Joint response to the EMA's consultation on its policy on access to documents

17 May 2017

1. European Medicines Agency policy on access to documents (EMA/729522/2016)

The policy on access to documents (EMA/ 729522/2016) highlights the European Medicines Agency's (EMA) approach to embrace openness of operations as an important feature and the widest possible access to the documents that it produces or receives and has in its possession. The policy has been revised to take into account experience gained since the introduction of the policy in 2010.

Please use the table below to comment on the European Medicines Agency policy on access to documents (EMA/729522/2016).

Line number(s) *(e.g. 20-23)*	Comment	Proposed changes, if any *(If changes to the wording are suggested, they should be highlighted)*
9-10	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*	To add: EMA shall, without delay, set up a comprehensive public register of all documents it produces and receives.

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	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 documents."	
43 – 55	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.	
53 - 55	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 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,	

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	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.	
53 -55	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.	
75 - 78	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 must fully comply with Regulation N°1049/2001 on access to documents and the Treaty on the Functioning of the EU (TFEU), which identifies the "*protection of health and life of humans*" as an overriding public interest and freedom of information as a fundamental right of European citizens. The objective of Regulation N° 1049/2001 is to provide the widest possible access to documents. Under Regulation 1049/2001, confidentiality is an exception: "*In principle, all documents of the institutions should be accessible to the public. However, certain public and private interests should be protected by way of exceptions*" (Regulation 1049/2001, recital 11).

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		The Regulation specifies that confidentiality does not apply if there is an overriding public interest in disclosure. In addition, the TFEU identifies the *"protection of health and life of humans"* as an overriding public interest. Access to regulatory documents, especially clinical study reports and decisions on medicines, is crucial to enhance public health.
81 - 83	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.	A sentence to be added after line 83: Redactions of patient numbers in clinical study reports shall not be allowed.
84 - 86		…, access to documents or parts thereof ~~may~~ **must** be granted whenever an overriding public interest in disclosure can be identified by EMA,…
87 - 94	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,	Sentences to be added: It is the regulator's duty to make available data underlying decision-making for all drugs in its purview. EMA shall put simple measures in place to at least partially address some problems: (1) EMA shall increase resources to deal with access to document requests in a timely manner. (2) To set up a permanent forum between the EMA and requestors helping each side maximise the efficiency of the data

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	such as Prescrire, have experienced increasing delays and difficulties with their own requests. EMA should increase resources to deal with 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.	request/release process through mutual education and exchange of views.[i] (3) To make publicly available a list of holdings by compound name to avoid unnecessary emails for identifying desired materials. EMA should launch a call to select independent volunteer researchers to help build a list of EMA holdings.[ii]
92 - 94	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	The following sentence must be added at the end of line 94: "Clinical data on medicinal products held by EMA (including third-party documents) are information in the public interest and must not be withheld. These documents don't require any redaction prior to

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	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 Food and Drug Administration (FDA) and the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA).	disclosure".
97 - 105	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.	Regarding agreements with non-EU regulators and international organisations, the following sentence should be added: The document or information shall be released if there is an overriding public interest in disclosure.

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112 -116	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 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.	Sentence to replace the proposed definition of commercially confidential information (CCI): The following definition of "commercially confidential information" (CCI) shall be applicable: Commercially confidential information (CCI) shall mean information that is not in the public domain or publicly available and where disclosure is duly justified to undermine the legitimate economic interest of the clinical trial sponsor during a period of time that should be specified to the requesting person. In general, clinical trial data cannot be considered CCI. That also applies to protocols, any additional documents, like financial and publication agreements with investigators, investigators' brochure, and results from toxicology studies which provide important insights in benefits and harms and the risk of bias. Public health interests outweigh considerations of CCI. If only parts of a requested document contain CCI, these might be blacked out while the entire document shall be released.
118 - 136	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.	A sentence to be added after line 136: In any case, whenever necessary, EMA shall, without delay, launch public alert campaigns about harmful adverse effects providing understandable and detailed information to allow health professionals to protect patients.

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	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. 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.	

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	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.	
137 - 149	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 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.	

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	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).	To be added: EMA commits to releasing a detailed document pointing out the occasions and circumstances where pharmaceutical companies might directly or indirectly influence EMA activities and underlying decision-making processes. This document shall be submitted for public consultation.
169	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 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	

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	confidentiality.	
173 - 176	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 EMA to ensure a smooth application of its access to documents	

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	policy during the course of these proceedings.	
192 -193	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.	Change in sentences 192-193: Third-party documents will either be classified as "releasable'' or, if otherwise, will be disclosed whenever there is an overriding public interest in disclosure.
206 – 236 216 - 218	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	

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	essence, regulatory data, created for public interest use. When Clinical Study Reports are received at EMA, 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.	
219 – 220	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).	
225 - 228	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.	

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	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 for independent research organisations' analyses.	
257	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	

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	Court of Justice of the EU, we strongly encourage the EMA to maintain a smooth functioning and policy regarding access to documents.	
284-287	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 should not be automatically classified as "non-releasable'', especially when the decision-making process is over.	
304 - 318	Handling of initial applications: Based on our experience with requests for documents, the EMA rarely meets its deadline to reply.	

2. Output of the European Medicines Agency policy on access to documents related to corporate documents (EMA/183710/2016)

This 'Output Table Corporate' relates to corporate documents, for example to conflicts of interest declarations, SOPs and WINs and corporate documents that are already publically available on the EMA's website.

Please use the table below to comment on the Output of the European Medicines Agency policy on access to documents related to corporate documents (EMA/183710/2016).

Line number(s) *(e.g. 20-23)*	Comment	Proposed changes, if any *(If changes to the wording are suggested, they should be highlighted)*
	General comment: We call upon EMA to prioritise proactive, rather than reactive, disclosure. This is equally valid for documents of a corporate nature. We also urge EMA to take in due consideration the principle of the overriding public interest in disclosure at all times.	

3. Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use (EMA/127362/2006, Rev. 1)

This "Output Table Scientific" lists the document types which may be subject to requests for access to documents related to medicinal products for human and veterinary use.

Please use the table below to comment on the Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use (EMA/127362/2006, Rev. 1).

Line number(s) *(e.g. 20-23)*	Comment	Proposed changes, if any *(If changes to the wording are suggested, they should be highlighted)*
	We call upon EMA to prioritise proactive, rather than reactive, disclosure. This is equally valid for documents of a corporate nature. We also urge EMA to take in due consideration the principle of the overriding public interest in disclosure at all times.	
7O - 71	Agendas and minutes of CHMP meetings: Currently, the agendas and minutes are made available on the EMA Website. However, the content of the minutes is so minimal that it is impossible to get an idea of issues at stake for individual discussion topics and the elements supporting the decisions. Agendas and detailed minutes should also be made available for the various Scientific Advisory Committees, including a list with name of participants and their declarations of interests.	

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New line 79 bis	Regulatory inspections: Data from regulatory inspections are usually considered out of public scrutiny. For the sake of public health, patient safety and transparency reasons, these data should be publicly made available[iii].	Data from regulatory inspections shall be made publicly available.
81 - 83	Scientific advice/protocol assistance/PRIME requests: To ensure EMA is transparent and accountable for its initiatives, including those involving the pharmaceutical industry, independent researchers must receive early insights into current discussions during early dialogues. At a minimum, there must be an independent assessment of the utility of such initiatives, which, to date, has not been possible due to confidentiality rules. See also our comments above (line 118–136).	
177	It would be helpful for the EMA and us to be updated about assessment reports for the re-evaluation of marketing authorisations. These reports are rarely published or are too rudimentary. There is also a need for more detailed EPARs for variations due to PSUR assessments.	
178	Publications of regular EMA analysis and detailed reports on medical errors would be very useful.	

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185 - 186	Marketing authorisation dossier / updates and changes to the Marketing authorisation dossier: It is surprising to see that one of the most important files submitted for a marketing authorisation, the Clinical Study Report is not mentioned. It is absolutely necessary for the EMA to set up a public register of all documents it holds related to marketing applications, including updates and revisions. Documents are often missing in clinical study reports (e.g., important appendices that are listed in the index of the report). The EMA must ensure that the companies have submitted everything they have listed in their reports, including appendices[iv]. Practical experience with the application of EMA's policy on access to documents shows that release can take considerable time and often only occurs following lengthy correspondence. Given the importance for independent research and public health to have duly access to scientific data, concrete measures must be implemented to make the system more efficient. EMA should increase resources to deal with access to document requests in a smooth and adequate manner.	To add: EMA shall set up a public register of all documents it holds related to the marketing authorisation application, their updates and changes. To add: EMA must ensure the companies have submitted everything listed in their reports, including protocols and related case reports and appendices. These documents should be publicly available.

Joint response from:

- Health Action International (HAI)
- International Society of Drug Bulletins (ISDB)
- NoGracias (Spain)
- Nordic Cochrane Centre
- Prescrire

[i] Doshi and Jefferson. Open data 5 years on: A case series of 12 freedom of information requests for regulatory data to the European Medicines Agency. *Trials* (2016) 17:78.
[ii] Doshi and Jefferson. Open data 5 years on: A case series of 12 freedom of information requests for regulatory data to the European Medicines Agency. *Trials* (2016) 17:78.
[iii] Charles Seife, MS. Research misconduct identified by the US Food and Drug Administration. Out of sight, out of mind, out of the peer-reviewed literature. *JAMA Intern Med*. (2015) 175(4) :567-577
"*RESULTS**:** Fifty-seven published clinical trials were identified for which an FDA inspection of a trial site had found significant evidence of 1 or more of the following problems: falsification or submission of false information, 22 trials (39%); problems with adverse events reporting, 14 trials (25%); protocol violations, 42 trials (74%); inadequate or inaccurate record-keeping, 35 trials (61%); failure to protect the safety of patients and/or issues with oversight or informed consent, 30 trials (53%); and violations not otherwise categorized, 20 trials (35%). Only 3 of the 78 publications (4%) that resulted from trials in which the FDA found significant violations mentioned the objectionable conditions or practices found during the inspection. No corrections, retractions, expressions of concern, or other comments acknowledging the key issues identified by the inspection were subsequently published.*
*CONCLUSIONS AND RELEVANCE**:** When the FDA finds significant departures from good clinical practice, those findings are seldom reflected in the peer-reviewed literature, even when there is evidence of data fabrication or other forms of research misconduct."*
[iv] Tarang Sharma, Louise Schow Guski, Nanna Freund, Peter C Gøtzsche. Suicidality and aggression during antidepressant treatment: Systematic review and meta-analyses based on clinical study reports. *BMJ* (2016) 352:i65 | doi: 10.1136/bmj.i65.
http://www.bmj.com/content/bmj/352/bmj.i65.full.pdf
"*We included 70 trials (64 381 pages of clinical study reports) with 18 526 patients. These trials had limitations in the study design and discrepancies in reporting, which may have led to serious under- reporting of harms. For example, some outcomes appeared only in individual patient listings in appendices, which we had for only 32 trials, and we did not have case report forms for any of the trials."*