EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Checking of mock-ups and specimens for all post-authorisation procedures other than line extensions, renewals and transfers		
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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 other post-authorisation procedures following the centralised procedure not covered by SOP/H/3013, SOP/H/3217 and SOP/H/3218.

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 3 (change responsibility from 'MuS Team/PTL' to 'MuS Team').

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- Step 4 (change responsibility from 'PTL' to 'PTL/AA).
- Step 10 (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.

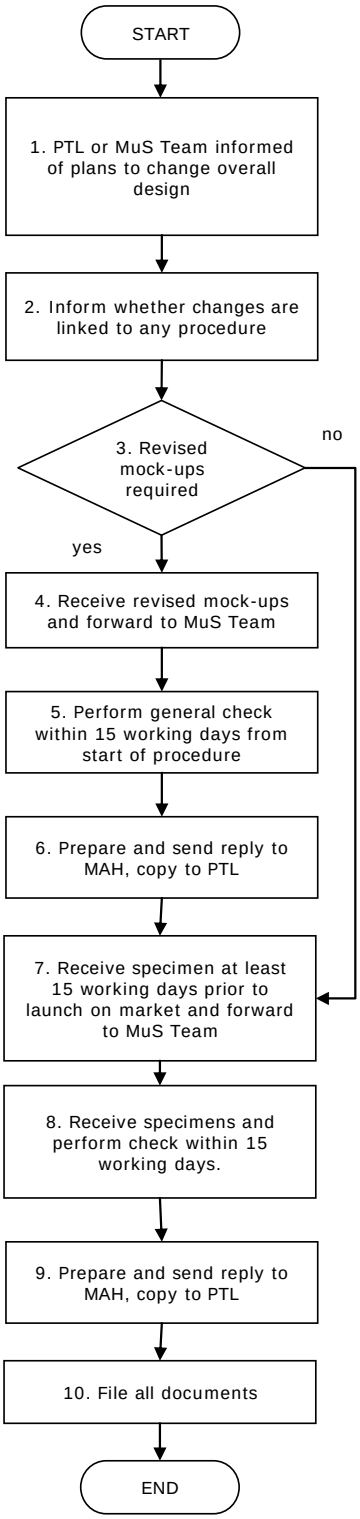
6. Related documents

- 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 3001: Type IA Variations.
- SOP 3002: Type IB Variations.
- SOP 3005: Type II Variations.
- SOP 3071 – 61(3) Notifications.
- SOP 3206: Type II Variations (30-day and 60-day procedure).
- 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
AA:	Administrative Assistant in Quality and Safety and Efficacy of Medicines Sectors
MAH:	Marketing Authorisation Holder
MuS Team:	Mock-ups and Specimens Staff within the Product Information Quality Section
EN:	English version
PI:	Product Information (SPC, Labelling and Package Leaflet)
c-MF:	Core Master File

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



9. Procedure

Step	Action	Responsibility
Mock-ups		
1	PTL or responsible person for mock-ups and specimens within the Product Information Quality Section (MuS Team) is informed of plans to change the overall design and readability of the labelling components. The MuS Team liaises with PTL.	MuS Team
2	PTL to inform MuS Team whether the changes are linked to any procedure.	PTL
3	Are any revised mock-ups required? If yes go to Step 4. If no go to Step 7.	MuS Team
4	Receive revised mock-ups and forward to responsible person for mock-ups and specimens within the Product Information Quality Section (MuS Team).	PTL/AA
5	Receive mock-ups from PTL and perform check within 15 working days.	MuS Team
6	Prepare reply regarding the mock-ups provided and send the comments to MAH, copy to PTL. Go to Step 4.	MuS Team
Specimens		
7	Receive specimens and forward to responsible person for mock-ups and specimens within the Product Information Quality Section (MuS Team).	V-PD-BUS
8	Receive specimens from V-PD-BUS and perform check within 15 working days.	MuS Team
9	Prepare reply regarding the specimens provided and send the comments to MAH, copy to PTL.	MuS Team
10	File all documents.	MuS Team

10. Records

When the specimens review is completed, if applicable, 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 prodect 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.