EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Output of the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use

Introductory remarks

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

- Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.
- European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use) (EMA/110196/2006).

This document, which contains guidance for the application of Regulation (EC) No 1049/2001 to categories of documents held by the European Medicines Agency (EMA), is not legally binding. For any document not listed, access will be granted or refused in accordance with the principles outlined in the European Medicines Agency policy on access to documents. It should, therefore, be noted that this document is a "living" document which is aimed at increasing the transparency of the Agency's classification of documents and it will require updating on a continuous basis taking into account the legal interpretation of Regulation (EC) No 1049/2001 given by the European Court of Justice, and further experience.

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This document lists the various document types which may be subject to requests for access to documents. These document types have been classified as follows:

1. Documents in relation to product-specific issues
    1.1. Documents related to CHMP[1]/CVMP[2] activities
    1.2. Documents related to COMP[3] activities
    1.3. Documents related to HMPC[4] activities
    1.4. Documents related to PDCO[5] activities
    1.5. Documents related to CAT[6] activities
2. Documents in relation to general scientific issues, organisational and operational aspects
3. Documents prepared by the EMA[7] in the context of the Agency's Transparency policy[8]
4. Documents submitted by applicants and MAHs[9]
5. Other documents

Furthermore this document provides the Agency's position on the disclosure of the names of individuals involved in an EMA activity and contained in EMA documents.

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
1. Documents in relation to product-specific issues						
1.1 Documents related to CHMP/CVMP activities						
CHMP/CVMP Opinion (centralised, arbitration, referral procedure)	No	C prior to Commission Decision granting or refusing the MA[17]/variation to the MA (or Committee Opinion if there is no subsequent Commission Decision, or company's letter notifying the withdrawal)	No	Art. 4.3. 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
CHMP/CVMP Assessment Report (centralised, arbitration, referral procedure)	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 Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
		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 Committee conclusion if there is no subsequent Committee Opinion or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
• **(Co)-Rapporteur Assessment Report** (centralised, arbitration, referral procedure) • **Written comments from CHMP/CVMP Members** (including comments received in the context of the peer review exercise) (centralised, arbitration, referral procedure) • **LoQs[18], LoOIs[19] and RSI[20]** (centralised, arbitration, referral procedure) • **Advise from Specialised Expertise** (either in the context of Working Parties (e.g. BWP[21] and PhVWP[22]), SAGs[23], Ad-hoc	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 Committee conclusion if there is no subsequent Committee Opinion or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
Expert Groups, or in the context of individual advice provided) (centralised, arbitration, referral procedure)		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 Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
• **Agendas of CHMP/CVMP meetings** • **Tables of Conclusions/Decisions of CHMP/CVMP meetings** • **Minutes of CHMP/CVMP meetings**	No	C for concerned medicinal product prior to Commission Decision 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. 4.3. 1st §		Not applicable
		P for concerned medicinal product once Commission Decision granting	Yes	Not applicable	Not applicable	Yes

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
		or refusing the MA/variation to the MA is available (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)				
• **Agendas of CHMP/CVMP Working Party[24] meetings** • **Tables of Conclusions/Decisions of CHMP/CVMP Working Party meetings** • **Minutes of CHMP/CVMP Working Party meetings**	No	C for concerned medicinal product prior to Commission Decision 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. 4.3. 1st §		Not applicable
		P for concerned medicinal product 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 Committee conclusion if there is no subsequent Committee Opinion, or	Yes	Not applicable	Not applicable	Yes

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
		company's letter notifying the withdrawal)				
• **Agendas of SAG and Ad-hoc Expert Group meetings** • **Minutes of SAG and Ad-hoc Expert Group meetings**	No	C for concerned medicinal product prior to Commission Decision 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. 4.3. 1st §		Not applicable
		P for concerned medicinal product 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 Committee conclusion if there is no subsequent Committee Opinion, or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
Activities relating to MRL[25] setting (CVMP Opinion, CVMP Assessment Report, (Co)-Rapporteur	No	C prior to the submission of the MA application for a veterinary medicinal product containing the	No	Art. 4.2. 1st indent		Not applicable

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
Assessment Report, written comments from CVMP Members, LoQs, advice from specialised expertise (either in the context of Working Parties, SAGs, Ad-hoc Expert Groups, or in the context of individual advice provided), time schedules for applications)		relevant active substance for use in a species to which the MRL evaluation relates (or company's letter notifying the withdrawal)				
		C prior to Commission Decision granting or refusing the MA for a veterinary medicinal product containing the relevant active substance for use in a species to which the MRL evaluation relates (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		P once Commission Decision granting or refusing the MA for a veterinary medicinal product containing the relevant active substance for use in a species to which the MRL evaluation relates is available (or company's letter notifying the withdrawal MAA)	Yes	Not applicable	Not applicable	Yes

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
GXP (GMP, GCP, GLP, PhV) Inspection Reports – inspections requested by EMA scientific committees and coordinated by EMA	No, once final and received by EMA	C	No	Art.4.2. 3rd indent		Not applicable
GXP (GMP, GCP, GLP, PhV) Inspection Reports – Inspection carried by NCAs under their national inspection programmes	Yes	C	No	Art. 4.2. 3rd indent		Not applicable
GXP (GMP, GCP, GLP, PhV) Inspection Reports –inspections conducted by third parties (non-EU countries or international organisations)	Yes	C	No	Art. 4.2. 3rd indent		Not applicable
• **Scientific Advice/Protocol Assistance Final Letters** • **Scientific Advice/Protocol Assistance Coordinators' Reports**	No	C prior to the submission of the MA application/variation application introducing the indication/additional population to which the Scientific Advice for the concerned product relates	No	Art. 4.2. 1st indent		Not applicable

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
		C from submission of the MA application/variation application and prior to Commission Decision granting or refusing the MA/variation to the MA introducing the indication/additional population to which the Scientific Advice for the concerned product relates (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		P once Commission Decision is available granting or refusing the MA/variation to the MA introducing the indication/additional population to which the Scientific Advice for the concerned product relates (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
1.2 Documents related to COMP activities						
Opinion on Orphan Designation (Opinion page only)	No	C prior to Commission Decision granting or refusing the designation (or to company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		P once Commission Decision granting or refusing the designation is available (or to company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
• **COMP Summary Report** (orphan designation) • **Written comments from COMP Members** • **LoQ**s	No	C prior to the submission of the orphan MA application/new orphan indication (or to the company's letter notifying the withdrawal)	No	Art. 4.2. 1st indent		Not applicable
		C prior to Commission Decision for concerned medicinal product granting or refusing the orphan MA/ new orphan indication (or company's letter notifying the withdrawal)		Art. 4.3. 1st §		Not applicable
		P once Commission Decision is available for concerned medicinal product granting or refusing the	Yes	Not applicable	Not applicable	Yes

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
		orphan MA/ new orphan indication (or company's letter notifying the withdrawal)				
• **Opinion on review of designation criteria at time of Marketing Authorisation/New Orphan Indication** • **Summary report of review of designation criteria at time of Marketing Authorisation/New Orphan Indication**	No	C prior to Commission Decision granting or refusing the orphan MA/new orphan indication (or to company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		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)	Yes	Not applicable	Not applicable	Yes

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
• **Agendas of COMP meetings** • **Minutes of COMP meetings**	No	C for concerned medicinal product prior to Commission Decision granting or refusing the orphan MA/new orphan indication (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		P for concerned medicinal product once Commission Decision granting or refusing the orphan MA/new orphan indication is available (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
1.3 Documents related to HMPC activities: prepared by HMPC Rapporteurs – HMPC Experts during the scientific assessment process for the establishment of Community herbal monographs and Community list entries						
HMPC Opinions	No	P after adoption by HMPC	Yes	Not applicable	Not applicable	No
HMPC Assessment Report	No	C before adoption by HMPC for publication	No	Art. 4.3. 1st §		Not applicable
		P after adoption by the HMPC	Yes	Not applicable	Not applicable	Yes
Bibliographic references (supporting HMPC assessment reports)	No	P	No[26]	Not applicable	Not applicable	Not applicable
Overviews of comments received during public consultation period	No	C before adoption by HMPC for publication	No	Art. 4.3. 1st §		Not applicable
Community herbal monographs and list entries (submitted by interested parties in accordance with the ''HMPC Procedure on management of proposals from interested parties for Community list entries and Community herbal monographs' (EMEA/HMPC/328575/2007))	Yes	C before the procedure establishing the HMPC monograph is finalised/the list entry is published by the European Commission	No	Art. 4.3. 1st §		Not applicable

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
		P after the procedure establishing the HMPC monograph is finalised/the list entry is published by the European Commission	Yes	Not applicable	Not applicable	No

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
1.4 Documents related to PDCO activities						
EMA Decisions on PIP[27], Modifications and Waivers	No	P once the EMA decision is available (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	No
PDCO Compliance Opinion	No	P once the PDCO Opinion is available (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	No
• **PDCO Opinions on PIP, Modifications and Waivers** • **EMA/PDCO Summary Reports on PIPs, waivers and PIP Modifications** • **PDCO compliance reports**	No	C prior to the submission of the MA application/new indication to which the PIP relates (or company's letter notifying the withdrawal)	No	Art. 4.2. 1st indent		Not applicable
		C prior to Commission Decision for concerned medicinal product granting or refusing the MA/new indication to which the PIP relates (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		P once Commission Decision is available for concerned medicinal product granting or refusing the MA/new indication to which the PIP relates (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
• **Agendas of PDCO meetings** • **Minutes of PDCO meetings**	No	C prior to Commission Decision for concerned medicinal product granting or refusing the MA/new indication (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		P once Commission Decision is available for concerned medicinal product granting or refusing the MA/new indication (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
1.5 Documents related to CAT activities						
CAT Draft Opinion	No	C prior to Commission Decision granting or refusing the MA/variation to the MA (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		P once Commission Decision granting or refusing the MA/variation to the MA is available (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
CAT Assessment Report	No	C prior to Commission Decision granting or refusing the MA/variation to the MA (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		P once Commission Decision granting or refusing the MA/variation to the MA is available (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
• **(Co)-Rapporteur Assessment**	No	C prior to Commission Decision	No	Art. 4.3. 1st §		Not applicable

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
Report • **Written comments from CAT Members** (including comments received in the context of the peer review exercise) • **LoQs and LoOIs** • **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)		granting or refusing the MA/variation to the MA or company's letter notifying the withdrawal)				
		P once Commission Decision granting or refusing the MA/variation to the MA is available (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
• **Agendas of CAT meetings** • **Tables of Conclusions/Decisions of CAT meetings** • **Minutes of CAT meetings**	No	C prior to Commission Decision for concerned medicinal product granting or refusing the MA/variation to the MA (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
		P for concerned medicinal product once Commission Decision granting or refusing the MA/variation to the MA is available (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
• **Agendas of CAT Working Party meetings** • **Tables of Conclusions/Decisions of CAT Working Party meetings** • **Minutes of CAT Working Party meetings**	No	C prior to Commission Decision for concerned medicinal product granting or refusing the MA/variation to the MA (or company's letter notifying the withdrawal)	No	Art. 4.3. 1st §		Not applicable
		P for concerned medicinal product once Commission Decision is available granting or refusing the MA/variation to the MA (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
Documents related to ATMP Certification (Request for supplementary information for ATMP Certification, CAT certification evaluation report (D90), CAT Opinion on certification, EMA Certificate for	No	C prior to Commission Decision for concerned medicinal product granting or refusing the MA application (or company's letter notifying the withdrawal)	No	Art. 4.2. 1st indent		Not applicable

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
ATMP certification or EMA advisory letter refusing ATMP certification)		P once Commission Decision is available for concerned medicinal product granting or refusing the MAA (or company's letter notifying the withdrawal)	Yes	Not applicable	Not applicable	Yes
Documents related to ATMP Classification (CAT Recommendation on classification as ATMP, List of questions for the ATMP classification procedure)	No	C prior to end of the procedure at Day 60	No	Art 4.3. 1st §		Not applicable
		P after the procedure at Day 60	Yes	Not applicable	Not applicable	Yes

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
2. Documents in relation to general scientific issues, organisational and operational aspects						
Agendas of CHMP/CVMP/COMP/ HMPC/PDCO/CAT meetings	No	P in principle around the time of the meeting	Yes	Not applicable	Not applicable	Yes
		C on a case-by-case basis, even after finalisation of discussions at Committee level	No	Art. 4.3. 2nd §		Not applicable
• **Tables of Conclusions/Decisions of CHMP/CVMP/COMP/ HMPC/PDCO/CAT meetings** • **Minutes of CHMP/CVMP/COMP/HMPC/PDCO/CAT meetings**	No	P in principle	Yes	Not applicable	Not applicable	Yes
		C on a case-by-case basis, even after finalisation of discussions at Committee level	No	Art. 4.3. 2nd §		Not applicable
Agendas of Working Party meetings	No	P in principle around the time of the meeting	Yes	Not applicable	Not applicable	Yes
		C on a case-by-case basis, even after finalisation of discussions at Committee level	No	Art. 4.3. 2nd §		Not applicable

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
• **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, even after finalisation of discussions at Committee level	No	Art. 4.3. 2nd		Not applicable
Workplans of the EMA Scientific Committees' Working Parties	No	P once discussions are finalised at the respective EMA Scientific Committee.	Yes	Not applicable	Not applicable	No
Mandates or equivalent documents such as Rules of Procedure of the EMA Scientific Committees and their Working Parties	No	P once discussions are finalised at the respective EMA 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
Guidelines and other related Community documents (as defined in the 'Procedure for EU guidelines and related documents within the pharmaceutical legislative	No	P once discussions at the respective EMA Scientific Committee or the Inspections Working Group are finalised either resulting in a release for	Yes	Not applicable	Not applicable	No

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
framework' (EMEA/P/24143/2004 Rev. 1 corr))		consultation or the final adoption				

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
3. Documents prepared by the EMA in the context of the Agency's Transparency Policy						
CHMP/CVMP/COMP/HMPC/PDCO /CAT Press Releases/Monthly Reports/Meeting Reports	No	P after embargo date and time	Yes	Not applicable	Not applicable	No
Product specific Press Releases/Public Statements/Q&A documents	No	P after embargo date and time	Yes	Not applicable	Not applicable	No
Summaries of CHMP Opinion (both pre- and post-authorisation)	No	P after embargo date and time	Yes	Not applicable	Not applicable	No
EPARs[28] (initial)	No	P once Commission Decision is available	Yes	Not applicable	Not applicable	No
EPARs (update)	No	P once Commission Decision is available (or Committee Opinion if there is no subsequent Commission Decision)	Yes	Not applicable	Not applicable	No
Withdrawal Assessment Reports	No	P once company's letter notifying the withdrawal is available	Yes	Not applicable	Not applicable	No

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
Public Summary of Opinion on Orphan Designation	No	P once Commission Decision on Orphan Designation is available	Yes	Not applicable	Not applicable	No
Summary of CAT Scientific Recommendation on ATMP Classification	No	P once the CAT Recommendation has been adopted	Yes	Not applicable	Not applicable	No
HMPC Assessment Report Summary for the Public	No	P after adoption by the HMPC	Yes	Not applicable	Not applicable	No
PIP and Waivers Decision / Opinion summaries (for publishing)	No	P once EMA Decision is available for concerned PIP/waiver	Yes	Not applicable	Not applicable	No
Annual Report on deferrals of PIP measures	No	P	Yes	Not applicable	Not applicable	No

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
4. Documents submitted by applicants and MAHs						
Marketing Authorisation dossier/ updates and changes to the Marketing Authorisation dossier including pre-authorisation applications (such as Scientific Advice requests, MRL applications etc.) (centralised, arbitration, referral procedure)	Yes	C prior to Commission Decision (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. 4.3. 1st §		Not applicable
		P once Commission Decision is available (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[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
5. Other Documents						
Documents held by the EMA, for which the EMA 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)/(v) minutes the Chairperson should be contacted)	C until the third-party consultation has been finalised	Depending on the outcome of the third-party consultation	Art. 4.5.[29]		Yes
Documents held by the EMA, for which the EMA is not the originator, and falling within the scope of PhVWP activities for non-CAPs	Yes and always requiring third-party consultation prior to disclosure (e.g. for PhVWP minutes the Chairperson should be contacted)	C until the third-party consultation has been finalised	Depending on the outcome of the third-party consultation	Art. 4.5.		Yes

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
Documents held by the EMA, for which the EMA 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 third-party consultation has been finalised	Depending on the outcome of the third-party consultation	Art. 4.5.		Yes
Documents in the framework of Sampling and Testing (product related and non-product related documents)	No	C	No	Art. 4.1.(a) 3rd indent		Not applicable
Reports linked to the EDQM Agreement as well as EDQM documents	Yes, and always requiring third-party consultation prior to disclosure	C until the third-party consultation has been finalised	Depending on the outcome of the third-party consultation	Art. 4.1.(a) 3rd indent		Yes
Documents held by the EMA in the context of international cooperation (e.g. Third Party bilateral agreements)	Yes	C	No	Art. 4.1.(a) 3rd indent		Not applicable
Documents held by EMA in the	Two situations	C (in both situations), until the	Depending on	Art. 4.1.(a) 3rd		Yes

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
context of Mutual Recognition Agreements (Assessment Reports of Regulatory Agencies, Annual Reports)	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	third-party consultation has been finalised	the outcome of the third-party consultation	indent		

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
6. Disclosure of names of individuals involved in an EMA activity and contained in EMA documents						
Names of CHMP/CVMP/COMP/ HMPC/PDCO/CAT 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. 4.3. 1st §		Not applicable
		P once Commission Decision granting or refusing the MA, or on the outcome of the arbitration/referral procedure is available, or the company's letter notifying the withdrawal is available	Yes	Not applicable	Not applicable	Not applicable

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
Names of CHMP/CVMP members expressing a divergent position in the Annexes of the Committee's opinion	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. 4.3. 1st §		Not applicable
		P once Commission Decision granting or refusing the MA, or on the outcome of the arbitration/referral procedure is available, or the company's letter notifying the withdrawal is available	Yes	Not applicable	Not applicable	Not applicable
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 medicinal 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. 4.3. 1st §		Not applicable
		P once Commission Decision granting or refusing the	Yes	Not applicable	Not applicable	Not applicable

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
		MA/variation to the MA is available, or the company's letter notifying the withdrawal is available				
Names of Inspectors	Not applicable	C	No	Art. 4.2. 3rd indent		Not applicable
Names of CHMP/CVMP assessors, part of the CHMP/CVMP (Co)-Rapporteur team (pre- and post-authorisation)	Yes[30]	C	No	Art. 4.5.		Not applicable
Names of Rapporteur(s), peer-reviewers and assessors involved in the establishment of Community herbal monographs and Community list entries	Not applicable	C before adoption by HMPC of the Assessment Report (final)	No	Art. 4.3. 1st §	Not applicable	Not applicable
		P after adoption by HMPC of the Assessment Report (final)	Yes	Not applicable	Not applicable	Not applicable
Names of HMPC (Co)-Rapporteurs and HMPC peer-reviewers involved in arbitration and referral procedures	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	No	Art. 4.3. 1st §	Not applicable	Not applicable

Document type[10]	Third-party document[11]	Classification[12]	Access[13]	Reference[14]	Additional justification[15]	Need for redaction of document prior to disclosure[16]
		the withdrawal				
		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
Names of EMA Staff involved in pre- and post-authorisation activities	Not applicable	C	No	Art. 4.1.(b)	Not applicable	Yes (replacing the name of the EMA Staff by the name of the organisational structure responsible for the handling of the dossier)

1 CHMP: Committee for Human Medicinal Products.
2 CVMP: Committee for Veterinary Medicinal Products.
3 COMP: Committee for Orphan Medicinal Products.
4 HMPC: Committee on Herbal Medicinal Products.
5 PDCO: Paediatric Committee.
6 CAT: Committee for Advanced Therapies.
7 EMA: European Medicines Agency.
8 Currently being revised following the public consultation.
9 MAH: Marketing Authorisation Holder.

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

[11] Means any natural or legal person, or any entity outside the EMA, including the Member States, other Community or non-Community Institutions and Bodies, and third countries. Either "Yes" or "No" to be filled in. "Yes" may/shall lead to a consultation exercise with the third party (cfr. policy for further details) with a view to assessing whether an exception listed in Article 4 of Regulation (EC) No 1049/2011. (see also footnote 14) is applicable, unless it is clear that the document shall or shall not be disclosed.

[12] Refers to classification in one of the following categories: Public (P) or Confidential (C).

[13] 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.

[14] Only to be filled in if access to EMA documents is refused by virtue of application of one of the exceptions mentioned in Article 4 of Regulation (EC) No 1049/2001, i.e. by referring to:

- Article 4.1.(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 EU or a Member State.
- Article 4.1.(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 EU legislation regarding the protection of personal data.
- Article 4.2. 1st indent
  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 4.2. 2nd indent
  The Agency shall refuse access to a document where disclosure would undermine the protection of court proceedings and legal advice.
- Article 4.2. 3rd indent
  The Agency shall refuse access to a document where disclosure would undermine the protection of the purpose of inspections, investigations and audits.
- Article 4.3. 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 4.3. 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.

[15] 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 4. Such additional justification will be included in the document on an ongoing basis once more experience is obtained.

[16] Redaction of EMA documents will be carried out to remove any reference to commercial confidential information or to personal data.

[17] MA: Marketing Authorisation.

[18] LoQs: List of Questions.

[19] LoIs: List of Outstanding Issues.

[20] RSI: Request for Supplementary Information.

[21] BWP: Biologics Working Party.

[22] PhVWP: Pharmacovigilance Working Party.

[23] SAG: Scientific Advisory Group.

[24] This includes the QRD (Quality Review of Documents) and NRG (invented Name Review Group) meetings, where relevant.

[25] MRL: Maximum Residue Limit.

[26] Copies of bibliographic data protected by copyright, according to Article 16 of Regulation (EC) No 1049/2001, cannot directly be provided by the EMA to the public.

[27] PIP: Paediatric Investigation Plan.

[28] EPAR: European Public Assessment Report.

[29] In line with Regulation (EC) No 1049/2001 a Member State may request not to disclose without its prior agreement.

[30] A third-party consultation has been undertaken resulting in the Memorandum of Understanding between the European Medicines Agency and the National Competent Authorities of the Member States on the monitoring of the scientific level and independence of the evaluation carried out by the National Competent Authorities for services to be provided to the Agency (Doc. Ref.: EMA/150487/2010).