European Medicines Agency

Attachment

London, 18 December 2008
Doc. Ref. EMEA/659316/2008/Final

OUTPUT OF THE DRAFT EMEA POLICY ON THE PRACTICAL OPERATION OF ACCESS TO EMEA DOCUMENTS IN THE CONTEXT OF THE AUTHORISATION AND SUPERVISION OF MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE

Introductory Remarks

This document needs to be read in conjunction with the following documents:

- Rules for the Implementation of Regulation (EC)No1049/2001 on Access to EMEA Documents (EMEA/MB/203359/2006 Rev1).
- Draft EMEA Policy on the Practical Operation of Access to EMEA Documents (EMEA/110196/2006/Final).

It should be noted that this document is a “living” document which will require updating on a continuous basis taking into account further experience. Information on access to documents related to medicinal products for paediatric use, including documents related to the Paediatric Committee’s activities, will be included at a later stage.

Public

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Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Documents prepared by CHMP/CVMP (Co)-Rapporteurs - CHMP/CVMP Experts - EMEA Secretariat during the scientific assessment process (both pre- and post-authorisation)						
CHMP/CVMP Assessment Report	No	C prior to Commission Decision granting or refusing the MA/variation to the MA (or Committee Opinion if there is no subsequent Commission Decision, or company's letter notifying the withdrawal)	No	Art. 3.3. 1st §		Not applicable
		P once Commission Decision granting or refusing the MA/variation to the MA is available (or Committee Opinion if there is no subsequent Commission Decision, or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
CVMP Assessment Report (establishment of MRLs)	No	C prior to Commission Regulation establishing the MRL	No	Art. 3.3. 1st §		Not applicable

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
		P once Commission Regulation establishing the MRL is available	Yes	Not applicable	Not applicable	Yes
- (Co)-Rapporteur Assessment Report - Written comments from CXMP Members (including comments received in the context of the peer review exercise) - List of Questions and List of Outstanding Issues - Advice from Specialised Expertise (either in the context of Working Parties (e.g. BWP and PhVWP), SAGs, Ad-hoc Expert Groups, or in the context of individual advice provided)	No	C prior to Commission Decision granting or refusing the MA/variation to the MA (or Committee Opinion if there is no subsequent Commission Decision, or company's letter notifying the withdrawal)	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision granting or refusing the MA/variation to the MA is available (or Committee Opinion if there is no subsequent Commission Decision, or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
– Time schedules for applications (both pre- and post-authorisation)	No	C prior to Commission Decision granting or refusing the MA/variation to the MA (or Committee Opinion if there is no subsequent Commission Decision, or company's letter notifying the withdrawal)	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision granting or refusing the MA/variation to the MA is available (or Committee Opinion if there is no subsequent Commission Decision, or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	No
GXP (GMP, GCP, GLP, PhV) Inspection Reports	No	C	No	Art. 3.2.c)	In addition, for GCP Inspection Reports Art. 30(2) of Directive 2005/28/EC applies	Not applicable
Status reports on quality defects	No	C until the closure of the event	No	Art. 3.2.c)		Not applicable

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
		P upon closure of the event, either meaning that all regulatory actions have been concluded, or that the decision has been taken that there is no need for (further) action	Yes	Not applicable	Not applicable	Yes
Scientific Advice/Protocol Assistance Final Letters	No	C prior to Commission Decision authorising the product in the relevant indication, or prior to the MA in the relevant indication if the product has been authorised through a non-centralised licensing route	No	Art. 3.3. 2nd §		Not applicable
		P once the Commission Decision authorising the product in the relevant indication is available, or the MA in the relevant indication is available if the product has been authorised through a non-centralised licensing route	Yes	Not applicable	Not applicable	Yes

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
SAWP Lists of Questions	No	C prior to Commission Decision authorising the product in the relevant indication, or prior to the MA in the relevant indication if the product has been authorised through a non-centralised licensing route	No	Art. 3.3. 2nd §		Not applicable
		P once the Commission Decision authorising the product in the relevant indication is available, or the MA in the relevant indication is available if the product has been authorised through a non-centralised licensing route	Yes	Not applicable	Not applicable	Yes

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Agendas and minutes of the various EMEA fora where the outcome of the scientific assessment is discussed for a particular medicinal product						
Agendas of CHMP/CVMP meetings[8]	No	C prior to Commission Decision for concerned medicinal product granting or refusing the MA/variation to the MA (or 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)	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision is available for concerned medicinal product granting or refusing the MA/variation to the MA (or 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)	Yes	Not applicable	Not applicable	Yes

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
- Tables of Conclusions/Decisions of CHMP/CVMP meetings - Minutes of CHMP/CVMP meetings	No	C prior to Commission Decision for concerned medicinal product granting or refusing the MA/variation to the MA (or 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)	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision is available for concerned medicinal product granting or refusing the MA/variation to the MA (or 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)	Yes	Not applicable	Not applicable	Yes

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Agendas of COMP meetings	No	C prior to Commission Decision for concerned medicinal product granting or refusing the orphan designation (or company's letter notifying the withdrawal)	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision is available for concerned medicinal product granting or refusing the orphan designation (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
- Tables of Decisions of COMP meetings - Minutes of COMP meetings	No	C prior to Commission Decision for concerned medicinal product granting or refusing the orphan designation (or company's letter notifying the withdrawal)	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision is available for concerned medicinal product granting or refusing the orphan designation (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Agendas of Working Party meetings	No	C prior to Commission Decision for concerned medicinal product granting or refusing the MA/variation to the MA (or 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)	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision is available for concerned medicinal product granting or refusing the MA/variation to the MA (or 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)	Yes	Not applicable	Not applicable	Yes

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
- Tables of Conclusions/Decisions of Working Party meetings - Minutes of Working Party meetings	No	C prior to Commission Decision for concerned medicinal product granting or refusing the MA/variation to the MA (or 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)	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision is available for concerned medicinal product granting or refusing the MA/variation to the MA (or 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)	Yes	Not applicable	Not applicable	Yes

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Agendas of SAG and Ad-hoc Expert Group meetings	No	C prior to Commission Decision for concerned medicinal product granting or refusing the MA/variation to the MA (or 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)	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision is available for concerned medicinal product granting or refusing the MA/variation to the MA (or 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)	Yes	Not applicable	Not applicable	Yes

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Minutes of SAG and Ad-hoc Expert Group meetings	No	C prior to Commission Decision for concerned medicinal product granting or refusing the MA/variation to the MA (or 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)	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision is available for concerned medicinal product granting or refusing the MA/variation to the MA (or 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)	Yes	Not applicable	Not applicable	Yes

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Documents in relation to general scientific issues, organisational and operational aspects, discussed at the level of the various EMEA fora						
Agendas of CHMP/CVMP/COMP/ HMPC/PDCO meetings	No	P in principle	Yes	Not applicable	Not applicable	Yes
		C on a case-by-case basis, prior to finalisation of discussions at Committee level, depending on the sensitiveness of the issue (e.g. TSE, pandemic influenza strategy	No	Art. 3.3. 2nd §		Not applicable.
- Tables of Conclusions/Decisions of CHMP/CVMP/COMP/ HMPC/PDCO meetings - Minutes of CXMP meetings	No	P in principle	Yes	Not applicable	Not applicable	Yes
		C on a case-by-case basis, prior to finalisation of discussions at Committee level, depending on the sensitiveness of the issue (e.g. TSE, pandemic influenza strategy)	No	Art. 3.3. 2nd §		Not applicable.

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Agendas of Working Party meetings	No	P in principle	Yes	Not applicable	Not applicable	Yes
		C on a case-by-case basis, prior to finalisation of discussions at Committee level (or Working Party level if there is no subsequent discussion at Committee level), depending on the sensitiveness of the issue (e.g. TSE, pandemic influenza strategy)	No	Art. 3.3. 2nd §		Not applicable.
- Tables of Conclusions/Decisions of Working Party meetings - Minutes of Working Party meetings	No	P in principle	Yes	Not applicable	Not applicable	Yes
		C on a case-by-case basis, prior to finalisation of discussions at Committee level (or Working Party level if there is no subsequent discussion at Committee level), depending on the sensitiveness of the issue (e.g. TSE, pandemic influenza strategy)	No	Art. 3.3. 2nd §		Not applicable.

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Workplans of the EMEA Scientific Committees' Working Parties	No	C prior to finalisation of discussions at the respective EMEA Scientific Committee	No	Art. 3.3. 2nd §		Not applicable
		P once discussions are finalised at the respective EMEA Scientific Committee.	Yes	Not applicable	Not applicable	No
Mandates or equivalent documents such as Rules of Procedure of the EMEA Scientific Committees and their Working Parties	No	C prior to finalisation of discussions at the respective EMEA Scientific Committee and subsequent adoption by the European Commission (adoption only for the CHMP/CVMP/PDCO)	No	Art. 3.3. 2nd §		Not applicable
		P once discussions are finalised at the respective EMEA Scientific Committee and subsequent adoption by the European Commission has been obtained (adoption only for the CHMP/CVMP/PDCO)	Yes	Not applicable	Not applicable	No

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Guidelines and other related Community documents as defined in the "Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework"	No	C prior to finalisation of the discussions at the respective EMEA Scientific Committee or the Inspections Working Group, either in the context of the release for consultation phase or the final adoption phase	No	Art. 3.3. 2nd § (consultation phase) Art. 3.3. 1st § (final adoption phase)		Not applicable
		P once discussions at the respective EMEA Scientific Committee or the Inspections Working Group are finalised either resulting in a release for consultation or the final adoption	Yes	Not applicable	Not applicable	No

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Documents prepared by the EMEA Secretariat in the context of the Agency's Transparency Measures						
CHMP/CVMP/COMP/ HMPC/PDCO Press Releases/Monthly Reports	No	C prior to embargo date and time	No	Art. 3.3. 2nd §		Not applicable
		P after embargo date and time	Yes	Not applicable	Not applicable	No
Product specific Press Releases/Public Statements/Q&A documents	No	C prior to embargo date and time	No	Art. 3.3. 2nd §		Not applicable
		P after embargo date and time	Yes	Not applicable	Not applicable	No
Summaries of CHMP Opinion (both pre- and post-authorisation)	No	C prior to embargo date and time	No	Art. 3.3. 2nd §		Not applicable
		P after embargo date and time	Yes	Not applicable	Not applicable	No
EPARs (initial)	No	C prior to Commission Decision	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision is available	Yes	Not applicable	Not applicable	Yes (in the context of the EPAR preparation)
EPARs (update)	No	C prior to Commission Decision (or Committee Opinion if there is no subsequent Commission Decision)	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision is available (or Committee Opinion if there is no subsequent Commission Decision)	Yes	Not applicable	Not applicable	Yes (in the context of the EPAR preparation)

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Documents submitted by applicants and MAHs						
MA application dossier	Yes	C	No	Art. 3.2.a)		Not applicable
Variation application dossier	Yes	C	No	Art. 3.2.a)		Not applicable
MRL application dossier	Yes	C	No	Art. 3.2.a)		Not applicable
Responses to LoQ, LoOI	Yes	C	No	Art. 3.2.a)		Not applicable
Responses to Inspection reports	Yes	C	No	Art. 3.2.a)		Not applicable
Responses to Testing Reports	Yes	C	No	Art. 3.2.a)		Not applicable
Follow-up data to the Commission Decision/CHMP/CVMP Opinion:						
▪ Specific Obligations data	Yes	C	No	Art. 3.2.a)		Not applicable
▪ Follow-up Measures data	Yes	C	No	Art. 3.2.a)		Not applicable
▪ Annual Reassessment data	Yes	C	No	Art. 3.2.a)		Not applicable
PSURs	Yes	C	No	Art. 3.2.a)		Not applicable

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Renewal application dossier	Yes	C	No	Art. 3.2.a)		Not applicable
Arbitration/Referral application dossier	Yes	C	No	Art. 3.2.a)		Not applicable
PAT briefing papers	Yes	C	No	Art. 3.2.a)		Not applicable
Orphan drug applications	Yes	C	No	Art. 3.2.a)		Not applicable
Answers to COMP List of Questions	Yes	C	No	Art. 3.2.a)		Not applicable

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Other Documents						
Documents held by the EMEA, for which the EMEA is not the originator, and falling within the scope of CMD(h)/CMD(v) activities	Yes and always requiring third-party consultation prior to disclosure (e.g. for CMD(h)/CMD(v) minutes the Chairperson should be contacted)	C until the agreement by the third party is obtained	Depending on the outcome of the third-party consultation	Art. 3.3. 2nd § (even after the decision has been taken)		Yes
Documents held by the EMEA, for which the EMEA is not the originator, and falling within the scope of PhVWP activities for non-CAPs (e.g. PhVWP assessment reports prepared by MSs, PSUR assessment reports)	Yes and always requiring third-party consultation prior to disclosure (e.g. the PhVWP member representing the MS author of the document should be contacted)	C until the agreement by the third party is obtained	Depending on the outcome of the third-party consultation	Art. 3.3. 2nd § (even after the decision has been taken)		Yes (in accordance with the third-party recommendations)

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Minutes of PhVWP meetings and falling within the scope of PhVWP activities for non-CAPs	Yes, and always requiring Chairperson consultation	C until the agreement by the Chairperson is obtained	Depending on the outcome of the Chairperson consultation	Art. 3.3. 2nd §		Yes (in accordance with the Chairperson recommendations)
Agreed outcome documents from PhVWP meetings and falling within the scope of PhVWP activities for non-CAPs (e.g. Reports agreed by the PhVWP; SPC wording agreed by the PhVWP, implementation plans agreed by the PhVWP)	Yes, and always requiring Chairperson consultation	C until the agreement by the Chairperson is obtained	Depending on the outcome of the Chairperson consultation	Art. 3.3. 2nd §		Yes (in accordance with the Chairperson recommendations)
Documents held by the EMEA, for which the EMEA is not the originator, and falling within the scope of Inspections Group activities for non-CAPs	Yes and always requiring third-party consultation prior to disclosure	C until the agreement by the third party is obtained	Depending on the outcome of the third-party consultation	Art. 3.3. 2nd § (even after the decision has been taken)		Yes
Documents in the framework of Sampling and Testing	No	C	No	Art. 3.1.a)		Not applicable

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Reports linked to the EDQM Agreement as well as EDQM documents	Yes, and always requiring third-party consultation prior to disclosure	C	Depending on the outcome of the third-party consultation	Art. 3.1.a)		Yes
Documents held by the EMEA in the context of international cooperation (e.g. Third Party bilateral agreements)[9]	Yes	C	No	Art. 3.1.a)		Not applicable
Documents held by the EMEA in the context of Mutual Recognition Agreements (Assessment Reports of Regulatory Agencies, Annual Reports)	Two situations are possible: - In those cases where there is a joint ownership, consultation will take place as per the joint ownership agreement - Where there is not a specific provision, third party consultation will take place	C (in both situations), until the agreement by the third party is obtained	Depending on the outcome of the consultation	Art. 3.1.a) in case of joint ownership Art. 3.4. in case of no joint ownership		Yes

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Disclosure of names of individuals contained in EMEA documents, in terms of identification of involvement in an EMEA activity						
Names of CHMP/CVMP/COMP/ HMPC/PDCO and Working Party members (composition of Committee/Working Party only)	Not applicable	P	Yes	Not applicable	Not applicable	Not applicable
Names of SAG core members (composition of SAG core group only)	Not applicable	P	Yes	Not applicable	Not applicable	Not applicable
Names of CHMP/CVMP (Co)-Rapporteurs involved in pre-authorisation activities, as well as in arbitration and referral procedures Names of CHMP/CVMP peer reviewers	Not applicable	C prior to Commission Decision granting or refusing the MA, or on the outcome of the arbitration/referral procedure, or prior to company's letter notifying the withdrawal	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision granting or refusing the MA, or on the outcome of the arbitration/referral procedure is available, or prior to company's letter notifying the withdrawal	Yes	Not applicable	Not applicable	Not applicable

Document Type[1]	Third Party Document[2]	Classification[3]	Access[4]	Reference[5]	Additional Justification[6]	Need for Redaction of Documents Prior to Disclosure[7]
Names of CHMP/CVMP (Co)- Rapporteurs involved in post-authorisation activities	Not applicable	P	Yes	Not applicable	Not applicable	Not applicable
Names of SAG additional members and Ad-hoc Expert Group members involved in the assessment process of a specific product	Not applicable	C prior to Commission Decision granting or refusing the MA/variation to the MA, or prior to company's letter notifying the withdrawal	No	Art. 3.3. 2nd §		Not applicable
		P once Commission Decision granting or refusing the MA/variation to the MA is available, or once the company has notified the withdrawal	Yes	Not applicable	Not applicable	Not applicable
Names of Inspectors	Not applicable	C	No	Art. 3.3. 2nd §		Not applicable
Names of CHMP/CVMP assessors, part of the CHMP/CVMP (Co)-Rapporteur team (pre- and post-authorisation)	Not applicable	C	No	Art. 3.3. 2nd §		Not applicable
Names of EMEA Staff involved in pre- and post-authorisation activities	Not applicable	C (only disclosure of the name of the EMEA organisational structure responsible for the handling of the dossier)	Yes	Art. 3.3. 2nd §		Yes (replacing the name of the EMEA Staff by the name of the EMEA organisational structure responsible for the handling of the dossier)

[1] Refers to any document the EMEA produces, receives or has in its possession.

[2] Means any natural or legal person, or any entity outside the EMEA, including the Member States, other Community or non-Community Institutions and Bodies, and third countries. Either "Yes" or "No" to be filled in. "Yes" will lead to a consultation exercise with the third party with a view to assessing whether an exception ranging from Article 3.1.a) to 3.2.c) (see also footnote [5]) is applicable, unless it is clear that the document shall or shall not be disclosed.

[3] Refers to classification in one of the following categories: public (P), restricted (R) or confidential (C).

[4] Either access to be granted (Yes) or to be refused (No); in case of third-party consultation the granting or not of access will depend on the outcome of such consultation.

[5] Only to be filled in if access to EMEA documents is refused by virtue of application of one of the exceptions mentioned in Article 3 of the "Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents" (Doc: Ref. EMEA/MB/67957/2006), i.e. by referring to:

- Article 3.1.a)
  The Agency shall refuse access to a document 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 Community or a Member State.
- Article 3.1.b)
  The Agency shall refuse access to a document where disclosure would undermine the protection of privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data.
- Article 3.2.a)
  The Agency shall refuse access to a document where disclosure would undermine the protection of commercial interests of a natural or legal person, including intellectual property.
- Article 3.2.b)
  The Agency shall refuse access to a document where disclosure would undermine the protection of court proceedings and legal advice.
- Article 3.2.c)
  The Agency shall refuse access to a document where disclosure would undermine the protection of the purpose of inspections, investigations and audits.
- Article 3.3. 1st paragraph
  Access to a document, produced, received or in possession of the Agency shall be refused if disclosure of the document would seriously undermine the decision-making process.
- Article 3.3. 2nd paragraph
  Access to a document containing opinions for internal use as part of deliberations and preliminary consultations within the Agency shall be refused even after the decision has been taken if disclosure of the document would seriously undermine the Agency's decision-making process.

[6] Additional justification to be provided in order to further elaborate on the rationale for not providing access as per the reference to the exceptions mentioned in Article 3. Such additional justification will be included in the document on an ongoing basis once more experience is obtained.

[7] Redaction of EMEA documents will be carried out to remove any reference to confidential information. This should be done in accordance with the dedicated WIN (WIN/EMEA/0070)

[8] This is without prejudice to the Heads of Medicines Agencies / EMEA recommendations on transparency related to agendas / minutes on product related issues, which will be subject to a specific implementation plan.

[9] In relation to the handling of requests for access to ICH documents, the European Commission needs to be consulted first before any guidance to EMEA Staff can be provided.