Human Medicines Division
EMA/185012/2023

Business process description

Title: Variations and other related post-authorisation processes		
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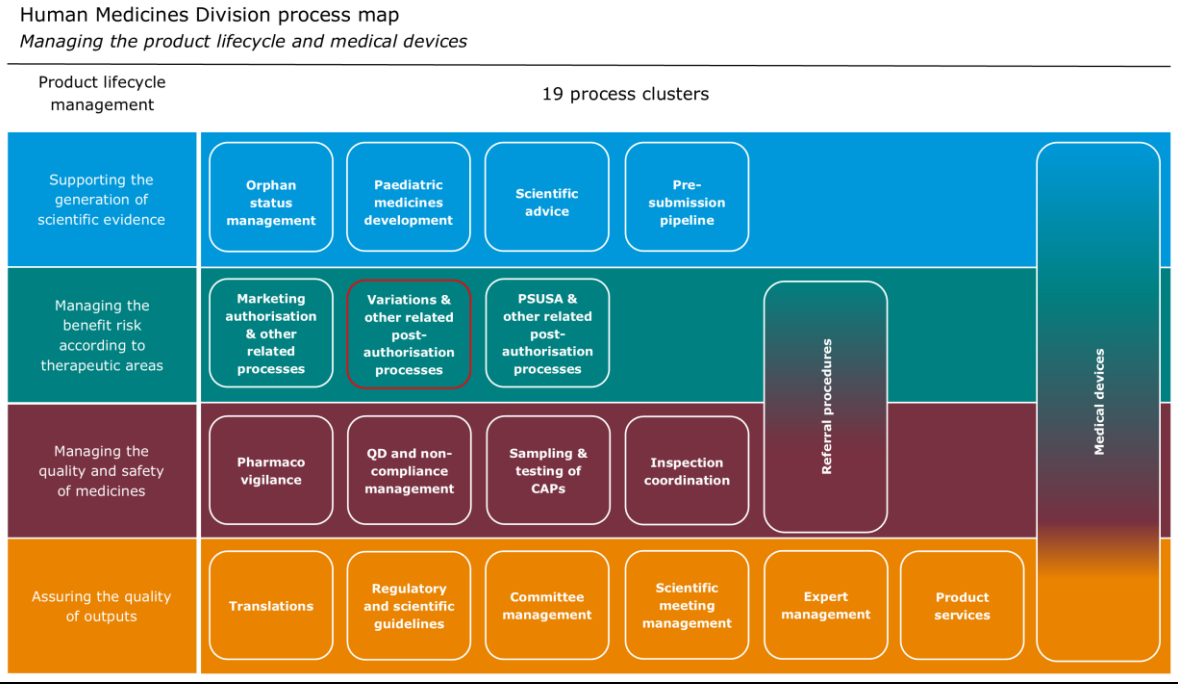
1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for the handling of submissions for variations (type IA, IB and II) and other related post-authorisation processes such as extensions of marketing authorisations, transfers of marketing authorisations, Article 61(3) notifications or yearly updates. This process covers centrally authorised products.

This process is part of the Human Medicines Division's process map (image below) which provides a high-level overview of the 19 process clusters within the operating model of the Human Medicines Division.



2. Changes since last revision

New business process description

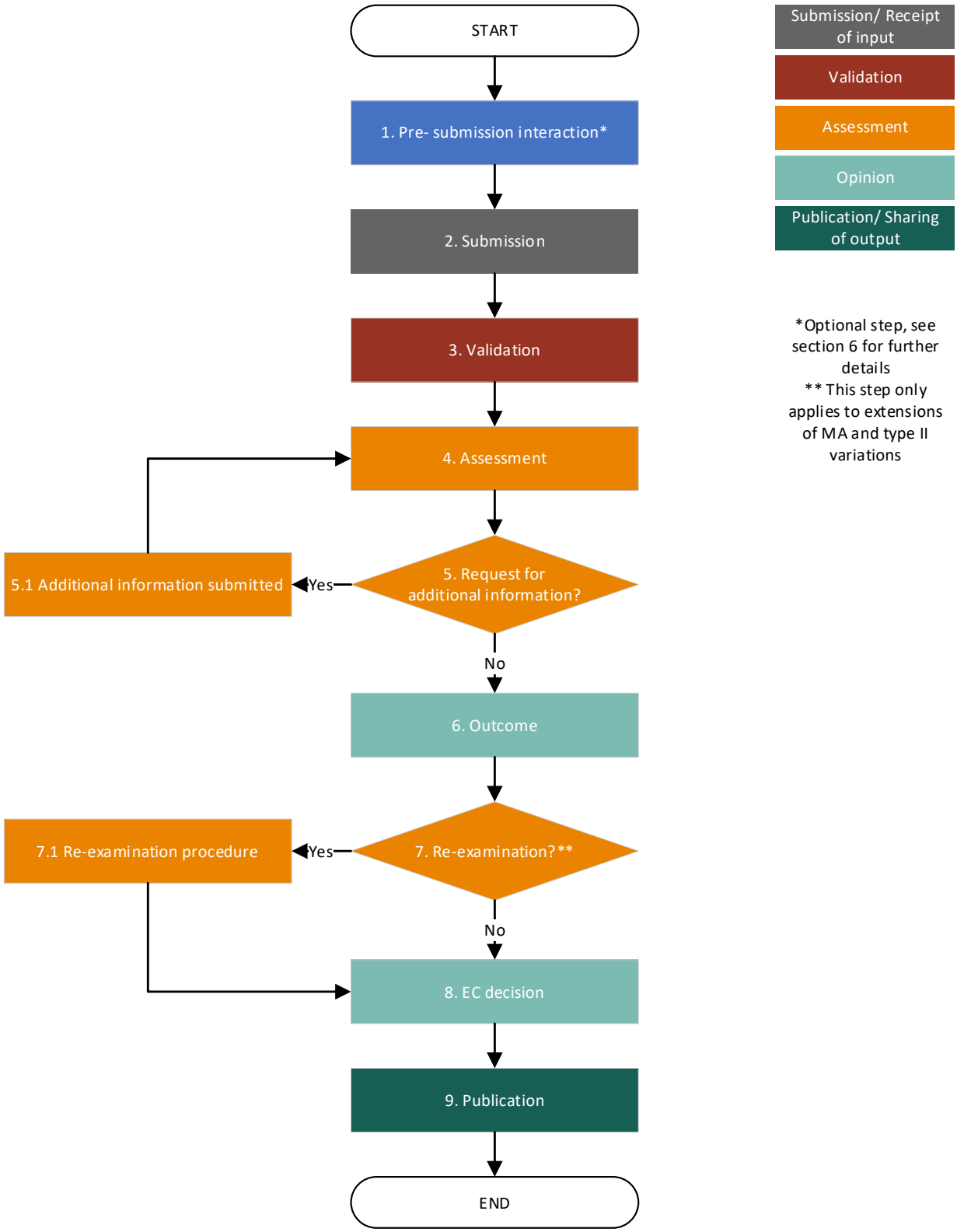
3. Related documents

- European Medicines Agency post-authorisation procedural advice for users of the centralised procedure
- Procedural advice on the re-examination of CHMP opinions

4. Abbreviations/Definitions

AR	Assessment report
CAT	Committee for Advanced Therapies
CAPs	Centrally authorised products
CHMP	Committee for Medicinal Products for Human Use
EC	European Commission
EMA	European Medicines Agency
EPAR	European public assessment report
MA	Marketing authorisation
MAH	Marketing authorisation holder
PIP	Paediatric investigation plan
PRAC	Pharmacovigilance Risk Assessment Committee
PSUSA	Periodic safety update report single assessment
QD	Quality defect
WS	Worksharing
WPs	Working parties

5. Process map(s)



Note: Blue colour represents other steps of a process that are not covered by the above legend

6. Procedure

Step	Description
1.	**Pre-submission interaction** Different types of interaction can occur depending on the type of process: • Extensions of MA: advance notice of submission, pre-submission meeting, and/or queries • Type II variations: letter of intent for WS Variations, advance notice of submission for extension of indication and others, and/or queries • Type IB variations: letter of intent for WS Variations, and/or queries • Type IA variations, Art 61 (3) and transfer of MA: queries *Note: This step is optional, except for letter of intent for WS variations submitted by the MAH*
2.	**Submission** The MAH submits the application dossier to the EMA and to the network for the following processes: • Extensions of MA (A request for additional data/ market protection, a similarity AR, or a request for PIP compliance statement might also be submitted together with the application dossier) • Type II variation (A request for additional data/ market protection, a similarity AR, or a request for PIP compliance statement might also be submitted together with the application dossier) • Type I variation (A request for PIP compliance statement might also be submitted together with the application dossier) • Article 61(3) • Transfer of MA
3.	**Validation** • Validate the submission, ensuring the content of the dossier is in compliance with the relevant standards and regulations, allocating the relevant internal and external resources and selecting the timetable *Note: Once the validation is positively concluded, the assessment procedure starts*
4.	**Assessment** • Type II variations, extensions of MA: Co-ordinate the assessment of the application by relevant committees (CHMP, CAT and PRAC as applicable) and relevant experts (e.g. expert meetings, WPs) • Type IB variations: Co-ordinate the assessment of the application by relevant committees (CHMP, CAT and PRAC as applicable) • Type IA variation: Review the application

Step	Description
	• Transfer of MA: Review the application • Art 61(3): Review the application or co-ordinate the assessment by CHMP
5.	**Request for additional information?** • If yes, go to step 5.1 • If no, go to step 6 *Note: The outcome must be reached within the regulatory deadlines, as applicable. For type II variations, type IB variations and Article 61(3), the request for additional information is formally named request for supplementary information, while for extensions of MA, it is formally named list of questions and list of outstanding issues.*
5.1	**Additional information submitted** • The MAH submits the responses to the request for additional information (go to step 4)
6.	**Outcome** • Type II variations, extensions of MA, transfer of MA: CHMP adopts an opinion, and the outcome is sent to the MAH and the EC • Type I variations, Art 61 (3): A positive or negative outcome is agreed, and a notification is sent to the MAH and to the EC for procedures affecting the Annexes
7.	**Re-examination?** • If yes, go to step 7.1 • If no, go to step 8 *Note: This step only applies to extensions of MA and type II variations*
7.1	**Re-examination procedure** • After the re-examination, CHMP adopts a final opinion (go to step 8)
8.	**EC decision** • Type II and type I variations (within criteria), extensions of MA, transfer of MA: An immediate European Commission decision is issued *Note: For other procedures and when no immediate Commission decision is issued, a yearly update of the Commission decision is triggered for the product*
9.	**Publication** • Update the content of the medicine's EPAR on the EMA corporate website