EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Human Medicines Division
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Business process description

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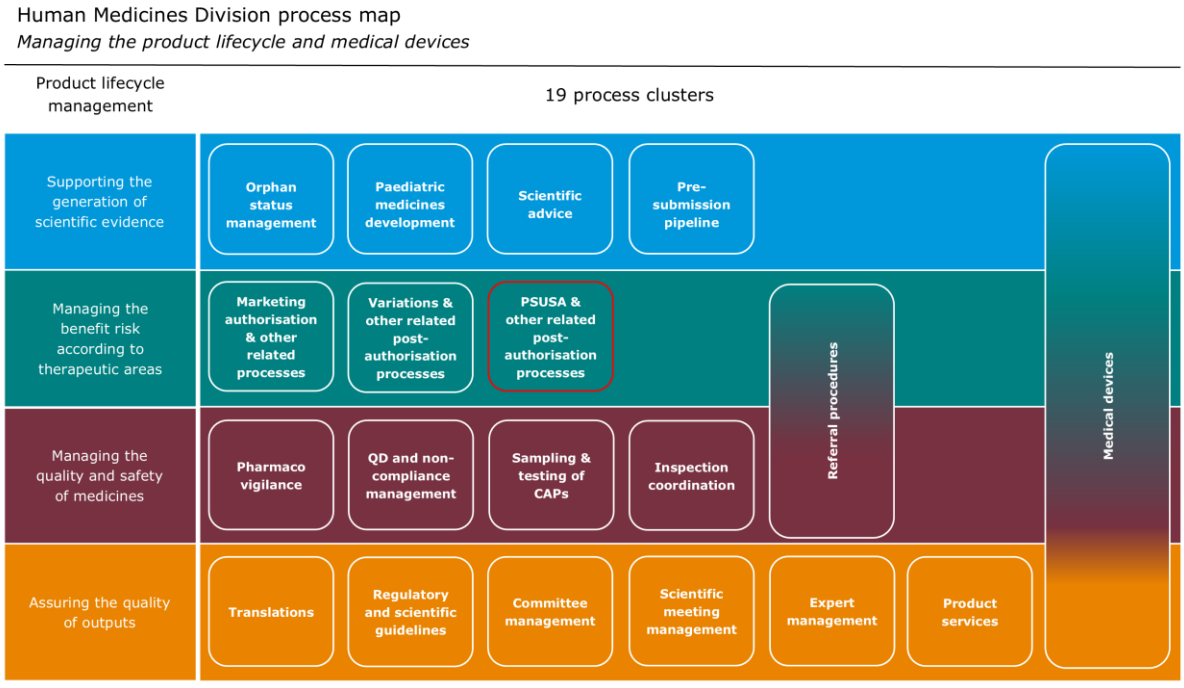
1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for PSUSA & other related post-authorisation processes, which enable the continuous evaluation of the benefit-risk profile of medicinal products throughout their lifecycle, authorised in the European Union based on a granted marketing authorisation.

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.



PSUSA & other related post-authorisation processes:

It describes the processes of:

- Periodic safety update single assessment
- Imposed post-authorisation safety study (protocol/study results)
- Post-authorisation measure
- Renewal of marketing authorisation and annual reassessment

Some of these processes cover nationally authorised products too.

2. Changes since last revision

New business process description

3. Related documents

Guidelines:

- Guideline on good pharmacovigilance practices (GVP) Module VII – Periodic safety update report (Rev 1) (europa.eu)
- Guideline on good pharmacovigilance practices (GVP) - Module VIII – Post-authorisation safety studies (Rev 3) (europa.eu)
- Guideline on the processing of renewals in the centralised procedure- clean version after public consultation (europa.eu)
- Scientific guidance on post-authorisation efficacy studies (europa.eu)
- Procedural advice on the re-examination of CHMP opinions

Relevant Information:

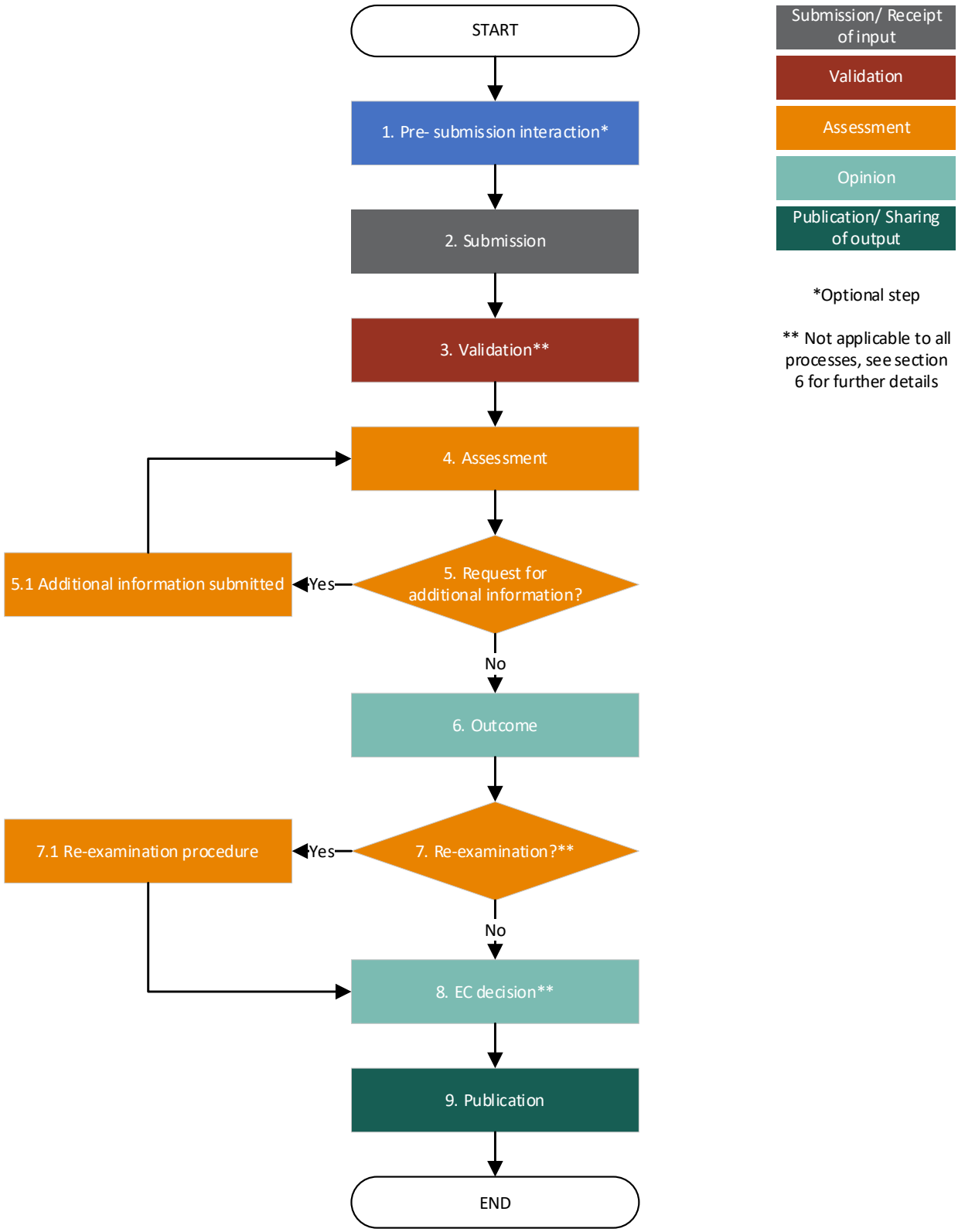
- Periodic safety update reports (PSURs) | European Medicines Agency (europa.eu)
- Post-authorisation safety studies (PASS) | European Medicines Agency (europa.eu)
- Post-authorisation measures: questions and answers | European Medicines Agency (europa.eu)
- Renewal and annual re-assessment of marketing authorisation | European Medicines Agency (europa.eu)

4. Abbreviations/Definitions

AR	Assessment report
CAPs	Centrally authorised products
CAT	Committee for Advanced Therapies
CHMP	Committee for Medicinal Products for Human Use
CMDh	Co-ordination group for Mutual recognition and Decentralised procedures - human
EC	European Commission
EMA	European Medicines Agency

EPAR	European public assessment report
HMA	Heads of Medicines Agencies
MA	Marketing authorisation
MAH	Marketing authorisation holder
MEA	PAM for additional pharmacovigilance activities in the RMP
MSs	Member States
NAP	Nationally authorised product
PAM	Post-authorisation measure
PASS	Post-authorisation safety study
PRAC	Pharmacovigilance Risk Assessment Committee
PSUR	Periodic safety update report (PSUR assessed under the PSUSA procedure)
PSUSA	Periodic safety update report single assessment
QD	Quality defect
RMP	Risk management plan

5. Process map



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 such as pre-submission meetings or queries, as necessary *Note: This step is optional*
2.	**Submission** The MAH submits the: • imposed non-interventional PASS protocol/study results • PSUR • PAM • Renewal and annual reassessment applications
3.	**Validation** • Validate the submission, ensuring the content of the dossier is in compliance with the relevant guidelines and regulations, allocating the relevant internal and external resources and selecting the timetable *Note: Once the validation is positively concluded, the assessment procedure starts. This step only applies to imposed non-interventional PASS, renewals and annual reassessments.*

4.	**Assessment**
	• Coordinate the assessment of the application by relevant committees (CHMP, PRAC, CAT as applicable)
	  ○ PSUSA, imposed non-interventional PASS, PAM for additional pharmacovigilance activities in the RMP, PAM subsequent to a procedure primarily assessed by PRAC: PRAC-led
	  ○ Other PAMs: CHMP (or CAT)-led
	  ○ Renewal, annual reassessment: CHMP-led with PRAC involvement

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 legal deadlines.* *For PSUSA, imposed non-interventional PASS study results, PAMs, renewals and annual reassessments, the request for additional information is formally named request for supplementary information.*
5.1	**Additional information submitted**

Step	Description
	• The MAH submits the responses to the request for additional information (go to step 4)
6.	**Outcome** • PSUSA & imposed non-interventional PASS study results: PRAC recommendation & CHMP opinion (in case of variation/suspension/revocation for CAPs) and/or CMDh position (in case of variation/suspension/revocation for NAPs) are sent to MAH • Imposed non-interventional PASS protocol: PRAC letter is sent to MAH • PAMs: PRAC or CHMP adoption of conclusions is sent to MAH • Renewal, annual reassessment: CHMP opinion is sent to MAH
7.	**Re-examination?** • If yes, go to step 7.1 • If no, go to step 8 *Note: This step only applies to renewals and annual reassessments.*
7.1	**Re-examination procedure** • After the re-examination, CHMP adopts a final opinion (go to step 8)
8.	**EC decision** • PSUSA & Imposed non-interventional PASS study results: when there is a CAP involved or when the CMDh position for NAPs is adopted by majority • Renewal, annual reassessment *Note: This step does not apply to PAMs, imposed non-interventional PASS protocol or when there is consensus in the CMDh position on a PSUSA or on imposed non-interventional PASS study results.*

9.	**Publication**
	• PSUSA:
	  ○ CAPs: EPAR published on the EMA corporate website
	  ○ NAPs: List of nationally authorised medicinal products & Annex C published on the EMA corporate website
	• Imposed PASS protocol:
	  ○ Protocol published on the HMA-EMA Catalogue of real-world data studies
	• Imposed PASS study results:
	  ○ CAPs: EPAR published on the EMA corporate website
	  ○ Mixed cases of CAPs & NAPs: NAPs' outcome of the assessment published on the EC Union Register
	  ○ NAPs only: Outcome of the assessment published on the EMA corporate website

Step	Description

	• PAMs:
	  ○ EPAR published on the EMA corporate website (applicable to Paediatric (Art. 46) only)
	• Renewal, annual reassessment:
	  ○ EPAR published on the EMA corporate website