EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Non-removal of the EPAR following withdrawal/expiry of the Marketing Authorisation		
Applies to: Safety and Efficacy of Medicines (H-SE) Sector in the Human Medicines Development and Evaluation (H) Unit and Communications Sector (D-CM) in Directorate		
Status: **PUBLIC**		Document no.: WIN/H/3202
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Signature: ON FILE	Signature: ON FILE	Supersedes: WIN/H/3202 (14-SEP-07)
Date: 06-SEP-12	Date: 11-SEP-12	TrackWise record no.: 2235

1. Changes since last revision

Update of the steps and responsibilities in watermarking the EPAR modules (step 3).

Update 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
DREAM	Document Records Electronic Archive Management
EPAR	European Public Assessment Report
EC	European Commission
PTL	Product Team Leader
MA	Marketing Authorisation

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Step	Action	Responsibility
1	Ensure that the EPAR version published on the website is the most up to date before the EC issues a Decision on the withdrawal or before the expiry date of the MA. If the EPAR needs to be updated please follow SOP/H/3012.	PTL/PTL Secretary
2	Upon receipt of the EC Decision and internal agreement on the public statement on the withdrawal/expiry (non-renewal) of the MA, complete the transmission slip TS - Withdrawn EPAR[1] and save it under the following product's folder (cabinets/1. Evaluation of medicines/H-C/<Product name-number>/05 Post Authorisation/Withdrawal of MA/Publication). Ensure that the reason for the withdrawal of the MA is clearly identified on the transmission slip (withdrawal at the request of the marketing authorisation holder, non-renewal, withdrawal by the EC for safety reasons or lapse under the 'sunset clause').	PTL Secretary
3	Locate **all** the PDF files that make up the latest EPAR and watermark them with "Medicinal Product no longer authorised" in the appropriate European Union official language. The agreed translation for "Medicinal Product no longer authorised" in all official languages must be followed (see annex). Older modules will be found in previous EPAR Revision folders, and in the initial EPAR folder.	PTL Secretary
4	Circulate the signature book, with the final agreed announcement. The process should be started as soon as possible, and in any case, publication of the watermarked PDFs should happen within 15 days of the publication of the announcement.	PTL Secretary
5	Save in the appropriate folder (G:/External Information Draft/SIGN OFF/unit or sector folder/topic folder): - the PDF version of the public statement, - the watermarked PDFs.	PTL Secretary
6	Upon receipt of the completed signature book: • change the product's status to 'withdrawn', • replace the HTML version of the EPAR summary with the appropriate text explaining the reason for the withdrawal/expiry of the MA, • publish the watermarked PDFs, • ensure that the link to the public statement on the withdrawal/expiry (non-renewal) of the MA also appears	Web team

[1] Available under Word, File, New, My template

Step	Action	Responsibility
	on the EPAR page of the withdrawn product.	
7	On publication of EPAR commit to CMF all final published files in DREAM and enter publication date to SIAMED. See guidance below. Closing an Application EMA/459672/2011 https://docs.eudra.org/webtop/drl/objectId/090142b2819623f7	PTL secretary

Annex - Official translation of the sentence to watermark all EPAR modules

English	Medicinal product no longer authorised
Bulgarian	Лекарствен продукт, който вече не е разрешен за употреба
Czech	Přípavek již není registrován
Danish	Lægemidlet er ikke længere autoriseret til salg
Dutch	Geneesmiddel niet langer geregistreerd
Estonian	Ravimil on müügiluba lõppenud
Finnish	Lääkevalmisteella ei enää myyntilupaa
French	Ce médicament n'est plus autorisé
German	Arzneimittel nicht länger zugelassen
Greek	Φαρμακευτικό προϊόν του οποίου η άδεια κυκλοφορίας δεν είναι πλέον σε ισχύ
Hungarian	A gyógyszerkészítmény forgalomba hozatali engedélye megszűnt
Icelandic	Lyfið er ekki lengur með markaðsleyfi
Italian	Medicinale non più autorizzato
Latvian	Zāles vairs nav reģistrētas
Lithuanian	Vaistinis preparatas neberegistruotas
Maltese	Prodott mediċinali li m'għadux awtorizzat
Norwegian	Legemidlet er ikke lenger godkjent for salg
Polish	Produkt leczniczy bez ważnego pozwolenia na dopuszczenie do obrotu
Portuguese	Medicamento já não autorizado
Romanian	Produsul medicinal nu mai este autorizat
Slovak	Liek s ukončenou platnosťou registrácie
Slovenian	Zdravilo nima veā dovoljenja za promet
Spanish	Medicamento con autorización anulada
Swedish	Läkemedlet är inte längre godkänt för försäljning