03 December 2018
EMA/770027/2018

Overview of comments received on 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)

Interested parties (organisations or individuals) that commented on the draft document 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

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Stakeholder no.	Name of organisation or individual
16	Medicines for Europe
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)
11	IQWiG generally supports EMA's approach to transparency of documents related to medicinal products for human and veterinary use. This transparency improves post-authorisation decision making by providing relevant information on the benefits and harms of drugs approved by EMA.	The Agency welcomes the comment.
6	LFB does not have any comment on this proposal.	The Agency notes the comment.
5	"UBA appreciates the efforts made by EMA to revise the policy on access to documents. We do not have specific comments on both Output Tables. However, we would like to stress that there is a high public interest in the results of the environmental risk assessment (ERA) of human and veterinary medicinal products. It is important that those 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. From an environmental perspective the focus is mainly on active pharmaceutical ingredients instead on medicinal products. Hence, for the interested public it would be helpful if the information on the ERA data is not only accessible via the specific medicinal product. Therefore, we recommend implementing an additional search function to retrieve all available ERA information on the active ingredient without prior knowledge for which products an ERA has been performed. In this way, the public access to environmental information of veterinary and human medicinal products could be optimised."	This comment falls outside the scope of this Policy. However, the relevant colleagues within the Agency who deal with environmental risk assessment (ERA) of human and veterinary medicinal products have been informed of the comments made.

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
Lines 68-69	11	IQWiG specifically supports transparency of the outcome of the assessment by the CHMP. These documents will improve the understanding of the final decisions on approval of a given drug.	The Agency welcomes the comment.
Lines 81-83	11	IQWiG specifically supports transparency of recommendations from scientific advice, protocol assistance and PRIME procedures. Making this information available to other manufacturers and to the scientific community facilitates regulatory science and potentially accelerates drug development.	The Agency welcomes the comment.
Lines 185-186	11	IQWiG specifically supports transparency of the marketing authorisation dossier (incl. updates and changes to the dossier). Making full information on study methods and results from this dossier available to post-authorisation decision making like e.g. health technology assessment or development of clinical guidelines is required to support these decision making steps and improve public health. Data requested based on Policy 0043 so far are provided only to the requestor of the data. Given the public interest in availability of full information on study methods and results the documents should also be made publicly available via EMA's clinical data website which is used to publish data according to Policy 0070. This wider access would also be an efficient use of the resources needed to prepare the	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 (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000169.jsp&mid=WC0b01ac0580a45420). Policy 0070 and the implementation of Regulation (EC) No 1049/2001 relating to access to documents have different purposes. The clinical study reports 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.

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		documents for providing them to the requestor.	
Lines 12-13	3	The output table is considered as a living document.	The Output Table should be considered as a “living” document which is aimed at increasing the transparency of the Agency's classification of documents. It will be updated through a public consultation on a continuous basis taking into account further experience, as well as the legal interpretation of Regulation (EC) No 1049/2001 given by the Court of Justice of the European Union. Stakeholders are informed of EMA public consultation and be invited to comment through announcements at the EMA website under News &Events.
Lines 65, 67, 69 and 72	3	The documents related to arbitration/ referral procedures (CAPs and NAPs) are non- releasable prior to Commission Decision (CD) on the Committee opinion as pointed in lines 64, 66, 68, and line after 71 and before 72. Thus, the relevant decision to trigger release of document for these procedures is CD. Therefore, the text in lines 65, 67, 69 and 72 need to be revised. Preliminary PRAC/CHMP Rapporteur assessment reports considered as preparatory documents and therefore should not be disclosed (incl. D80 and D150 assessment reports in initial MAA review).	The text in lines 65, 67, 69 and 72 was revised to indicate that the documents referred to these lines are released once Commission Decision on the Committee opinion on the outcome of the arbitration/referral procedure is available. (Preliminary) PRAC/CHMP Rapporteur assessment reports: 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.

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			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 111 - 112	3	According to the revised Output table COMP Summary Report (orphan designation), Written comments from COMP Members and LoQs are releasable once Commission Decision granting or refusing the designation is available (or company's letter notifying the withdrawal). We strongly believe that the release of information related to orphan designation that early in development is against the principles described in the revised Policy 0043. Thus, release of orphan designation documents prior to marketing authorisation is unacceptable. • The documents contain commercially confidential information that cannot be safely redacted. • Such a release will disincentivise innovation. • The released documents can support similar submissions globally. The documents contain commercially confidential information that cannot be safely redacted: We strongly believe that COMP Summary Report (orphan	The revised version of the Output table on access to documents applies to all the documents produced/held by EMA and reflects the Agency's current practices taking into account the legal provisions of Regulation (EC) No 1049/2001, case law of the Court of Justice of the European Union and the recommendations of the European Ombudsman. Documents included in a finalised Orphan designation application procedure follow the Agency's practice when subject to access to documents requests. These documents are considered releasable subject to redactions in accordance of Article 4 of the Regulation, when such Orphan designation has been granted, refused or withdrawn and a Marketing Authorization application has or has not (yet) been submitted by the Applicant. According to the access to documents procedure, the Agency will consult with the owner (third party) of the requested document(s) so that they have a chance to propose redactions to it and justify which information should not be released according to the exceptions provided for in Article 4 of the Regulation. The third party should provide a demonstration that each and every element of the requested

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		designation) in particular contains a substantial amount of commercially confidential information (CCI) throughout the complete document, more specifically in sections Section B1: Prevalence of the orphan disease of condition in the community, Section C: Potential for return on investment, Section D3: Justification of significant benefit, and Section E1: Summary of the development of the product. Section B1: Prevalence of the orphan disease of condition in the community. Even though EMA has Points to consider on the calculation and reporting of the prevalence of a condition for orphan designation, there is a fair and significant element of innovation on how each sponsor will use and combine the different sources to calculate the prevalence. Additionally, commercial registries may be used to support these calculations, and as a result, there may be also a body of information that has its own economic value. Section C: Potential for return on investments. This section includes information on Grants and tax incentives, Past and future costs, Production and marketing costs, Expected revenues, which is clearly commercially confidential information and should by no circumstances be released to the public. Section D3: Justification of significant benefit The information in this section describes in effect the process that will be used to generate the data that, at the time of MA, will allow a company to claim the key	documents is commercially confidential or covered by any other of the exceptions set out in Article 4 of the Regulation. The Agency thereafter assesses the received justification(s) accordingly and its decision concerning the requests for access to documents is based on the provisions of the Regulation. Based on the above, it should be emphasised that since the Agency's current practice in relation to the release of documents included in an Orphan designation application, the Agency has received no legal challenges against its decisions regarding the granting of access to the requested (part of) document(s). Furthermore, it should be noted that (part of) documents released in the frame of access to documents requests, are released to the requester only and are not "publicly releasable". In the release letter to the requester the Agency indicates that according to Article 16 of the Regulation, the release of the requested document(s) in accordance with this Regulation is without prejudice to any existing rules on copyright which may limit a third party's right to reproduce or exploit released documents. The EMA shall assume no liability for any unlawful or unauthorised use, disclosure or reproduction of these documents.

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		incentive 10- year market exclusivity (ME). The public disclosure of this information or part of it early in the development may block the company from enjoying the ME in the future. Section E1: Summary of the development of the product. This section often includes information on non-clinical PK and metabolism studies that may not be publically available yet. Simple redaction of these sections from the document will not be sufficient to protect the CCI because other parts of the Report will be still giving reference and potentially hints on the information in sections B1, D3 and E1. Additionally, we believe that all of the sections include a combination of public data and secret data, which in itself is an inventive strategy. Such a release will disincentivise innovation in orphan conditions/indications: Regulation 141/2000 on orphan medicinal products has been put in place in order to incentivise development in these rare conditions/indications. However, making publically releasable detailed information on the orphan designation early in product development will have the opposite effect on the industry. One of the key incentives for orphan product is the 10-year market exclusivity (ME). However, the ME is applicable only for the first product approved in the specific therapeutic indication unless significant clinical benefit is	

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		established. Therefore, the timing of the MA submission is essential for the possibility to utilise the key incentive. Release of information on orphan designation early in development may be used by other companies to undermine the first company's commercial interest and to potentially prevent it from utilising the 10 years ME. The released documents can support similar submission globally: Companies are applying for orphan designations early in the drug development. For strategic reasons, it is possible that the application in EU is earlier than in other regions. If this information released following the EC decision on orphan designation then the document package including arguments can be used for orphan designation submission in the EU and outside of the EU for similar compounds, and this may undermining the company commercial interest globally. In addition, it has to be noted that the currently effective Output table clearly states that this type of information can be made public only "P once Commission Decision is available for concerned medicinal product granting or refusing the orphan MA/ new orphan indication (or company's letter notifying the withdrawal)". Based on the rationale above we strongly believe that the text in the Output table has to be revised as proposed below which is in line with the currently	

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		effective Output table.	
Lines 128 and 182	3	We understand that this refer to a full publication of the EMA decision on the PIP and not to the publication of the redacted version as currently foreseen in SOP/H/3455 (http://www.ema.europa.eu/docs/en_GB/document_library/Standard_Operating_Procedure_-_SOP/2009/09/WC500003019.pdf). In addition to the above, because paediatric investigation plans (PIPs) must be agreed early in development, disclosing such information that early is fully unacceptable because: • PIPs contain commercially confidential information and, • such a release would disincentivises innovation. Commercially confidential information: Section 4 of Annex I "Details of Agreed Measures" includes detailed information about the development plan including clinical, non-clinical and quality measures for the paediatric development. Because PIPs are linked to products that have competitors, this premature disclosure of a complete development program that contains innovative information is putting development at risk. Additionally these documents may contain valuable CCI also related to innovative new formulations and administration regimes designed specifically for	Line 128: As indicated in the output table, line 128 refers to EMA Decisions on PIP, PIP modification and product-specific waiver (excluding the Summary Report part) which are published on EMA website once the EMA Decision is available. These EMA decisions (together with the PDCO opinion and annexes are published further to deletion of confidential information. The procedure is described in the public SOP/H/3445 ("EMA decision-making process for decisions on Paediatric Committee opinions)". Line 182: As indicated in the output table, line 182 refers to PIP and waiver decisions/public summary of the proposed evaluation of the PIP/waiver which is published on EMA website once the EMA Decision is available for concerned PIP/waiver. These EMA decisions are published further to deletion of confidential information. The procedure is described in the public SOP/H/3445 ("EMA decision-making process for decisions on Paediatric Committee opinions)".

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		pediatric populations, which are of public health benefit. Such a release would disincentivise innovation: It is an obligation for the sponsor to submit PIP early in development. However, publication of EMA Decisions on PIPs may lead to delayed submission of all paediatric development plans and, in particular, put paediatric-only indication development at risk because it will disclose the full product development plan. Further, in order to protect commercially confidential information, companies developing first in class products may decide to delay their PIP submission in order to avoid public release of information in the competitive environment. This will be in direct contradiction to the Paediatric Regulation (EC) No 1901/2006, which is aiming to "facilitate the development and accessibility of medicinal products for use in the paediatric population" (Recital 4). Therefore, we strongly believe that that such level of details should not be made publically available on the EMA website proactively but should be released only upon third party request under the conditions specified below.	
Line 132	3	Often the paediatric studies do not lead to granting or refusing MA or new indication to which PIP decision relates. PIP studies may lead only to inclusion of PIP	The output table has been revised accordingly (addition is underlined): "R once the Competent Authority's Decision is available for

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		data in the Summary of Product Characteristics.	the concerned medicinal product, granting or refusing the MA/new indication or amending the SmPC to which the PIP Decision relates (or company's letter notifying the withdrawal of the MA)".
Page 58, Footnote 7	3	Footnote 7 states that "Redaction of EMA documents will be carried out to remove any reference to commercial confidential information or to personal data." [emphasis added]. Is this claim still valid today, given how our understanding of what may legally constitute personal data has evolved since 2010? Anecdotal experience under Access to Documents suggests EMA expects a "lighter touch" with regard to anonymisation than is true under Policy 0070. But this is not spelled out in the policy, nor any rationale offered for a difference in approach, if there is one.	Personal data Policy 0070 and Policy 0043. In the context of a request for access to documents pursuant to Regulation (EC) No 1049/2001 (Policy/0043), the Agency may only refuse access to a document or parts of a document if one or more of the exceptions provided in Article 4 of Regulation (EC) No 1049/2001 are applicable. Article 4 (1) b provides for an exception from disclosure for information that may undermine the privacy and integrity of the individual, in particular with regard to EU data protection legislation. Given definition of personal data contained in the applicable data protection legislation (i.e. Regulation (EC) No 45/2001), EMA considers that CSRs consist mostly of pseudonymised aggregated data and that they cannot be published or made available further to request for access to documents as such, but that they need to be anonymised. It is therefore important to recall that with regard to the publication under Policy 0070, pharmaceutical companies are requested to submit clinical reports that have been rendered anonymous for the purpose of publication. The extent to which CSRs must be subject to redaction of information or alternative anonymization techniques will depend on the assessment that each MAA/MAH will make depending on each individual case and the contextual information concerning a specific trial. The context of the publication of clinical data for medicinal products for human use under Policy 0070 is therefore

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			different from that under Regulation (EC) No 1049/2001 on access to documents and the level of anonymisation that MAA/MAH 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/MAHs (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. Under Policy 0043, are there are any restrictions on how recipients may use the disclosed reports, such as attempting to re-identify trial participants or releasing the reports publicly? This would affect the anonymisation standard. EMA releases only anonymised copies of CSRs and no personal data of trial participants is included in the disclosed documents. The release of documents by EMA under Regulation (EC) No 1049/2001 is without prejudice to the application of legislation setting out rules on the protection of personal data or in accordance with Article 16 of Regulation (EC) No 1049/2001, to any existing rules on copyright which may limit a third party's right to reproduce or exploit released documents. The European Medicines Agency shall assume no liability for any unlawful or unauthorised use, disclosure or reproduction of these documents or for any unlawful action that the recipients of the documents will take with regard to the attempts to the re-identification of trial participants. Does EMA accept full legal responsibility for protection of

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			personal data under Policy 0043? As an EU Agency, EMA is subject to the provisions of Regulation (EC) No 45/2001 concerning the protection of personal data. It has been already clarified that in accordance with Regulation (EC) No 1049/2001, no personal data of trail participants are disclosed in the documents released to the public and that EMA redacts any information contained in the documents that may constitute personal data of trial participants, as per the definition of Article 2 (a) of Regulation (EC) No 45/2001. It should be recalled that in accordance with relevant EU pharmaceutical legislation, the third party/MAH is responsible for submitting to the EMA the results of clinical trials (Cfr. Article 6 of the Regulation (EC) 726/2004 referring to the particulars of Article 8 and Annex I of Directive 2001/83/EC). In submitting the documentation related to clinical trials, the applicant for a marketing authorisation of a medicinal product is responsible and certifies that the trials have been conducted in accordance with Good Clinical Practices, including the respect of patient confidentiality (see: Principle 2.11 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s)). This means that the records submitted by the MAH should not contain information of a personal nature that may result in an unlawful processing of personal data in violation of the GCP rules prior to the submission to regulatory bodies such as EMA according to the intended

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			purposes.
Lines 7O - 71	7, 12,14,15,19	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. 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.	Information on what documents are published and when can be found in our webpage (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000169.jsp&mid=WC0b01ac0580a45420). 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 which are published on a publically available website where personal data must be duly protected and commercial confidential information respected. Given that the Agency already proactively publishes a large number of corporate documents on its webpage, including annual reports, work programmes, accounts, policies and procedures, and even documents discussed and/or adopted by the Management Board after each meeting, it considers that it already prioritises proactive disclosure of the main corporate documents. In addition, other corporate documents are disclosed, when applicable, upon request. The Agency considers that no additional action can be taken on the basis of the nature of the comments and the level of transparency for corporate documents. Declarations of interest of experts are available on the EMA corporate website.
New line 79 bis	7,12,14,15,19	Regulatory inspections: Data from regulatory inspections are usually	Line 79 of the Output Table reflects the wording of Article 4(2) third indent Regulation (EC) No 1049/2001 which states: “The institutions shall refuse access to a document where

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		considered out of public scrutiny. For the sake of public health, patient safety and transparency reasons, these data should be publicly made available.	disclosure would undermine the protection of …— the purpose of inspections, investigations and audits, unless there is an overriding public interest in disclosure". As stated in the EMA/EMA Guidance on the identification of commercially confidential information and personal data within the structure of the marketing authorisation application, information on the outcome of inspections (e.g. compliance/non compliance/outstanding issues to be addressed) is not regarded as confidential and in principle are released. However specific details e.g. information regarding facilities and equipment are considered commercially confidential and are considered as non-releasable. Any information available at EudraGMP cannot be considered commercially confidential information considering it is already in the public domain.
Lines 81 - 83	7,12,14,15,19	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).	The comment is noted and was forwarded to the relevant EMA colleagues.
Line 177	7,12,14,15,19	It would be helpful for the EMA and us to be updated about assessment reports for the re-evaluation of	These comments fall outside the scope of this Policy. However, the relevant colleagues within the Agency who deal

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		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.	with these procedures have been informed of the comments made. Please note that changes to centralised marketing authorisations (regarding for instance variation, annual re-assessments, renewals and line extensions) are published at time of CHMP opinion and at the update of the EPAR. Please see a detailed overview of What the Agency publishes and When at the Guide to information on human medicines evaluated by the EMA.
Line 178	7,12,14,15,19	Publications of regular EMA analysis and detailed reports on medical errors would be very useful.	Please note that information on medical errors/medication errors is available at the European database of suspected drug reaction reports (http://www.adrreports.eu/). This comment falls outside the scope of this Policy. The relevant colleagues within the Agency to be informed of the comments made.
Line 185 - 186	7,12,14,15, 19	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	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

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		companies have submitted everything they have listed in their reports, including appendices. 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.	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 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 Once a Marketing Authorisation application is submitted to EMA the Agency performs a technical and regulatory/administrative validation to ensure that the submitted application fulfils the European legislative requirements of Directive 2001/83/EC as amended. EMA Committees may request additional data during the assessment process in order to perform the benefit risk scientific assessment of the application. As of October 2016, EMA introduced the proactive publication of clinical data for medicinal products for human use (EMA Policy/0070) and publishes clinical data (including Clinical Study Reports, CSRs) submitted by pharmaceutical companies to support their regulatory applications for human medicines under the centralised procedure. CSRs of human medicines authorised under the centralised procedure that do not fall within the frame of EMA Policy 0070, may be made available reactively via access to documents requests.
Section 4 (page	2	The second draft "output" document lists the various document types which may be subject to requests for access to documents related to medicinal products for	The proposal is accepted and the Output table was revised accordingly.

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49/58)		human and veterinary use. However, no explicit reference is made to the clinical study reports (CSRs) which are the most exhaustive source of information on medicines and are essential to the good conduct of medical research, to the development of new medicines and medical treatments, and to expand scientific knowledge on those medicines and treatments. Since the research and medical community but also the general public may require access to this information, this should be reflected in the table.	
Lines 65, 67, 69 and 72	16	The documents related to arbitration/ referral procedures (CAPs and NAPs) are non- releasable prior to a Commission Decision (CD) on the Committee opinion as pointed out in lines 64, 66, 68, and line after 71 and before 72. Thus, the relevant decision to trigger release of document for these procedures is CD. Therefore, the text in lines 65, 67, 69 and 72 needs to be revised.	The text in lines 65, 67, 69 and 72 was revised to indicate that the documents referred to these lines are released once Commission Decision on the Committee opinion on the outcome of the arbitration/referral procedure is available.
Line 13	10	It is noted the document is intended to be a living document subject to continuous change. In which case how will stakeholders be informed of planned changes and have the chance to comment on changes?	The Output Table should be considered as a “living” document which is aimed at increasing the transparency of the Agency's classification of documents. It will be updated through a public consultation on a continuous basis taking into account further experience, as well as the legal interpretation of Regulation (EC) No 1049/2001 given by the European Court of Justice. Stakeholders are informed of EMA public consultation and be invited to comment through announcements at the EMA

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			website under News & Events.
Line 15-17	10	Reference is made to the guidance on human medicines. In the absence of veterinary specific guidance the EMA approach is to follow directly the guidance for human medicines.	In the absence of veterinary specific guidance the EMA approach is to follow directly the guidance for human medicines.