EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Preparation of referral opinions for publication on the EMA website (Referrals according to Article 5(3), 5(11),6(12), 6(13), 13, 20, 29(4), 29 (paediatric), 30, 31, 36 and 107 for medicinal products for human use)		
Applies to: Community Procedures Section		
Status: **PUBLIC**		Document no.: WIN/H/3205
Lead Author	Approver	Effective Date: 28-OCT-10
Name: Petra Fiedler	Name: Anabela De Lima Marçal	Review Date: 28-OCT-13
Signature: ON FILE	Signature: ON FILE	Supersedes: WIN/H/3205 (23-MAY-08)
Date: 22-SEP-10	Date: 27-OCT-10	TrackWise record no.: 2739

1. Changes since last revision

Extensive revision to the WIN.

2. Records

Transmission slip for publishing referral documents on the European Medicines Agency's external website is located under X:\Templates\File\new\Transmission Slips and is called TS - Referrals. Questions and answers document located under X:\Templates\File\new is prepared by P-MI-PIN. Electronic records are saved in the appropriately labelled folder in DREAM (see SOP/H/3193 on Master Files for Referrals).

3. Instructions

a) Abbreviations

CHMP: Committee for Medicinal Products for Human Use

DREAM: Document records electronic archive management

EMA: European Medicines Agency

EPAR: European public assessment report

INN: International non-proprietary name of the product

MA: Marketing authorisation

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MAH: Marketing authorisation holder

P-MI-PIN: Public Information and Stakeholder Networking section

PDF: Format of the document using Acrobat Distiller software

PL: Package leaflet

PTL: Product team leader

SIAMED: Database management system which tracks medicinal product data

SPC: Summary of product characteristics

Q&A: Questions and answers

V-PD-DIS: Document and Information Services section

WORD: Format of the document using Microsoft Office Word software

b) Article 20 procedures

To publish Article 20 procedure EPAR, please refer to SOP/H/3012 "Updating of the European Public Assessment Report for a medicinal product". The documents (scientific conclusion, product information and revised module 8/8b*) are published as part of the EPAR. The same approach is to be taken as for the publication of the extension of indication EPAR.

* Once Article 20 CHMP opinion is adopted, the following steps must be carried out in SIAMED in order to generate the revised module 8/8b:

Products/i. Opinion data

- select product name
- select application type - VARIATION
- select application number
- check if all presentations affected by the procedure are ticked
- enter CHMP opinion date
- save and exit

Products/e. Variation: No new MA/presentations

- select product name
- select application number
- tick relevant annexes (Annex I/II/IIIA/IIIB/A)
- enter the scope from the CHMP opinion in 'Scope (public)' field
- enter the following sentence in 'Scientific summary' field: Please refer to scientific conclusions: EMA/<product number>/A20/<procedure number>
- enter relevant dossier parts in 'Part of dossier' field
- save and exit

c) Referral procedures according to Article 5(3), 5(11), 6(12), 6(13), 13, 29(4), 29 (paediatric), 30, 31, 36 and 107

The following documents are to be published in all European languages except Norwegian and Icelandic on the European Medicines Agency's website: Home ➢ Regulatory ➢ Human medicines ➢ Referral procedures ➢ Final decisions.

1. Q&A

2. Annexes to the opinion

Step	Action	Responsibility
1	**Q&A**	
	Receive translations of "Q&A" document from V-PD-DIS (for actions preceding this task, please see SOP/H/3144, SOP/H/3192, SOP/H/3177 and SOP/H/3215). Make sure all translations have a same date and a same DREAM document reference number as the English version. The date is the date of the commission decision. Name the documents as follows: *{INN(s)*}_Q&A_{language code}* * In case of more than one INN, separate INNs by underscores. Check that there is no highlighted text in the documents and create PDF files of all translations except Norwegian and Icelandic versions. Check if all web-links in the PDF files are working and navigating to correct web pages (please note that 'CutePDF' is not suitable for publishing as web-links would not work).	Secretary
2	**Annexes to the opinion**	
	The following annexes to the opinion are to be published as appropriate: • List of applicants/MAHs and products • Scientific conclusions • SPC, labelling and PL • Conditions of the marketing authorisation • CHMP assessment report (for Art. 29 (paediatric) only) Receive translations of Annexes, "Scientific conclusions" and "Conditions of the marketing authorisation" (if applicable) from V-PD-DIS. Receive translations of Annexes "List of applicants/MAHs and products" and "SPC, labelling and PL" (if applicable) from Applicants/MAHs. Compile all Annexes per language in one WORD document in the following order:	Secretary

Step	Action	Responsibility
	1. List of applicants/MAHs and products 2. Scientific conclusions 3. SPC, labelling and PL (if applicable) 4. Conditions of the marketing authorisation (if applicable) Name the documents as follows: *{INN(s)*}_Annexes_{language code}.* * In case of more than one INN, separate INNs by underscores. Check that there is no highlighted text in the documents and create PDF files of all documents except Norwegian and Icelandic versions. <u>CHMP assessment report (for Art. 29 (paediatric) only):</u> Format the document as follows: • change the title page (see attached enclosure to this document), • delete the "product information" table in the report, • delete names of PTL and assessors/evaluation team members, • delete commercially confidential information, • remove the list of annexes together with their title pages, • check numbering of all headings, • re-run the table of contents, • check page numbering. Check that there is no highlighted text in the document and a create PDF file. Please note that this document is only published in English.	
3	**Sign-off folder**	
	Fill in the transmission slip and print it out. Place the following documents in the sign off folder: • English version of Q&A (double-sided print) • English version of compiled Annexes in double-sided print, four pages per sheet. Follow the signature and checking process as described on the transmission slip. Once signed by all concerned staff members, save prepared documents for publication (PDF files) under folder G:\External Info Draft/SIGN OFF/Human unit/Referrals and send the sign off folder to Web Team by Internal Mail.	Secretary

Enclosure: Title page of the CHMP assessment report for publication (for Art. 29 (paediatric) only)

<Commission decision date>
<EMA document reference number>
Patient Health Protection

Assessment report for <product name> and associated names

International non-proprietary name: <INN name>

Procedure number: EMEA/H/A-29 PAD/<xxx>

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

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