EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Transparency of outcome of resubmission in previously published Refusals or Withdrawal EPARs		
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/3242
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/3242 (18-JUN-08)
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1. Changes since last revision

Update to reflect the new organisational names in the Agency.

2. Records

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

3. Instructions

Step	Action	Responsibility
1	**Identify need to re-publish (PTL)** PTL identifies need to link previously published documents to the outcome of a resubmission by checking that the product is indicated as a resubmission in SIAMED:	PTL

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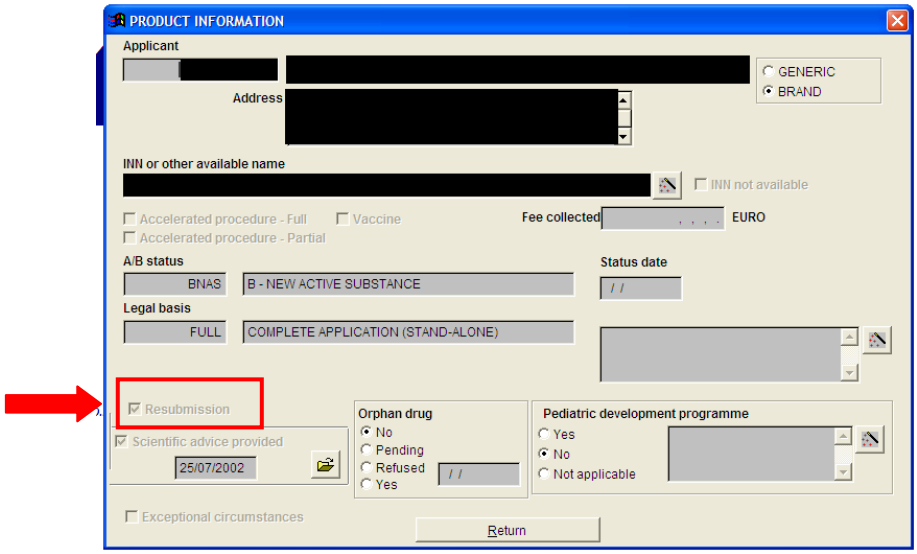
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Step	Action	Responsibility
	 While information about the resubmission should appear in the public assessment report, there CANNOT be a link from the new EPAR to the previous one. All links must go from the old EPAR to the new one.	
2	**Identify documents to republish (PTL secretary)** a. Identify documents previously published (question-and-answer documents and public assessment report). • If the previous outcome was a refusal, the information that has been published on the external website can be accessed: – Initial authorisation: from the following address: Find medicine\Human medicines\European Public Assessment Reports - refused – Extension of indication: the documents are published within the existing EPAR under the 'assessment history' tab. • If the previous outcome was a withdrawal of application, the information that has been published on the external website can be accessed: – Initial application: from the following address: Find medicine\Human medicines\Withdrawn applications - initial authorisation application – Extension of indication: from the following address: find medicine\Human medicines\withdrawn applications - post-authorisation application b. Locate corresponding files in DREAM. The files will be located in the folder of the product that was previously withdrawn or refused. The exact location will depend on the timing of the withdrawal (at day 120 or 180) or refusal	PTL/PTL secretary

Step	Action	Responsibility
	(e.g. whether there was a re-examination or not).	
3	**Prepare standard text** a. Check with web publishing team the address that will be used to publish the outcome of the resubmission. b. Use the standard text given in table 1 and prepare a product-specific version by including this web address as link to the word 'here' in all language versions of the text.	PTL secretary
4	**Create new versions for publication** a. Edit the Word version of the files to be republished to add the sentence in the appropriate language. This is added in the question-and-answer documents and in the public assessment report. Press Releases are NOT edited. The text is added as a boxed paragraph on the front page only of each document: Verdana, point size 9, centred, boxed with a single line 2 points from the text: This product was later resubmitted to the EMA. See here for information on outcome of resubmission. b. Save updated files in DREAM as new versions and create PDF versions of all files.	PTL secretary
5	**Submit for publication** Prepare the new PDF files for publication using the general web content transmission slip, requesting the replacement of the published PDFs by the new ones. This is coordinated with the sign off of the new EPAR for the resubmitted product, i.e. both sign-off books are handled together.	PTL secretary
6	Upon receipt of the completed signature book: a. replace PDFs as appropriate; b. ensure that the appropriate cross reference/link is added on the withdrawal of application/refusal of application page to the subsequent EPAR.	Web team
7	On publication of EPAR commit to CMF all final published files in DREAM and enter publication date to SIAMED. Closing an Application EMA/459672/2011 https://docs.eudra.org/webtop/drl/objectId/090142b2819623f7 Path: Cabinets/13. Projects/01-000-00082-SIAMED-II/08 Deployment/Quick Reference Guides/Approved Versions	PTL secretary

Table 1:

English	EN	This product was later resubmitted to the EMA. See here for information on the outcome of the resubmission.
Bulgarian	BG	За този продукт по-късно в ЕМА отново е подадено Заявление за разрешаване за употреба. За информация относно резултата от повторното подаване, вижте тук.
Czech	CS	Žádost o registraci tohoto přípravku byla později opět předložena EMA. Informace o výsledku tohoto řízení viz zde.
Danish	DA	EMA modtog på et senere tidspunkt en genansøgning for dette produkt. Information om resultatet af denne genansøgning findes her.
Dutch	NL	Dit product is later opnieuw ingediend bij de EMA. Klik hier voor informatie over het besluit van deze nieuwe indiening.
Estonian	ET	Informatsioon selle ravimi kohta esitati EMA-le uuesti läbivaatamiseks. Informatsiooni lõpptulemuse leiate siit.
Finnish	FI	Tätä valmistetta koskeva hakemus on jätetty myöhemmin uudelleen EMAan. Katso täältä tiedot uudelleen jätetyn hakemuksen käsittelyn tuloksesta.
French	FR	Ce produit a fait l'objet d'une resoumission. Des informations sur l'issue de la resoumission sont disponibles ici.
German	DE	Für dieses Arzneimittel wurde später erneut ein Antrag auf Zulassung bei der EMA gestellt. Informationen zum Ergebnis dieser erneuten Einreichung, siehe hier.
Greek	EL	Για το προϊόν αυτό είχε και παλαιότερα υποβληθεί αίτηση για έγκριση στον ΕΜΑ . Πατείστε εδώ για πληροφορίες σχετικά με την έκβαση της νέας κατάθεσης αίτησης.
Hungarian	HU	E készítmény forgalomba hozatali kérelmét a későbbiekben újból benyújtották az EMA. Az újonnan benyújtott kérelem elbírálásának eredményéről itt tájékozódhat.
Icelandic	IS	Umsókn vegna lyfsins var send Lyfjastofnun Evrópu að nýju. Upplýsingar um afgreiðslu umsóknarinnar í það skipti eru hér.
Italian	IT	Per questo medicinale è stata successivamente presentata all'EMA una nuova domanda di autorizzazione all'immissione in commercio. Clicca qui per ulteriori informazioni sull'esito di tale domanda.
Latvian	LV	Šis produkts vēlāk tika iesniegts atkārtoti EMA. Informāciju par atkārtotas iesniegšanas rezultātiem skatīt šeit.
Lithuanian	LT	Šio vaistinio preprato paraiška Europos vaistų agentūrai (EMA) buvo pateikta pakartotinai, informaciją apie šios paraiškos rezultatus galite rasti čia.
Maltese	MT	Dan il-prodott medicinali rega' gie sottomess iktar tard lil EMA. Ara hawn ghal iktar informazzjoni dwar il-konkluzjoni ta' din il-sottomissjoni.

Norwegian	NO	EMA har på et senere tidspunkt mottatt en ny søknad for dette preparatet. Informasjon om utfallet av denne søknaden finnes her.
Polish	PL	Dokumentacja tego produktu została ponownie złożona do rozpatrzenia w EMA w terminie późniejszym. W celu uzyskania informacji o wyniku ponownego rozpatrzenia patrz tutaj.
Portuguese	PT	Este medicamento foi posteriormente resubmetido à EMA. Veja aqui informação sobre o resultado da resubmissão.
Romanian	RO	Produsul a fost depus din nou spre evaluare de către EMA. Aici se pot vedea informaţii referitoare la rezultatele acestei depuneri.
Slovak	SK	Tento produkt bol neskôr opätovne predložený EMA. Informácie o závere opätovného predloženia pozri tu.
Slovene	SL	Dokumentacija za zdravilo je bila kasneje ponovno predložena na EMA. Za informacije o zaključku postopka za ponovno predloženo vlogo glejte tukaj.
Spanish	ES	Posteriormente se ha presentado una nueva solicitud de autorización para este medicamento. Pinche aquí para obtener más información.
Swedish	SV	Man har igen ansökt hos EMA om godkännande för denna produkt. Se här information om utfallet av denna ansökan.