Human Medicines Division
EMA/272204/2024

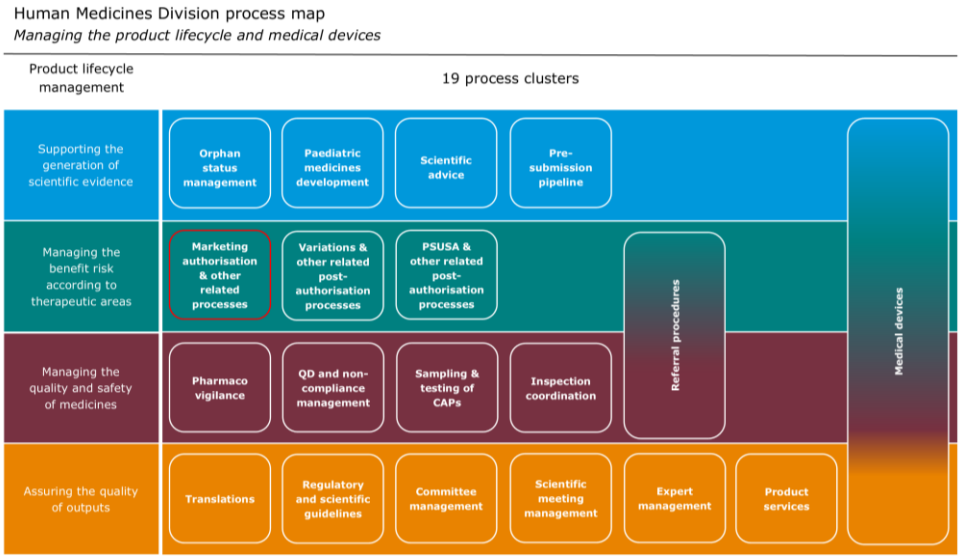
Business process description

Title: Marketing authorisation and other related processes		
Status: **PUBLIC**		Document no.: BPD/H/005
Author: Process Lead	Approver: Lead Process Manager	Effective date: 20-FEB-25
Name: [On file]	Name: [On file]	Review date: 20-FEB-28
Signature: [On file]	Signature: [On file]	Supersedes: N/A

1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for marketing authorisation in the centralised procedure, which enables the evaluation and recommendation for approval of medicinal products throughout the European Union based on a single marketing authorisation application. This business process description also describes the processes of providing scientific opinions for medicines intended for markets outside the EU under the EU-M4all procedure, recommendations for compassionate use programmes and consultations for companion diagnostics and ancillary medicinal substances incorporated in medical devices.

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.



Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

2. Changes since last revision

New business process description

3. Related documents

Relevant information:

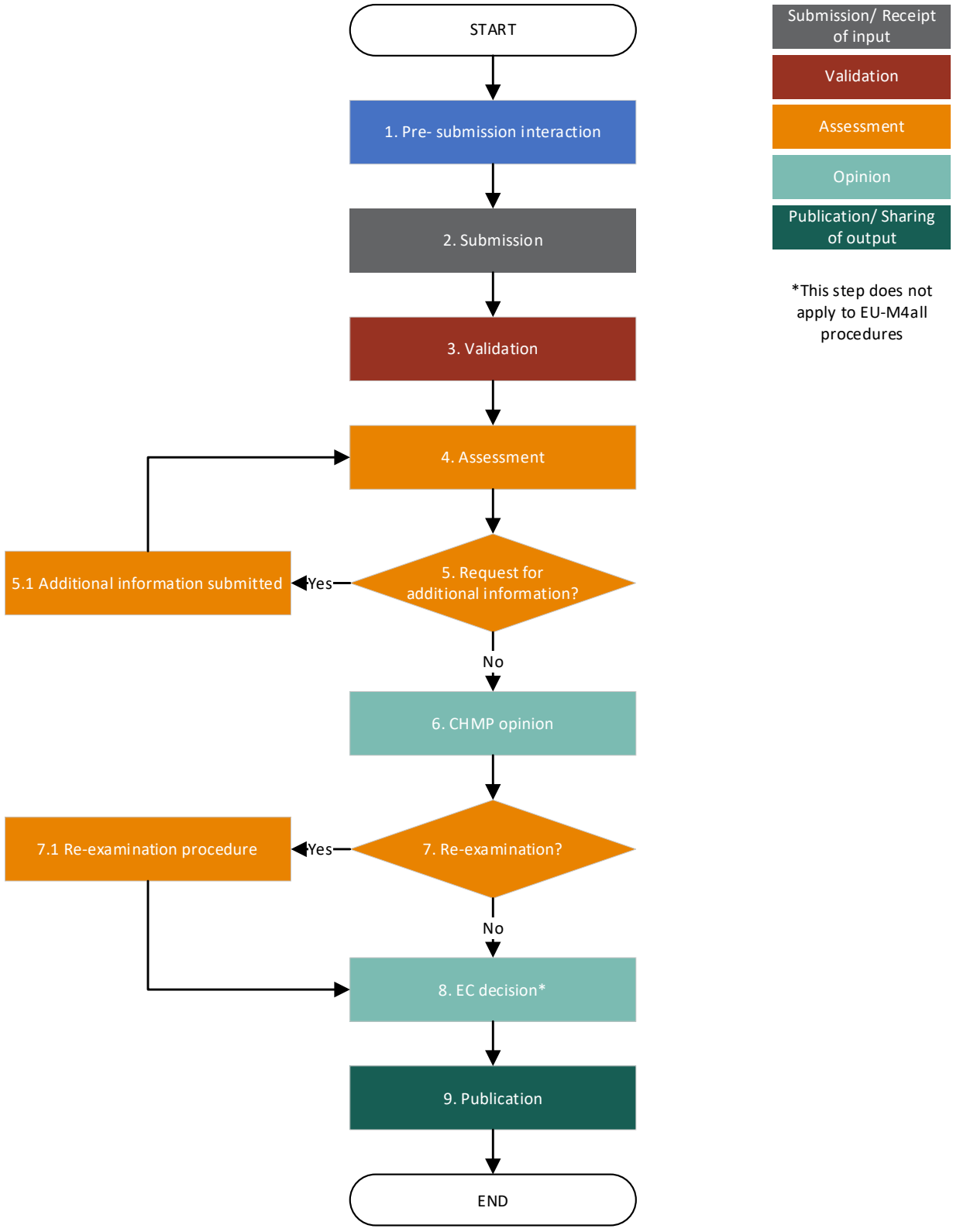
- Compassionate use
- Companion diagnostics ('in vitro diagnostics')
- Consultation procedure for ancillary medicinal substances in medical devices
- Medicines for use outside the European Union
- Pre-authorisation guidance
- Procedural advice on the re-examination of CHMP opinions

4. Abbreviations/Definitions

CAPs	Centrally authorised products
CAT	Committee for Advances Therapies
CE	(Conformité Européene) European Conformity
CHMP	Committee for Medicinal Products for Human Use
CPAR	Consultation public assessment report
CU	Compassionate use
EC	European Commission
EMA	European Medicines Agency
EPAR	European public assessment report
EU	European Union
EU-M4all	EU-Medicines for all
MA	Marketing authorisation
MS	Member State
NB	Notified body
PRAC	Pharmacovigilance Risk Assessment Committee
PSUSA	Periodic safety update report single assessment
QD	Quality defect
WHO	Work Health Organisation
WPs	Working parties

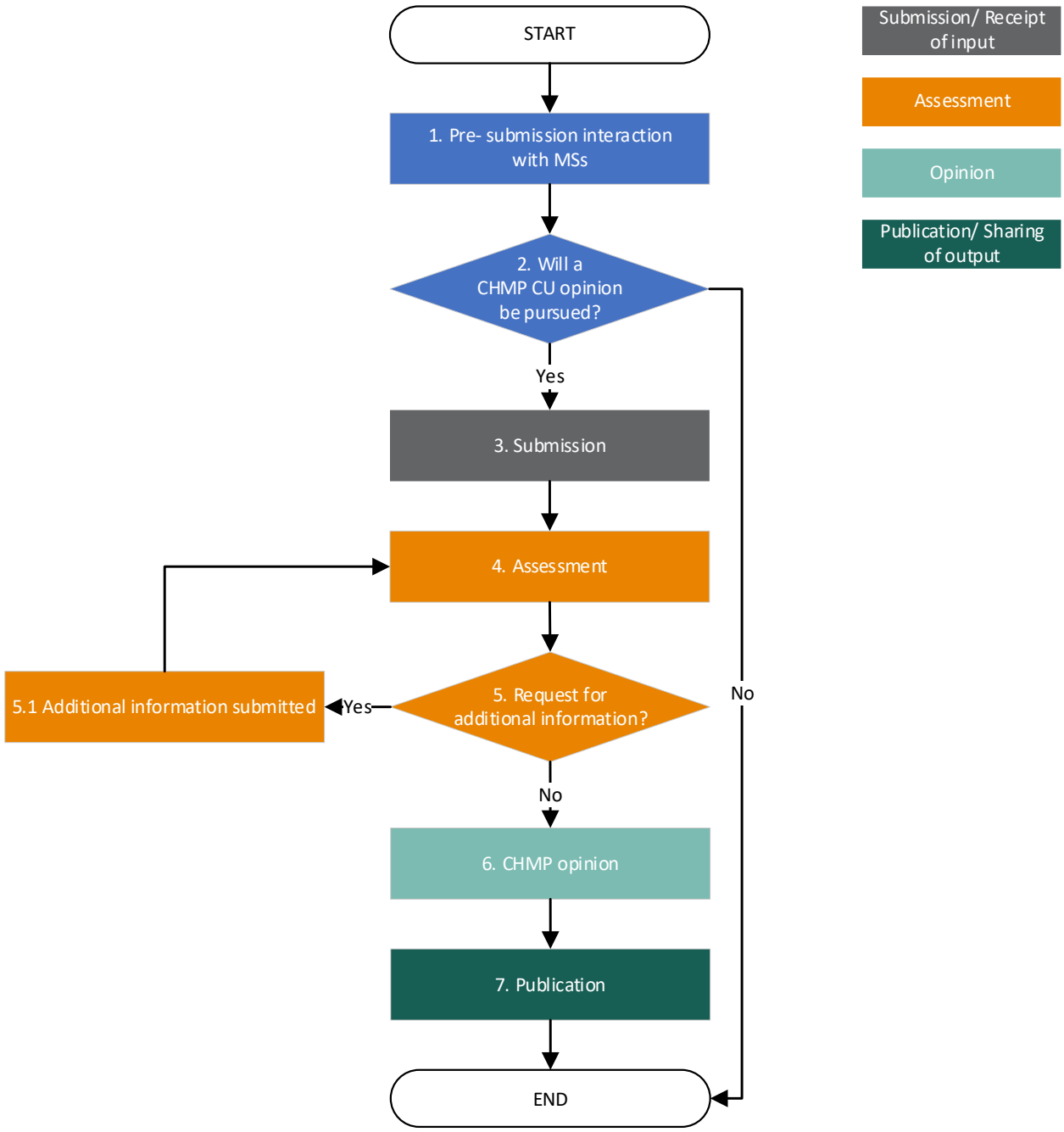
5. Process map

5.1 The initial MA and EU-M4all



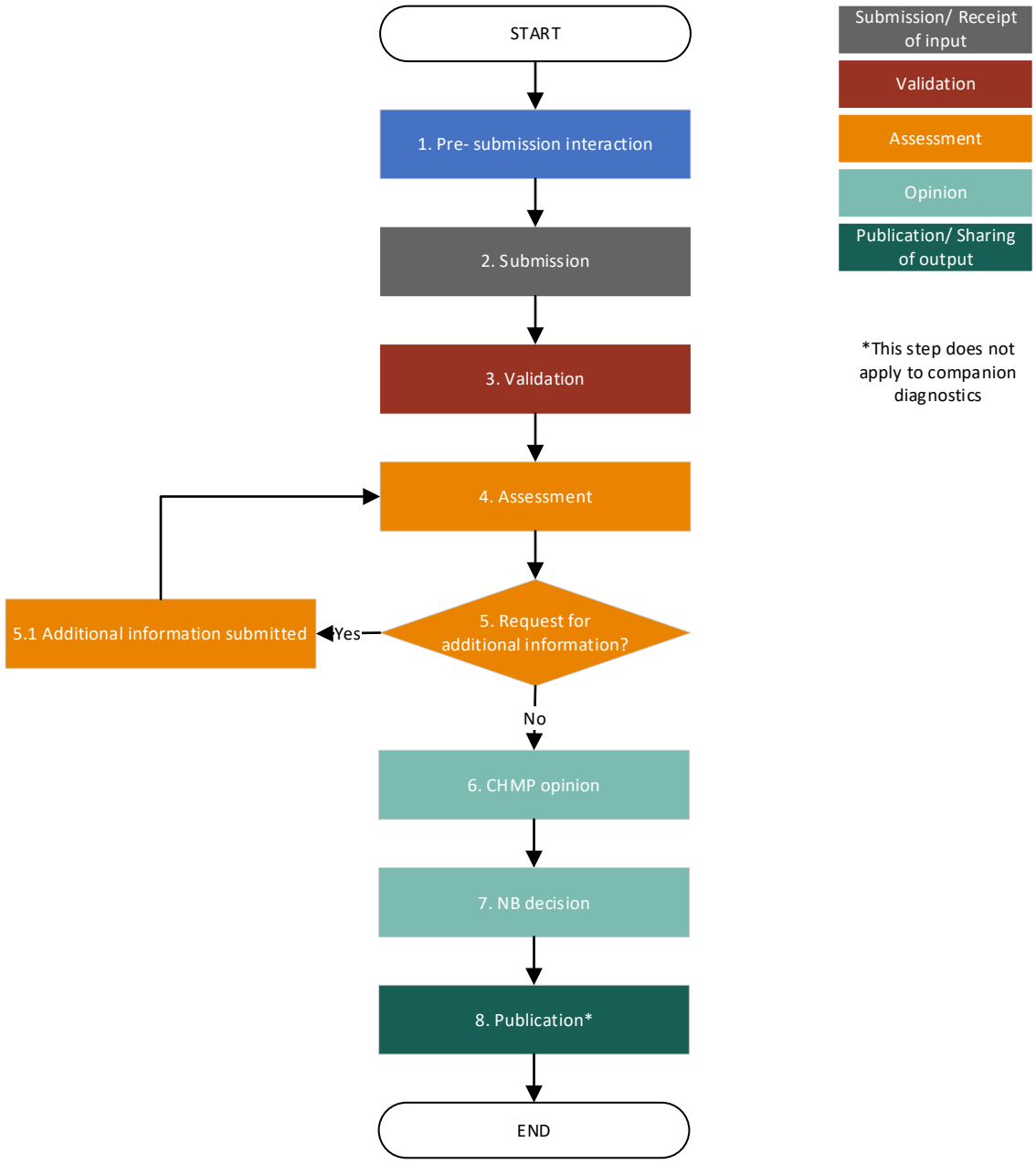
Note: Blue colour represents other steps of a process that are not covered by the above legend

5.2 The compassionate use programme



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

5.3 The consultation for companion diagnostics and ancillary medicinal substances in medical devices



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

6. Procedure

6.1 The initial MA and EU-M4all

Step	Description
1.	**Pre-submission interaction** • An eligibility request and a notification of intention to submit an application are submitted • Any type of pre-submission interaction, such as pre-submission meetings with EMA/rapporteurs and queries, might be held
2.	**Submission** • The applicant submits the application dossier
3.	**Validation** • Validate the submission *Note: Once the validation is positively concluded, the assessment procedure starts*
4.	**Assessment** • Co-ordinate the assessment of the application by relevant committees (CHMP and PRAC, CAT if applicable) and relevant expert groups as applicable. For EU-M4all, WHO experts and observers from target countries are also involved.
5.	**Request for additional information?** • If yes, go to step 5.1 • If no, go to step 6 *Note: In the context of the initial MA procedure, the request for additional information is formally named list of questions and list of outstanding issues. The opinion must be reached within the legal deadline.*
5.1	**Additional information submitted** • The applicant submits the responses to the request for additional information (go to step 4)
6.	**CHMP opinion** • The CHMP adopts an opinion
7.	**Re-examination?** • If yes, go to step 7.1 • If no, go to step 8
7.1	**Re-examination procedure** • After the re-examination, CHMP adopts a final opinion (go to step 8)
8.	**EC decision**

Step	Description
	• An EC decision is issued *Note: This step does not apply to EU-M4all procedures*
9.	**Publication** • Publish the EPAR on the EMA corporate website

6.2 The compassionate use programme

Step	Description
1.	**Pre-submission interaction with MSs** • At least two notifications for the same compassionate use programme are submitted by two different MSs, or; • A request for CHMP opinion on compasionate use is submitted by a MS
2.	**Will a CHMP CU opinion be pursued?** • If yes, the assessment starts - go to step 3 • If no, then the process ends
3.	**Submission** • The applicant submits the CU data package to the EMA
4.	**Assessment** • Co-ordinate the assessment of the application by relevant committees (CHMP and PRAC, CAT if applicable) and relevant expert groups as applicable
5.	**Request for additional information?** • If yes, go to step 5.1 • If no, go to step 6
5.1	**Additional information submitted** • The applicant submits the responses to the request for additional information (go to step 4)
6.	**CHMP opinion** • The CHMP adopts an opinion
7.	**Publication** • Publish the summary on compassionate use and conditions for use on the EMA corporate website

6.3 The consultation for companion diagnostics and ancillary medicinal substances in medical devices

Step	Description
1.	**Pre-submission interaction** • An intention to submit letter is submitted by the applicant, i.e. the NB • Any type of pre-submission interaction among the EMA and the NB, such as pre-submission meetings and queries, might be held
2.	**Submission** • The applicant submits the application dossier
3.	**Validation** • Validate the submission *Note: Once the validation is positively concluded, the assessment procedure starts*
4.	**Assessment** • Co-ordinate the assessment of the application by CHMP and relevant expert groups as applicable. For companion diagnostics, other relevant committees (PRAC and/or CAT) might also be involved.
5.	**Request for additional information?** • If yes, go to step 5.1 • If no, go to step 6 *Note:* *- The request for additional information is formally named:* o *list of questions and list of outstanding issues for ancillary medinical substances in medical devices* o *list of questions for companion diagnostics* *- The opinion must be reached within the legal deadline*
5.1	**Additional information submitted** • The applicant submits the responses to the request for additional information (go to step 4)
6.	**CHMP opinion** • Following the assessment of the responses, the CHMP adopts an opinion, and the outcome is sent to the NB. For ancillary medicinal substances, the outcome is also sent to the National competent authority of the MS where the NB is based.
7.	**NB decision** • Taking into consideration the CHMP opinion, the NB makes its decision and informs EMA
8.	**Publication**

Step	Description
	• Publish the CPAR on the EMA corporate website *Note: This step is applicable only for ancillary medicinal substances in medical devices*