency to reconsider its decision by sending a written request called a “Confirmatory Application” via the EMA web form: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&mid=WC0b01ac05806499f0 In the event that the Agency does not reply to the requester's Confirmatory Application, the requester may complain to the European Ombudsman or alternatively, the requester can

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			institute legal proceedings before the General Court of the European Union in accordance with Article 263 of the TFEU (see Article 8 of the Regulation (EC) No 1049/2001).
Lines 112-116	2	The EMA policy on access to documents states that "EMA will ensure protection of commercial interest in accordance with the notion of commercial confidential information. In view of the lack of a legal definition and for the purpose of this policy 'commercial confidential information' shall mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information". While it is understood that commercially confidential information can be critical to pharmaceutical companies, CPME insists that public interest should always prevails over commercial interests. In particular all results of clinical trials, whether they are positive, negative or inconclusive, should be made publicly available in a systematic way. The legitimate economic interest of the pharmaceutical companies should therefore be defined in a restrictive way and should not take precedence over the public legitimate interest to gain knowledge and be informed in a timely manner about medicines that are on the EU market or that are being investigated. In line with the decision of the European Ombudsman on its own-initiative inquiry OI/3/2014/FOR concerning the partial refusal of the European Medicines Agency to give public access to studies related to the approval of	In accordance with the case-law of the Court of Justice of the European Union, EMA is required to apply and interpret any exception to the public right of access to documents strictly and narrowly. It, therefore, follows that only clear and specific arguments can justify the application of the exception provided pursuant to the first indent of Article 4(2) of Regulation (EC) No 1049/2001. Where a risk to the legitimate commercial interests of a legal person is reasonably foreseeable, an assessment of whether there is an overriding interest in disclosure must be performed. This requirement is provided pursuant to the final clause of Article 4(2) of Regulation (EC) No 1049/2001.

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		a medicinal product (Humira), CPME considers that EMA should systematically investigate if "there is a compelling overriding public interest for documents to be disclosed where the information they hold has clinical value to clinicians and researchers (as regards understanding the safety and efficacy of a product for uses to which it is put, including off-label use)".	
Lines 53-55	16	The sentence is not very clear. Does it refer to the documents not listed in the "output table" (as those in "output table" are already classified as Non-R/ R)?	EMA has in place an internal classification system that regulates internal access to information by staff working in different parts of the Agency or by contractors. For example, information regarding a tender procedure will be classified internally to protect the confidential nature of such a procedure. Only the persons working internally on the procedure would have the relevant internal access. The internal classification structure is only for the purpose of internal security and to protect against external threats. All documents are subject to access to document's legislation regardless of any internal security information classification policy. Access to document's legislation overrides any internal classification policy.
Lines 84-86; 134-136; 279; 282; 287	16	The term "overriding public interest" is rather broad and gives considerable space for interpretation by the EMA and remains unclear for other parties. To keep consistency in the decision-making process and to increase understanding of this term by interested parties (both, requestor and originator of data), disclosure of some past examples where public interest has overridden other concerns would help to understand the EMA interpretation.	EMA would like to highlight that the existence of an overriding public interest to justify disclosure is envisaged in accordance with Article 4(2) and Article 4(3) of Regulation (EC) No 1049/2001. In accordance with the Court of Justice of the European Union, this clause will be interpreted and applied strictly. To this end, arguments used to support the existence of a public interest must be of a concrete and specific nature and considered on an individual case-by-case basis.

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Lines 60-61	16	The definition of “third party” is quite explicit on the “authorities/ institution side”, but not very clear on the private sector side (sponsor? MAH?). As this is critical in view of consultation prior to disclosure of documents, it would be beneficial to also give examples from the private sector explicitly.	The definition of "third party" provided in Section 3 of the policy reflects the definition provided in accordance with Article 3(b) of Regulation (EC) No 1049/2001. EMA considers that the language is sufficiently clear in this regard.
Lines 87-94	16	As mentioned in the general comments section, the activities related to disclosure shall not overwhelm the essential activities of the EMA and we support the principle of proportionality applied by the EMA (including the dialogue with applicants in order to seek agreement on a fair and reasonable solution whenever the request addresses a long list of documents). The same principle should apply for MAHs in terms of reviewing documents (as third-party authors) prior to disclosure. Lastly, we understand that when several requests are submitted in parallel, EMA only processes one request at a time.	If the access to documents request concerns several documents and the Agency has to examine each document individually to ensure that no private or public interests are being compromised, the Agency consults on sets of documents at certain intervals and documents are sent for consultation in batches in line with the principle of proportionality. Usually, the third party is given five working days to provide their comments and only in exceptional cases further to communication with the third party an extension of this deadline is considered in view of the short overall deadline for the processing of access to documents requests in accordance with the Regulation whereby a reply is provided within 15 working days (this period may be extended to a further 15 working days in exceptional circumstances in accordance with the Regulation (EC) No 1049/2001). The Agency systematically asks requestors to indicate priority when making multiple requests. Regarding the proposal for the third party concerned (e.g. MAH) to be informed that a series of requests have been made, even though some may be on hold, we will review the feasibility of this proposal considering the Agency's Access to Documents Service workload and the specifications of the IT

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			tool used by the access to documents service. Based on the above practice, EMA Policy/0043 is proposed to be amended in lines 92-94 as follows (proposed underlined additions): “Accordingly, EMA will liaise with the requester in order to seek an agreement on a fair and reasonable solution (e.g. priority list of documents) whenever the request addresses a long list of documents or the document(s) the requester is interested in require extensive redaction before being disclosed. The third party may liaise with the Agency on a case-by-case basis in order to seek an agreement on a reasonable and timely feasible consultation of the requested documents (e.g. batch release).”
Line 105	16	The reference to the data protection is to the 45/2001, we suggest referring to the new regulation would be more appropriate now.	EMA does not accept your proposal. First, it is highlighted that Regulation (EU) 2016/679 will not apply to Union institutions, bodies, offices and agencies. It is, however, envisaged that Regulation (EC) No 45/2001 to which the Agency is currently subject to, will be replaced by a proposed Regulation. As the proposed Regulation has not yet entered into effect, any change to the revised policy will, therefore, not be considered at this time.
Lines 139-141	16	Article 4 of Regulation (EC) 1049/2001 states that the EMA shall consult with the originator.	The Policy will be amended (Line 140) to reflect the provision of Art 4.4 of Regulation (EC) No 1049/2001: "...EMA shall consult the third party..."
Lines 192-193	16	As the disclosure/ access to documents principles are defined in two separate documents (Policy 0043 and	Policy 0070 - clinical data publication and the implementation of Regulation (EC) No 1049/2001 on access to documents

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		Policy 0070), it is important that the principles for CCI and PPD are applied in the same way.	have different purposes. The clinical study reports published proactively under Policy 0070 follow this policy and are published on a publically available website where personal data must be duly protected and commercial confidential information respected. The standard applicable to personal data on a public website must ensure that the personal data is protected and obviate the risk of personal identification linkage of data available through alternative sources on the internet. Access to document requests including also clinical study reports are different as they are released to only the requester that made the access to documents request. In respect of commercial confidential information, the Agency aims for the fullest disclosure possible while respecting the economic interest involved. The Agency is committed to a policy of transparency. A large range of material is published proactively for public information on its website.
Lines 274; 281; 285-286; 288-289	16	New highlighted text in the annex to policy 0043 ("it determines that"; "determines that"; "has already been determined") has the effect of shifting the decision-making authority on what constitutes "commercial interests of a natural or legal person" (exclusively) to the EMA. The inference is that the EMA intends to consult less with relevant third-parties. The industry perception to determine what constitutes a "commercial interest" is crucial and consultation with the relevant third-party shall be assured.	In the Annex of the policy (Section 1) to which these comments relate, correspond directly to the relevant provisions of Article 4 of Regulation (EC) No 1049/2001 and are reflected for completeness of information for the reader. As a general principle, therefore, the Agency does consult with third parties regarding access to document requests and there is no change to this approach which is in line with the applicable legislation.
Lines 288-290	16	As currently written, the guideline could be viewed as suggesting that EMA need not consult with a third party prior to disclosure if EMA has already made up	The Policy reflects the provision of Art 4.4 of Regulation (EC) No 1049/2001.

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		its mind about whether a document is releasable. EMA should consult with the third party to assess whether an exception to disclosure applies unless EMA has already previously consulted with the third party to determine whether the document shall be disclosed.	
Lines 304-318 Lines 319-333 Lines 348-352	16	Regulation EC 1049/2001 states that the EMA should within 15 days of registering a request, either grant access to “the document” or state the reasons for not doing so in writing. We understand that the reality is that many requests are not for a single document but for large or large and multiple documents. This may not have been foreseen when the original Rules for Implementation were drafted. In the light of practical experience, the revision is an opportunity to revisit the unrealistically short duration defined in the original Policy 0043 guidance document. A public status table for Policy 0043 requests would facilitate the workload planning management for MAHs but also make the process more clear and understandable for the general public, patients and academia.	• We cannot define a “large” request by specifying the number of document(s) requested or the number of pages concerned. In reality, it is case-by-case exercise which depends on the nature and type of the requested data contained in the relevant document(s). In addition, a “large” request may apply to documents where the third party provided during the consultation phase with lots of comments. In this case the Agency has to perform an individual and specific assessment of each and every of the comments received in relation to the information contained in the document in order to ensure that no private or public interests are being compromised in accordance to the provisions of Article 4 of the Regulation (EC) No 1049/2001 (the Regulation). In case of a “large” request, the Agency considers to consult on sets of document(s) at certain intervals and document(s) are sent for consultation in batches in line with the principle of proportionality. • Usually, the third party is given five working days to provide their comments and only in exceptional cases (further to communication with the third party) an extension of this deadline is considered in view of the short overall deadline for the processing of access to documents requests in accordance with the Regulation

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			whereby a reply is provided within 15 working days. Therefore, an automatic 15 day extension cannot be applied. • The Agency systematically asks requestors to indicate priority when making multiple requests. • Regarding the proposal for the EMA to publish on regular basis a table with the number of pending requests, the company impacted and the estimated timeline for processing, we will review the feasibility of this proposal considering the Agency's Access to Documents Service workload and the specifications of the IT tool used by the access to documents service.
Lines 361-362	16	The copyright policy referred to covers documents under EMA copyright. The guidance should spell out that third-party documents, or parts thereof, may be protected under third-party copyright.	The policy will be updated to incorporate reference to Article 16 of Regulation (EC) No 1049/2001. In this regard, it will be clarified that public access to a document will be treated in accordance with the aforementioned provision.
Lines 11-12	1	It should be clarified what the ownership of the documents means. Just possessing documents does not imply owning them. This is particularly important for documents which are exclusively owned by the applicant and sent to the EMA for enabling regulatory decisions.	EMA holds the view that the concept of "ownership" of documents does not require elaboration. Article 2(3) of Regulation (EC) No 1049/2001 clearly provides that it "shall apply to all documents held by an institution, that is to say, documents drawn up or received by it and in its possession, in all areas of activity of the European Union" (emphasis added). In accordance with the policy, when an applicant requests access to a third-party document, EMA will always inform the originator prior to disclosure that a request for access has been received.
Lines 44-45	1	Documents received by EMA and therefor in the possession of EMA may only be disclosed if the	Under the scope of the policy, EMA aims to ensure the widest possible access to the documents that it produces or receives

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and 280		respective preconditions are fulfilled.	or has in its possession. Regulation (EC) No 1049/2001, Article 4 sets outs some exceptions to disclosure. These exceptions are re-produced for the information of the reader in the annex to the policy. With an access to document request, in some cases, these exceptions may apply.
Line 75	1	Adequate protection of CCI is essential.	The Agency proactively publishes clinical study reports in line with Policy 0070, EMA policy on publication of clinical data for medicinal products for human and veterinary use (2/10/2014). Commercial confidential information is addressed in the joint HMA/EMA recommendations on transparency (EMA/484118/2010) that is published on the EMA website. In this document, in view of the lack of a legal definition and for the purpose of harmonisation '"commercial confidential information"' shall mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information. As common principle it can be agreed that information that is already in the public domain cannot be regarded as commercially confidential. The Agency will inform the third party owner of the document of the access to documents request. In addition, the Agency consults the third party owner regarding an access to document request for an originator's document. Where the author of the document has already disclosed it e.g. through publication or on a public website the document in question has now entered the public domain and consultation of the third-party author is not required. The Agency always aims to find the current third party owner of a document that is subject to a third party

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			request.
Line 92-93	1	As this extensive redaction would have to be performed by the originator, how does EMA intend to involve the originator of the document(s) here so that this concerned company is able to plan the resources needed for the redaction work package? Timeline for provision of redacted document(s) should be agreed upon case by case.	EMA revised the Policy as follows: "Accordingly, EMA will liaise with the requester in order to seek an agreement on a fair and reasonable solution (e.g. priority list of documents) whenever the request addresses a long list of documents or the document(s) the requester is interested in require extensive redaction before being disclosed. The third party may liaise with the Agency on a case-by-case basis in order to seek an agreement on a reasonable and timely feasible consultation of the requested documents (e.g. batch release)."
Lines 112-113	1	What is meant exactly by the term "notion" of commercially confidential information? In addition, please explain the way EMA will ensure and implement the protection of CCI. Please reference to line numbers 181-182.	In absence of a definition of the concept of commercial confidential information in the applicable legislation or the established case law of the Court of Justice of the European Union, the EMA, in close cooperation with the EU Member States developed a single harmonised concept of commercially confidential information. This concept is reflected in the joint HMA/EMA recommendations on transparency (EMA/484118/2010) that is available on the EMA website. In this document, commercial confidential information, is defined as "any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information". Please note that the above definition has not been, since its creation, held to be invalid or incompatible with the applicable

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			EU law. Neither was it questioned or challenged by the European Ombudsman. EMA will ensure protection of commercial interest with the establishment of a formal procedure for consulting the third party (owner of the information) in accordance with Article 4(4) of Regulation (EC) No 1049/2001 for ensuring adherence to the protection of commercially confidential information (see also section 4.3. of this document).
Lines 113-116	1	This definition of CCI is appreciated. However, it should be clarified here, that the originator of the document(s) is the owner of the information.	In absence of a definition of the concept of commercial confidential information in the applicable legislation or the established case law of the Court of Justice of the European Union, the EMA, in close cooperation with the EU Member States developed a single harmonised concept of commercially confidential information. This concept is reflected in the joint HMA/EMA recommendations on transparency (EMA/484118/2010) that is available on the EMA website. In this document, commercial confidential information, is defined as “any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information”. Please note that the above definition has not been, since its creation, held to be invalid or incompatible with the applicable EU law. Neither was it questioned or challenged by the European Ombudsman. EMA will ensure protection of commercial interest with the establishment of a formal procedure for consulting the third

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			party (owner of the information) in accordance with Article 4(4) of Regulation (EC) No 1049/2001 for ensuring adherence to the protection of commercially confidential information (see also section 4.3. of this document).
Lines 125-126 and 132-133	1	Information and documents are non-releasable after receipt of a withdrawal letter.	EMA publishes information/withdrawal assessment reports in line with Article 11 of Regulation EC 726/2004, which states: “If an applicant withdraws an application for a Marketing Authorisation submitted to the Agency before an opinion has been given on the application, the applicant shall communicate its reasons for doing so to the Agency. The Agency shall make this information accessible and shall publish the assessment report, if available, after deletion of all information of commercially confidential nature”. A procedural advice on publication of information on withdrawals of applications related to the marketing authorisation of human medicinal products is available on the EMA website (please see EMA/599977/2012 rev. 1 of 23 June 2013).
Lines 134-136	1	In the cases described in these lines, disclosure may only be done after consenting consultation of the applicant.	The Policy was revised with the following additional wording: “As regards third party documents, EMA shall, as required by Article 4(4) of Regulation (EC) No 1049/2001, consult the third party with a view to assessing whether any of the exceptions set out in Articles 4(1) and 4(2) of the Regulation EC) No 1049/2001 is applicable, unless it is clear that the document shall not be disclosed or shall be disclosed with no redactions (e.g. a document that has already been made public)."

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Lines 139-141	1	In order to ensure protection of CCI and to avoid any disclosure of information which may undermine the economic interest or competitive position of the owner of the information any doubts on the part of EMA should be clarified and consulted with the originator before taking any decision. This belongs to reliable and good business conduct.	The Policy was revised as follows: “As regards third party documents, EMA shall, as required by Article 4(4) of Regulation (EC) No 1049/2001, consult the third party with a view to assessing whether any of the exceptions set out in Articles 4(1) and 4(2) of the Regulation EC) No 1049/2001 is applicable, unless it is clear that the document shall not be disclosed or shall be disclosed with no redactions (e.g. a document that has already been made public)."
Line 149	1	Procedures which safeguard the applicant’s rights to enter an objection or to appeal a court should at least be mentioned here.	Handling of confirmatory applications is covered in section 4 of the annex to policy 0043. In the event of a total or partial refusal, EMA shall inform the applicant of the remedies open to him or her, namely to lodge a complaint to the European Ombudsman or institute Court proceedings against EMA. In accordance with Article 228 or Article 263 of the Treaty on the Functioning of the European Union, respectively.
Line 181-182	1	Because this formal procedure is a prerequisite to operate the policy on access to documents more concrete information is needed, especially the legal category of this procedure and date of coming into force.	The Agency already has in place a formal procedure in place that includes a consultation with the owner of the documents to ensure the protection of both commercially confidential information and personal data. The procedure can be found here: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/11/WC500177739.pdf In view of the fact that the procedure is already existing and that it may be subject to updates and/or changes, as needed, the Agency considers that the addition of this information is unnecessary in the policy.

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Line 192	1	Third-party documents' should be clarified. i.e. documents which the EMA received from a third party. This includes and is not limited to all documents received from the applicant.	Third party documents are the documents listed in the Output table of the EMA access to documents policy (EMA/127362/2006, rev 1).
Line 194	1	In terms of EMA's continuous commitment to transparency (line numbers 211-212) may we ask which EMA functions are working at the dedicated internal entity, the Document Access and Publication Service? Is this entity also responsible for receiving and answering to potential complaints of originators? Could the originator address complaints or revealed errors during disclosure process also to an ombudsman at the EMA?	The composition of the Documents Access and Publication Service team falls outside the scope of Policy/0043. "A Guide on access to unpublished documents-Access to unpublished documents" (EMA/304162/2014, 26 August 2014) is available at the EMA website and provides detailed procedural guidance to requesters. Any complaints/errors/comments from the originators/requesters should be addressed to the ATD coordinator in charge of the request by e-mail at any stage of the access to documents procedure, quoting the initial request reference number (i.e. ASK-1234). In addition, in the event the Agency does not agree with some of the redactions proposed by the originator, or the Agency has not received any response from the originator to the consultation letter, the Agency will implement its decision no sooner than 10 working days after the document(s) concerned has been sent to the originator. The originators are informed by EMA in the "Notification to the MAH of the Agency's decision to disclose documents" that should they wish to avail themselves of the remedies available under Union law against this decision, they can bring a complaint before the European Ombudsman, pursuant to Article 228 of the Treaty on the Functioning of the European Union (TFEU). Alternatively, they can institute legal

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			proceedings before the General Court of the European Union in accordance with Article 263 of the TFEU.
Line 205	1	Does this mean a quality assurance system has been already built into this redaction process or will it be established in the future? By whom has it been or will it be built?	Some of the measures included in the quality assurance system built into the redaction process are the consultation phase with the originator, a clear process that includes quality control steps and the 10 working day period provided by the Agency prior to implementing its decision. Please see the “Guide on access to unpublished documents-Access to unpublished documents” (EMA/304162/2014, 26 August 2014) which is available at the EMA website and provides a detailed procedural guidance to requesters and outlines the above mentioned quality assurance measures built into the redaction process.
Lines 234-236	1	In case of incorrect disclosure of commercially confidential information or too short timelines for redaction of documents by the originator remedial action should be applied by EMA on a short-term basis and not only after a lengthy revision process of the policy. In terms of EMA’s continuous commitment to transparency (line numbers 211-212) it would be necessary to clarify the involvement of the originators for collection of “lessons learnt”.	The wording of Lines 234-236 relate to lessons learnt from experience to implement EMA's policy on access to documents and does not relate to individual requests. Therefore, the proposed wording is not accepted.
Line 245	1	We appreciate this classification.	The comment is noted.
Line 274 and 281	1	It is not a matter of a sole decision by the EMA alone whether a protection is undermined.	In the Annex of the policy, Section 1 to which these comments relate correspond directly to the relevant provisions of Article 4 of Regulation (EC) No 1049/2001 and

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			are reflected for completeness of information for the reader. As a general principle, therefore, the Agency does consult with third parties regarding access to document requests and there is no change to this approach which is in line with the applicable legislation.
Line 336 and 345	1	It is not clear which Article 3 is meant.	The comment is noted and the wording in section 5.1 of the annex to the policy will be revised as follows: "..... provided for by Section 1 of this annex applies". The wording of section 5.4 of the annex to the policy will also be revised as follows: ".... referred to in Section 1 of this annex".
General	10	IFAH-Europe appreciates the opportunity to comment on this document. IFAH-Europe notes the significant differences between the human medicines sector and the veterinary medicines sector, and that these policies need to be implemented in the veterinary medicines sector in a manner that reflects the specific characteristics of the sector. This includes: • the small size of the sector (anonymity is harder to achieve – it is easier to link 'information' to a company, particularly for products and product areas). • The significantly different manner in which	The comments fall outside the scope of this Policy. However, the relevant colleagues within the Agency who deal with veterinary medicinal products are informed of the comments made.

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		veterinary medicines influence public health; with the exception of tissue residues in food-producing animals and zoonotic disease control there is limited direct Public Health interest in veterinary medicine. • The significantly different way issues associated with veterinary medicines might be considered to be of over-riding public interest; it might be assumed that there will be less scope for allowing an over-riding public interest justification. • The human medicines sector generally publishes study reports through peer review or makes them available through clinical trial transparency initiatives. This is not the case for the veterinary medicines sector. Another general concern is the release of information in the absence of context. Information must be sufficiently complete and comprehensible that the receiver should not be misled: i.e. a single PSUR line list will not reflect the safety profile for the product.	
Lines 150 - 159	10	A significant concern is the absence in this section of the policy document of a reference to Article 16 of the Reg. 1049/2001 (“This Regulation shall be without prejudice to any existing rules on copyright which may limit a third party's right to reproduce or exploit released documents”). It should be an openly stated policy that the EMA will remind systematically their copyright obligations to the	The policy was updated to incorporate reference to Article 16 of Regulation (EC) No 1049/2001. In this regard, it will be clarified that public access to a document will be treated in accordance with the aforementioned provision.

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		requestors.	
Line 20	9	In order to be able to make a request for information, the enquirer should be able to see and get information about what is available as documents. Therefore, we invite the EMA to make publicly available and easily located on its website a list of all documents it generates and/or receives.	The output tables have been revised following the Agency's experience of implementing Regulation (EC) No 1049/2001 and its commitment to transparency. These output tables dealing with both medicinal products for human and veterinary use and separately with corporate documents contain guidance for the application of Regulation (EC) No 1049/2001 regarding access to document requests in each category and also indicate the point when the documents are made publically available such that no access to document request is required. In accordance with Article 12 of Regulation (EC) No 1049/2001 documents shall as far as possible be directly accessible to the public in electronic form or through a register in accordance with the rules of the institution concerned. The Agency maintains a number of electronic document databases and information systems that are available to the public. These databases and systems reflect the various roles and obligations of the Agency in relation to protection of public health and regulation of medicinal products in the EU. This electronic access is part of a two-fold approach of direct access, proactive publication of material on the Agency's website or under Policy 0070 and in combination with access to document requests. Within the context of EMA's work a register would not address all the elements of '"document"' as defined under in accordance with Article 3(a) of Regulation (EC) No 1049/2001. The Agency's approach ensures the wide access for citizens. The Agency considers that the various electronic document databases and systems currently made publicly available by the Agency enable effectively the citizens to exercise the rights given to

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			them by Regulation (EC) 1049/2001, as required by Article 73 of Regulation (EC) 726/2004 and Articles 2(4) and 11 of Regulation (EC) 1049/2001.
Line 53-54	9	It should also be noted that EMA reserves to classify documents for internal purposes such as for internal security reasons or to manage access to its databases according to separate procedures and criteria. Having separate procedures and criteria for access to EMA databases does not contribute to transparency and will complicate access. All rules about EMA's policy on access to various types of documents should be dealt with comprehensively on its website.	EMA has in place an internal classification system that regulates internal access to information. For example, information regarding a tender procedure will be classified internally to protect the confidential nature of such a procedure. Only the persons working internally on the procedure would have the relevant internal access. The internal classification structure is only for the purpose of appropriate internal security and to guard against external threats. All documents are subject to access to documents legislation regardless of any internal security information classification policy.
Line 75-78	9	Whilst providing adequate protection of commercial confidential information, personal data and other conflicting interests as identified (see below section on specific interests for further information), access to a requested document will be denied only if one of the exceptions listed in Article 4 of Regulation (EC) No 1049/2001 will be considered applicable Public access to regulatory and corporate documents should be stressed as based on public interest that renders necessary the disclosure of documents. The draft policy should focus more on positive aspects for disclosure.	EMA publishes regularly regulatory and corporate documents at its website. Furthermore, EMA publishes information on human and veterinary medicinal products at various stages of their life cycles, from the early developmental stages through to EMA's evaluation of authorisation applications, post-authorisation changes, safety reviews and withdrawals of authorisation. The "Guide to information on human medicines evaluated by EMA-What the Agency publishes and when" provides the different types of information the Agency currently publishes for both centrally and non-centrally authorised medicines, as well as publication times and location on EMA's website. It aims to help stakeholders know what kind of information to expect on medicines undergoing evaluations and other

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			regulatory procedures.
Line 111-116	9	EMA will ensure protection of commercial interest in accordance with the notion of commercial confidential information. In view of the lack of a legal definition and for the purpose of this policy'commercial confidential information' shall mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of 115 the owner of the information. The proposed definition of "commercially confidential information" is too broad and does not cover public interest. The proposed definition of "commercially confidential information" is too broad and does not cover public interest.	EMA complies with Article 4.2 first indent of the Regulation (EC) No 1049/2001 whereby EMA shall refuse access to (parts of) a document where disclosure would undermine the protection of commercial interests of a natural or legal person including intellectual property unless there is an overriding public interest in disclosure. The requester may submit a confirmatory application in writing against this decision to the EMA, within 15 working days of the release of the document(s) . Should the requester wishes to do so, they are kindly invited to provide their reasons against the Agency's decision to refuse access to the document / redact (part of) the document(s) at this stage, or detail any considerations in terms of public interest which they believe should be taken into account by the Agency in adopting a final decision.
Line 118-136	9	With regard to the specific principle not to undermine the decision-making process, EMA shall only release final documents once the concerned procedure has been finalised. This will exclude from disclosure preparatory documents, i.e. working documents, internal notes, and documents containing opinions for internal use6 or related to preliminary consultations within EMA, without prejudice to the Heads of Medicines Agencies/EMA recommendations on transparency In practice this means for documents related to medicinal products that these will be considered as non-releasable prior to the availability of the Commission Decision granting, refusing or	A public alert campaign is not in the scope of the policy on access to documents. Other regulatory mechanisms are used in such cases. In specific circumstances if regulatory action is needed regarding a medicinal product, information that is circulated through the national competent authorities' networks is provided to health care professionals.

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		varying the marketing authorisation for the particular medicinal product, or prior to the receipt of the withdrawal letter submitted by the pharmaceutical company. In case there is no subsequent Commission Decision, the documents will be considered non-releasable until the time of the scientific committee Opinion (irrespective if there is no subsequent Commission Decision or if the procedure is subject to the annual decision of the European Commission). In case of an assessment made by those EMA scientific committees, where the assessment is part of an ongoing marketing authorisation application or variation, this assessment is considered non-releasable until the availability of the Commission Decision on the granting or refusal on, or the variation to the marketing authorisation, or the receipt of the withdrawal letter submitted by the pharmaceutical company. EMA shall consider, on a case-by-case basis, the need to grant public access prior to the finalisation of the concerned procedure in case of an overriding public interest in disclosure, either further to a request for access to documents, or on its own initiative. Delays in access to information or data (e.g., adverse effects) represents a risk to patients. The webpage for adverse reactions of medicines is not user-friendly thus limiting the information it provides. Scientific advice should be publicly available in a timely manner.	
Line 219-	9	EMA may establish other rules regarding the publication of documents in order to ensure an	A provision of Regulation (EC) No 726/2004 that sets out the remits and responsibilities of the Agency is Article 80 which

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220		appropriate level of transparency, in accordance with Article 80 of Regulation (EC) No 726/2004. This statement requires clarification as to the rules to be established.	states that to ensure an appropriate level of transparency, the Management Board, on the basis of a proposal by the Executive Director and in agreement with the Commission, shall adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products which is not of a confidential nature. The internal rules and procedures of the Agency, its committees and its working groups shall be made available to the public at the Agency and on the Internet. Policy 0070 Clinical Data Publication was established under this article. The Agency is committed to transparency and in line with this article it may be possible to take further initiatives in future.
Line 284-287	9	Access to a document containing opinions for internal use as part of deliberations and preliminary consultations within EMA shall be refused even after the decision has been taken if EMA determines that disclosure of the document would seriously undermine the Agency's decision-making process, unless there is an overriding public interest in disclosure. Opinions for internal use and preliminary consultations should be made available publicly, when EMA has made a decision on them and not be labeled as "non-releasable", particularly after the decision making process has been completed.	EMA would like to highlight that lines 284 to 287 of the revised policy reflect the wording provided in the second subparagraph of Article 4(3) of Regulation (EC) No 1049/2001. The Agency is, therefore, required to observe the applicable legislation.
	18	Dear Madam/Sir, There is a high public interest in the results of the environmental risk assessment (ERA) of human and veterinary medicinal products. To close knowledge	Through Policy 0070 Clinical Data Publication the Agency proactively publishes clinical study reports for a human medicinal product following the Commission Decision. The initiative of the CRED evaluation method is noted. European

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		gaps is also of high interest for the newly developed EU strategy on pharmaceuticals which has just been published: http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-2210630_en For retrospective and prospective risk-assessment perspective it is important that results are systematically published in the PARs/EPARs throughout all different authorisation procedures and are made publicly available. This does not only apply to the overall result of the assessment, but also to the endpoints of all studies generated for the active substance and not for the product. In close collaboration with 75 risk assessors from 12 nations we have developed a transparent ecotoxcity data evaluation and reporting method called CRED which might facilitate this. “The CRED evaluation method is currently piloted and recommended in the revision of the EU Technical Guidance Document for EQS values for key studies and applied in the revision of EQS proposals for Switzerland. Additionally, the CRED criteria are applied in the Literature Evaluation Tool of the Joint Research Centre, as well as in the reliability evaluation of ecotoxicity studies for data bases, such as the NORMAN EMPODAT. In addition, the CRED evaluation method is being considered for inclusion in the project Intelligence-led Assessment of Pharmaceuticals in the Environment (iPiE), which is financed by the pharmaceutical industry and the EU Commission.” More information and two related publications about	Public Assessment Reports are updated in line with the regulatory status of a medicinal product.

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		CRED are available at: http://www.ecotoxcentre.ch/projects/risk-assessment/cred/?_ga=2.243791302.235873458.1495132857-2010536200.1495132857 With more data transparency and an appropriate data exchange tool, the public access to environmental information of veterinary and human medicinal products can be optimized and knowledge gaps can be closed effectively. Sincerely	
	17	On behalf of the Dutch Medicines Evaluation Board, I would like you to know that we support further initiatives to proceed transparency and publicity. However, it is important to us that data which are reducible to persons are deleted, such as the names of experts who are involved in an assessment of a medicinal product, because it breaches their personal living ambiance. We would appreciate it when you could consider our opinion when deciding about your policy. When you have any questions or comments, please do not hesitate to contact me.	Under the access to document output table related to medicinal products for human and veterinary products, section 6, as a general principle the names of the members of CHMP/CVMP/PRAC/COMP/HMPC/PDCO/CAT and Working Party members as well as the names of SAG core members are published on the EMA website. The names of CHMP/CVMP and PRAC (Co) Rapporteurs involved in pre-authorisation activities, as well as in arbitration and referral procedures and the names of scientific committee peer reviewers are released only following the Commission Decision to grant or to refuse the marketing authorisation or following the Committee Opinion on the outcome of the arbitration/referral procedure is available or upon availability of the company's letter notifying the withdrawal. The names of CHMP/CVMP members expressing a divergent position in the annexes of the Committee's opinion are published at the time of the opinion unless re-examination has been requested. In the case of re-examination, the names will be published at the time of the outcome of the re-examination or upon availability of the company's letter notifying the withdrawal. The names of

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			CHMP/CVMP and PRAC (Co)-Rapporteurs involved on post-authorisation activities are published on the EMA website. The names of Rapporteur)s), peer-reviewers and assessors invovled in the establishment of Community herbal monographs and Community list entries are releasable after adoption by HMPC of the Assessment Report.The names of CHMP/CVMP and PRAC assessors who are part of the CHMP/CVMP (Co)-Rapporteur team are not released or published.