EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Checking of mock-ups and specimens for renewals		
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Lead author	Approver	Effective date: 17-DEC-10
Name: Ana Sempere Ortega	Name: Noël Wathion	Review date: 17-DEC-13
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1. Purpose

The purpose of this document is to ensure a consistent and efficient approach to review the mock-ups (if applicable) and the specimes for renewals following the centralised procedure.

2. Scope

This SOP applies to the Human Medicines Development Evaluation Unit, the Patient Health Protection Unit and the Veterinary Medicines and Product Data Management Unit.

3. Responsibilities

It is the responsibility of each Head of Unit, Sector and Section to ensure that this procedure is adhered to within their own unit, sector or section. The responsibility for the execution of each step is identified under **9. Procedures**.

4. Changes since last revision

Updated to reflect the new organisational names in the Agency, the new corporate identity, the new electronic system for archive management the new electronic submission of the dossier, the new SOP on core master files (SOP/PDM/1004) and the alignment of the way to communicate the comments on the mock-ups to the MAH, independently on whether the overall design and readability has changed.

Revision of the following steps:

- Step 1.1 (change responsibility from ‘MuS Team/PTL’ to ‘MuS Team’).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

- Step 1.3 (replacement of 'Prepare comments on mock-ups and forward them to PTL' with 'Prepare comments on mock-ups and forward them to MAH').
- Step 1.4 (deletion of 'Receive comments on mock-ups and forward them to the MAH').
- Step 1.7 (change responsibility from 'MuS Team/PTL' to 'MuS Team').
- Step 3 (replacement of 'Are there any specimens included in the Module 1.3.3' by 'Have specimens also been forwarded by MAH?').
- Step 7 (change responsibility from 'MuS Team/PTL' to 'MuS Team').

Revision of the following sections:

- 10. Records: inclusion of definition of record.

5. Documents needed for this SOP

Template 1: Mock-ups form

Template 2: Specimens fax to MAH

These templates can be found in X:\Templates\Others\H – Mock Ups & Specimens.

6. Related documents

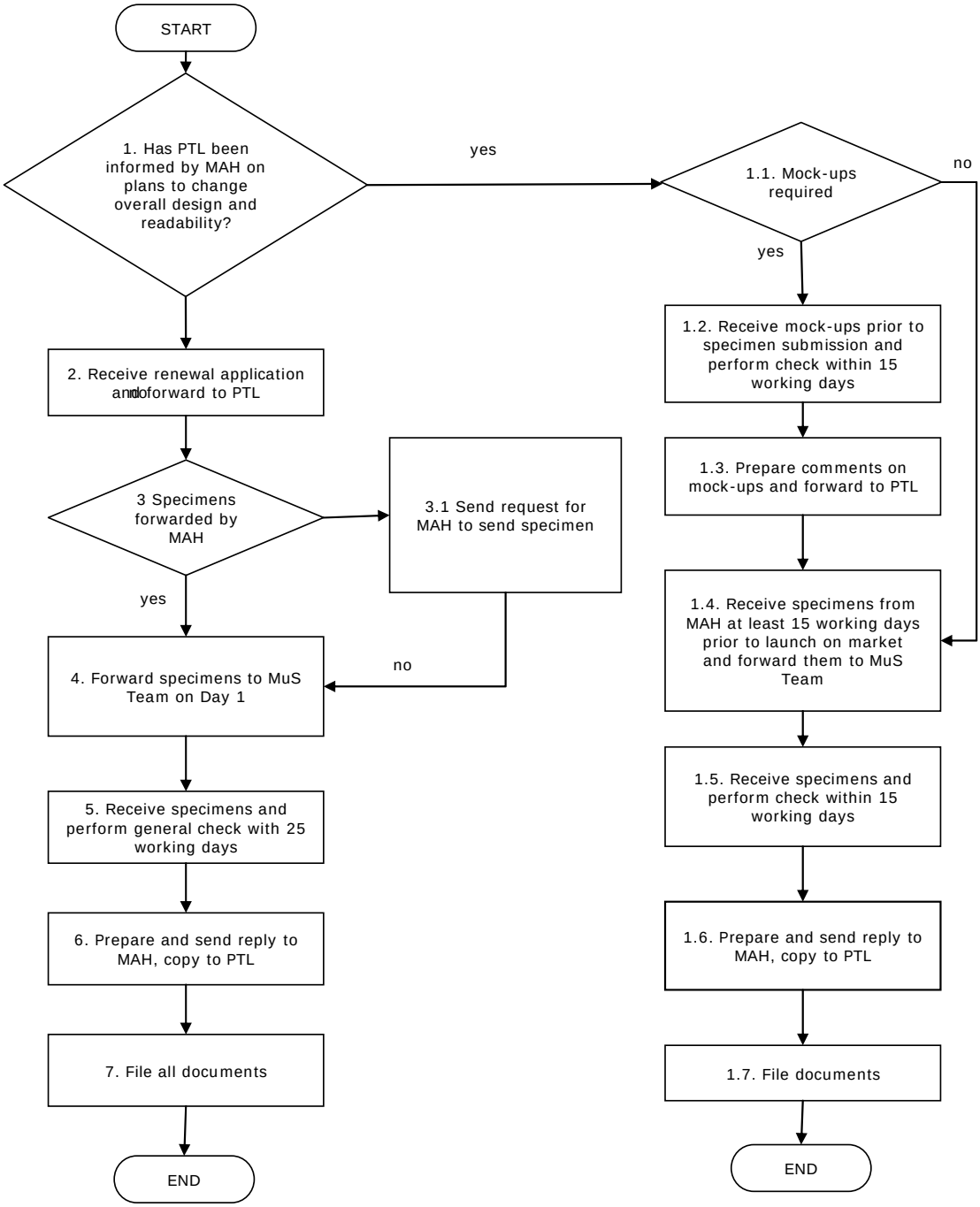
- The revised checking process of Mock-Ups and Specimens of outer/immediate labelling and package leaflets of human medicinal products in the Centralised Procedure (EMEA/305821/2006), see EMA website: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004891.pdf
- SOP/H/3016: Renewal of Marketing Authorisation (5 year renewal).
- SOP/PDM/1004: Core master files of medicinal products for human and veterinary use following the centralised procedure.
- Post-authorisation procedural advice: Human medicinal products, see EMA website: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500003981.pdf

7. Definitions

V-PD-BUS:	Product and Application Business Support
DREAM:	Document Records Electronic Archive Management
PTL:	Product Team Leader
PTM:	Product Team Member
MAH:	Marketing Authorisation Holder
MuS Team:	Mock-ups and Specimens Staff within the Product Information Quality Section
PIQ:	Product Information Quality
EN:	English version

PI:	Product Information (SPC, Labelling and Package Leaflet)
QRD:	Quality Review Documents
c-MF:	Core Master File

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
CHANGES to the Overall Design and Readability		
Pre-Submission Phase		
1	Has the PTL been informed by MAH on plans to change the overall design and readibility of the labelling components? If yes go to Step 1.1 If no go to Step 2	PTL
Pre-Opinion		
1.1	Are there any mock-ups required? If yes go to Step 1.2 If no go to Step 1.5	MuS Team
1.2	Receive mock-ups and perform the review of them prior to specimen submission and within 15 working days from receipt.	MuS Team
1.3	Prepare comments on mock-ups and forward them to the MAH, copying PTL.	MuS Team
Post-Opinion		
1.4	Receive specimens from MAH at least 15 working days prior to launch of the product on the market and forward them to responsible person for mock-ups and specimens within the Product Information Quality Section (MuS Team).	V-PD-BUS
1.5	Receive specimens and perform check within 15 working days.	MuS Team
1.6	Prepare reply regarding the specimens provided and send the comments to MAH, copying PTL.	MuS Team
1.7	File all documents.	MuS Team
NO CHANGES to the Overall Design and Readability		
Validation		
2	Receive Renewal application and forward to PTL	V-PD-BUS
3	Have specimens also been forwarded by MAH? If no go to Step 3.1 If yes go to Step 4	PTL
3.1	Send request to MAH to provide Specimens. Go to Step 4.	PTL
Pre-Opinion		
4	Forward specimens to responsible person for mock-ups and specimens within the Product Information Quality Section (MuS Team) on Day 1.	PTL
5	Receive specimens and perform check within 25 working days.	MuS Team
6	Prepare reply regarding the specimens provided and send the comments to MAH, copy to PTL.	MuS Team
7	File all documents.	MuS Team

10. Records

When the specimens review is completed, the original signed fax with the specimens check comments is filed in the core master file (c-MF).

The following electronic documents are saved and declared as records as appropriate in the concerned product folder in DREAM:

- Mock-up check comments, if applicable.

Paper copies of the mock-ups and the comments are not declared as records but are filed for internal use in the concerned product binder within MIS.