EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Checking of mock-ups and specimens for transfer of marketing authorisation		
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1. Purpose

The purpose of this document is to ensure a consistent and efficient approach to review the mock-ups and specimens for transfers 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 and the new SOP on core master files (SOP/PDM/1004).

Revision of the following steps:

- Step 2 (change responsibility from 'PTL' to 'AA').
- Step 9: (change responsibility from 'MuS Team/PTL' to 'MuS Team').

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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.

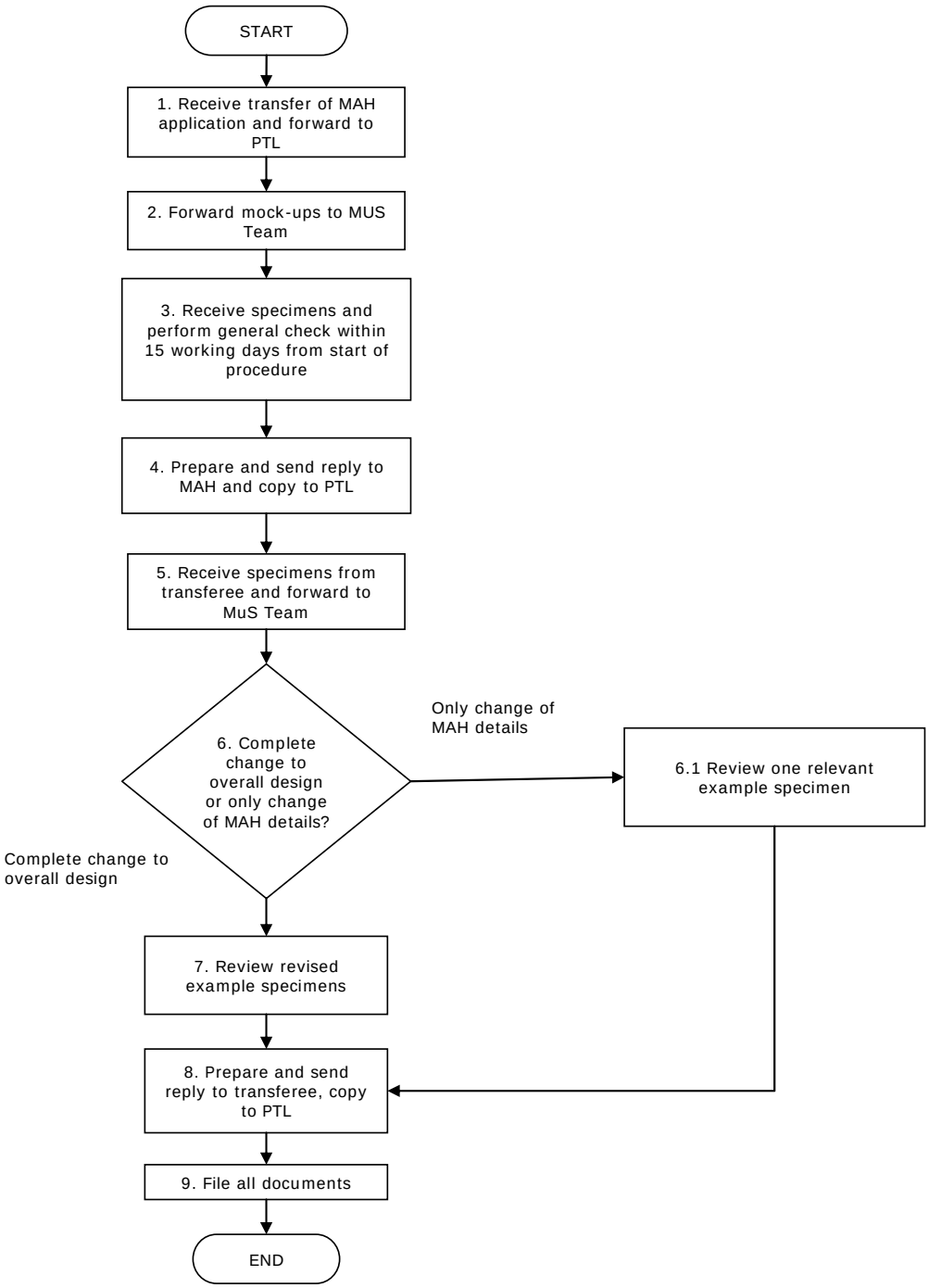
6. Related documents

- 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/3000: Transfer of marketing Authorisation.
- 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
AA:	Administrative Assistant in Quality and Safety and Efficacy of Medicines Sectors
PTL:	Product Team Leader
MAH:	Marketing Authorisation Holder
MuS Team:	Mock-ups and Specimens Staff within the Product Information Quality Section
Transferee:	The person to whom the transfer is to be granted
c-MF:	Core Master File

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



9. Procedure

Step	Action	Responsibility
Receipt of the application (Day 0)		
1	Receive transfer application and forward to Administrative Assistant in Quality and Safety and Efficacy of Medicines Sectors (AA).	V-PD-BUS
Checking of mock-ups (Day 0-5)		
2	Forward mock-ups to responsible person for mock-ups and specimens within the Product Information Quality Section (MuS Team).	AA
3	Receive mock-ups and perform check within 15 working days.	MuS Team
4	Prepare reply regarding the mock-ups provided and send the comments to MAH, copy to PTL and to AA.	MuS Team
Post-Opinion		
5	Receive specimens from transferee 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
6	Did the overall design and readability of the labelling components change at the time the mock-ups review or just the MAH details? If only the MAH details changed go to Step 6.1 If the overall design and readability changed go to Step 7	MuS Team
6.1	Perform check of only one relevant specimen within 15 working days. Go to step 8.	MuS Team
7	Perform check of revised example specimens, submitted in line with the procedure for checking specimens for new MAA and line extensions (see SOP/H/C/3013), within 15 working days.	MuS Team
8	Prepare reply regarding the specimens provided and send the comments to transferee, copy to PTL and to AA.	MuS Team
9	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.