



Work instructions

Title: Non-removal of the EPAR following suspension of the Marketing Authorisation (MA)		
Applies to: Safety and Efficacy of Medicines (H-SE) Sector in the Human Medicines Development and Evaluation (H) Unit, Community Procedures section (P-R-CP) and Communications Sector (D-CM) in Directorate		
Status: PUBLIC		Document no.: WIN/H/3216
Lead Author	Approver	Effective Date: 12-SEP-12
Name: Jill Kieffer	Name: Noël Wathion	Review Date: 12-SEP-15
Signature: ON FILE	Signature: ON FILE	Supersedes: WIN/H/3216 (01-JUL-08)
Date: 06-SEP-12	Date: 11-SEP-12	TrackWise record no.: 2735

1. Changes since last revision

Updated to reflect the new organisational names in the Agency.

2. Records

Electronic copies are saved in the appropriately labelled folder in DREAM and in CMF.

3. Instructions

This WIN refers to SOP/H/3012: Updating of the EPAR for a human medicinal product.

Definitions

CMF	Core Master File
CP	Community Procedures
DREAM	Document Records Electronic Archive Management
EPAR	European Public Assessment Report
EC	European Commission
PTL	Product Team Leader
MA	Marketing Authorisation



Step	Action	Responsibility
1	<p>Ensure that the EPAR version published on the website will be the most up-to-date when the MA is suspended. It should reflect all completed post-authorisation procedures and in particular the outcome of the procedure under Article 20 of Regulation (EC) 726/2004 triggering the suspension.</p> <p>Preparation of Article 20 procedure for publication e.g. liaison with MAH for deletion of commercially confidential information.</p> <p>Follow SOP/H/3012 'Updating EPARs'.</p>	<p>PTL</p> <p>CP PTL</p>
2	<p>Once the suspension of the MA is official (e.g. on receipt of the Commission Decision for the procedure under Article 20), complete the transmission slip TS - Suspended EPAR¹ and save it under the following product folder (cabinets/1. Evaluation of medicines/H-C/<Product name-number>/05 Post Authorisation/Suspension of MA/Publication).</p>	<p>PTL Secretary or CP PTL Secretary if based on Art. 20</p>
3	<p>Locate all the PDF files that make up the EPAR, including the Article 20 assessment report, and watermark them with the text 'Marketing authorisation suspended' (in English only).</p> <p>Older modules will be found in previous EPAR Revision folders, and in the initial EPAR folder. Summaries of opinion that are published under the 'assessment history' tab are also watermarked.</p>	<p>PTL Secretary</p> <p>CP PTL for Art. 20 documents</p>
4	<p>Circulate the signature book.</p>	<p>PTL Secretary</p> <p>CP PTL for Art. 20</p>
5	<p>Save the watermarked PDFs, including the Article 20 assessment report, in the appropriate folder (G:/External Information Draft/SIGN OFF/unit or sector folder/topic folder).</p>	<p>PTL Secretary</p> <p>CP PTL for Art. 20</p>
6	<p>Upon receipt of the completed signature book:</p> <ul style="list-style-type: none"> - change the status of the product to 'suspended', - publish the watermarked PDDFs, including the Article 20 assessment report. 	<p>Web team</p>
7	<p>On publication of EPAR commit to CMF all final published files in DREAM.</p>	<p>PTL secretary</p> <p>CP PTL for Art. 20</p>

¹ Available under Word, File, New, My template

Step	Action	Responsibility
8	Inform the web team when: <ul style="list-style-type: none">- The suspension of the MA is lifted (then the EPAR can be updated, see SOP/H/3012),- The MA is voluntarily withdrawn by the MAH or revoked by the EC (then the EPAR needs to be marked as withdrawn, see WIN/H/3202 on the non-removal of EPARs following withdrawal of MA).	PTL
