EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Orphan electronic product folders		
Applies to: Orphan medicines in Product Development Scientific Support Department, Facilities Support Services in Staff Regulations and Support Department and Medical and Health Information Service, Communication Department		
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Signature: [On ile]	Signature: [On file]	Supersedes: SOP/H/3047(25-NOV-11)
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1. Changes since last revision

Title changed. Old title "Saving of documentation regarding the submission of an application for orphan medicinal product designation or amendment of an existing designation, and any other product related correspondence".

Addition of parties this WIN is applicable to A-ST-FSS and S-CO-MHI.

Introduction of DREAM labelling and versioning system.

Instruction on naming procedure documents.

Information on off-site archive.

Addition of related documents.

Minor revision of DREAM product folder structure.

2. Records

Pre-submission meeting documents are saved in DREAM in Cabinets/01. Evaluation of Medicines/H-O Orphan Drugs/Potential Applicants/Pre Submission Meetings.

Electronic product folders are saved and stored in DREAM in Cabinets/01 Evaluation of Medicines/H-O Orphan Drugs.

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Orphan medicines applications data is entered in the orphan database.

All products related documents and correspondence are saved by scientific officers and OME assistants in the relevant product folders.

Old paper product master files are stored in the off-site archive and recorded in Archive database. A-ST-FSS retrieve paper master files upon OME request.

3. Related documents

All OME SOPs (with defined steps of procedure and responsible staff member for saving relevant documents)

SOP/EMA/0138 Records disposal procedure

Security Policy – Policy/0076 (EMA/530488/2014)

Records Management Policy - Policy/0026 (EMA/590678/2007)

4. Definitions

A-ST-FSS	Facilities Support Services in Staff Regulations and Support Department in Administration and Corporate Management Division
COMP	Committee for Orphan Medicinal Products
D-DS-OME	Orphan Medicines Office in Product Development Scientific Support Department in Human Medicines Research and Development Support Division
DREAM	Document records electronic archive management system
EC	European Commission
EMA	European Medicines Agency
EudraLink	EMA regulatory network's secure file-transfer system used for exchanging information for regulatory purposes
MAH	Marketing authorisation holder
MHI writer	Medical writer (in S-CO-MHI)
MMD	Meeting Management of Documents system
OME	Orphan Medicines Office in Product Development Scientific Support Department in Human Medicines Research and Development Support Division
OME Asst	OME Assistant (in D-DS-OME)
OME co	Co-ordinator (scientific officer in D-DS-OME)
PIS	Product information sheet
PSO	Public summary of opinion
S-CO-MHI	Medical and Health Information Service, Communication Department in Stakeholders and Communication Division

5. Instructions

Electronic product folder

Step	Action	Responsibility
	Saving documentation related to the submission of an orphan application	
1	Receive application via Eudralink	OME Asst
2	Download files	OME Asst
3	Register application in orphan database and allocate orphan procedure number (EMA/OD/XXX/XX).	OME Asst
4	Create product folder in DREAM Cabinets/01. Evaluation of Medicines/H-O Orphan Drugs, following the established product folder structure[1]: **01 Pre-submission** **02 Validation** **+ Application** **+ Bibliography** **03 Evaluation** **04 Post opinion** **+ Public summary of opinion** **05 Post designation** **06 Legal** **07 Amendment** **08 CMF** Create additional subfolders (listed below) as required.	OME Asst
5	Name the product folder with the name of the active substance followed by the allocated orphan procedure number.	OME Asst
6	Save complete application under 02 Validation/Application. The bibliography should be saved in a subfolder.	OME Asst
	Saving documentation related to an orphan procedure (except for the submission of an application as described above)	
1	All documents and correspondence should be saved in the corresponding folders/subfolders according to the relevant stage of the procedure. The main documents of the procedure are listed below.	All as applicable

[1] Folder structure template is available in Cabinets/14. Working areas/14.01 D-Division/02. D-DS Activities/D-DS-OME Activities/Section activities/Templates and DREAM labels

Step	Action	Responsibility
	01 Pre-submission	
	Relevant subfolder with following documents should be linked here from pre-submission meeting folder:	OME Asst
	Draft application	
	Sponsor's minutes	
	Relevant correspondence	
	02 Validation	
	+ Application	
	+ Bibliography	
	+ Revised application following validation	
	+ Bibliography	OME Asst
	Application receipt acknowledgement	OME-co
	Validation issues letters	OME-co
	Validation checklists	OME Asst
	Start of procedure e-mail	All as applicable
	Other relevant correspondence	
	03 Evaluation	
	+ Supplementary information	
	+ Experts	
	+ Written procedure	OME Asst
	Opinion	OME Asst
	Summary report	OME Asst
	OME co presentation	OME Asst
	Sponsor's presentation	All as applicable
	Other relevant correspondence	
	04 Post opinion	OME Asst
	Notification of COMP positive opinion to sponsors	OME Asst
	Confirmation opinion and summary report sent to sponsor[2]	OME Asst
	Notification of Commission Decision	All as applicable

[2] Letter to the EC listing all adopted at the COMP meeting opinions and translations document are saved in relevant COMP meeting folder Cabinets/02b. Administration of Scientific Meeting/COMP - Administration/2. Meeting Organisation/01. Plenary meetings/year/month/Shortcuts to opinions

Step	Action	Responsibility
	Other relevant correspondence	
	+ Public summary of opinion	MHI writer
	PSO	OME Asst
	PIS	
	+ Appeal	
	+ Grounds for appeal	OME Asst
	Opinion	OME Asst
	Summary report (linked from 02 Evaluation)	All as applicable
	Other relevant correspondence	
	05 Post designation	
	+ Review of orphan designation	
	+ Sponsor's report	
	+ Supplementary information	
	+ Experts	
	+ Written procedure	OME Asst
	COMP review report	OME Asst
	COMP review opinion	OME Asst
	OME co review presentation	OME Asst
	Sponsor's review presentation	
	+ Public summary of opinion	MHI writer
	Review PSO	All as applicable
	Other relevant correspondence	
	+ Transfers	OME Asst
	Sponsor transfer request	OME Asst
	Opinion on transfer	OME Asst
	Other relevant correspondence	
	+ Annual reports	OME Asst
	Annual report documentation	
	+ Change of name or address of the sponsor	OME Asst
	Sponsor's request and relevant correspondence	
	+ Review of market exclusivity	

Step	Action	Responsibility
	+ Supplementary information	
	+ Correspondence with MAH	
	+ Correspondence with EC	
	+ Experts	
	+ Written procedure	OME Asst
	COMP opinion	OME Asst
	COMP report	OME Asst
	OME-co presentation	OME Asst
	Sponsor's presentation	All as applicable
	Other relevant correspondence	
	+ Public summary of opinion	MHI writer
	PSO	
	+ Withdrawal from Register	OME Asst
	Sponsor's request	OME Asst
	EC confirmation	
	06 Legal	All as applicable
	Relevant correspondence	
	07 Amendment	OME Asst
	Copy folder structure (01-06) from step 4	
	08 CMF	

Labelling and versioning procedure documents

Summary reports (for all OME procedures) are versioned and labelled for tracking procedural steps and electronic verification process. Opinions are labelled for recording final version and possible correction, revisions and corrigenda as applicable. Detailed labelling and versioning instructions are available in Cabinets/14. Working areas/14.01 D-Division/02. D-DS Activities/D-DS-OME Activities/Section activities/Templates and DREAM labels.

Naming procedure documents

Active substance name (can be partial) and procedure number (xxx-xx) without "EMA" should be used in all cases, e.g.:

<active substance xxx-xx> – summary report

<active substance xxx-xx> – opinion

Following special characters disturb DREAM search and MMD deep export functions and shouldn’t be used in the file/folder name:

:;,.!?/\@~#!”£$%^&*(){}[]<>

’ should be replaces by _