Human Medicines Division
EMA/233986/2024

Business process description

Title: Paediatric medicines development		
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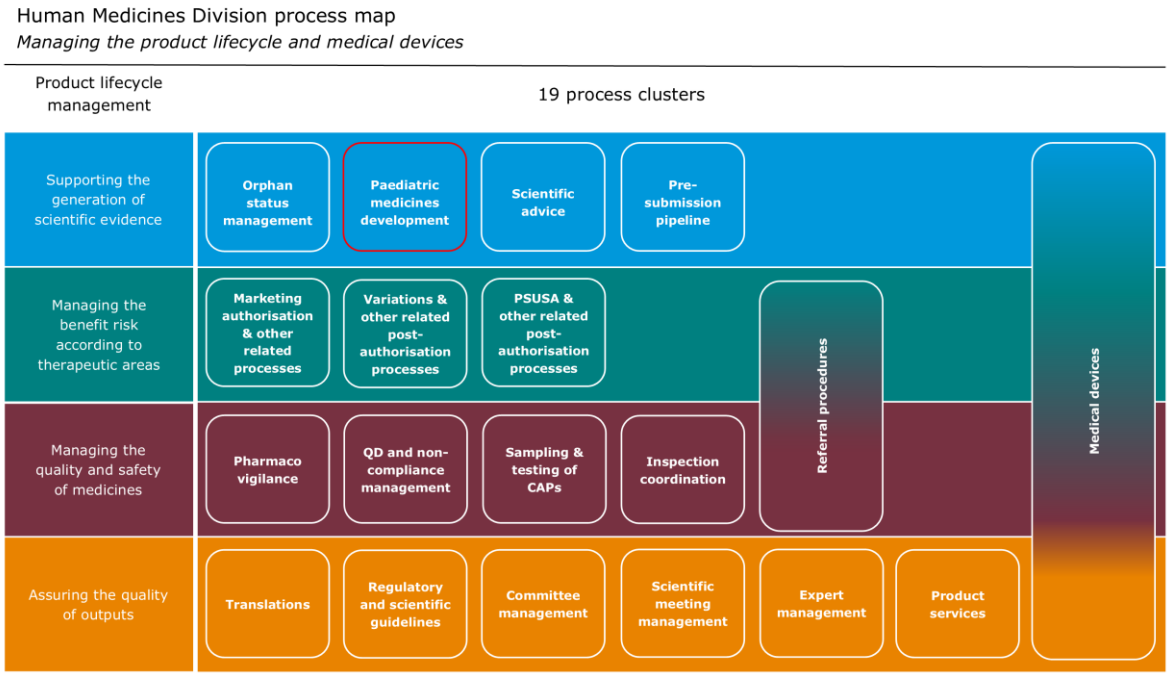
1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for paediatric medicines development, which supports the development of medicines for children by providing objective scientific opinions on paediatric investigation plans, ensuring high quality, ethically researched and appropriately authorised medicines for use in children.

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.



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Paediatric medicines development process:

It describes the process for:

- Application for a paediatric investigation plan
- Application for a product-specific waiver
- Application for modification of an agreed paediatric investigation plan
- Application for compliance check of a paediatric investigation plan

2. Changes since last revision

New business process description

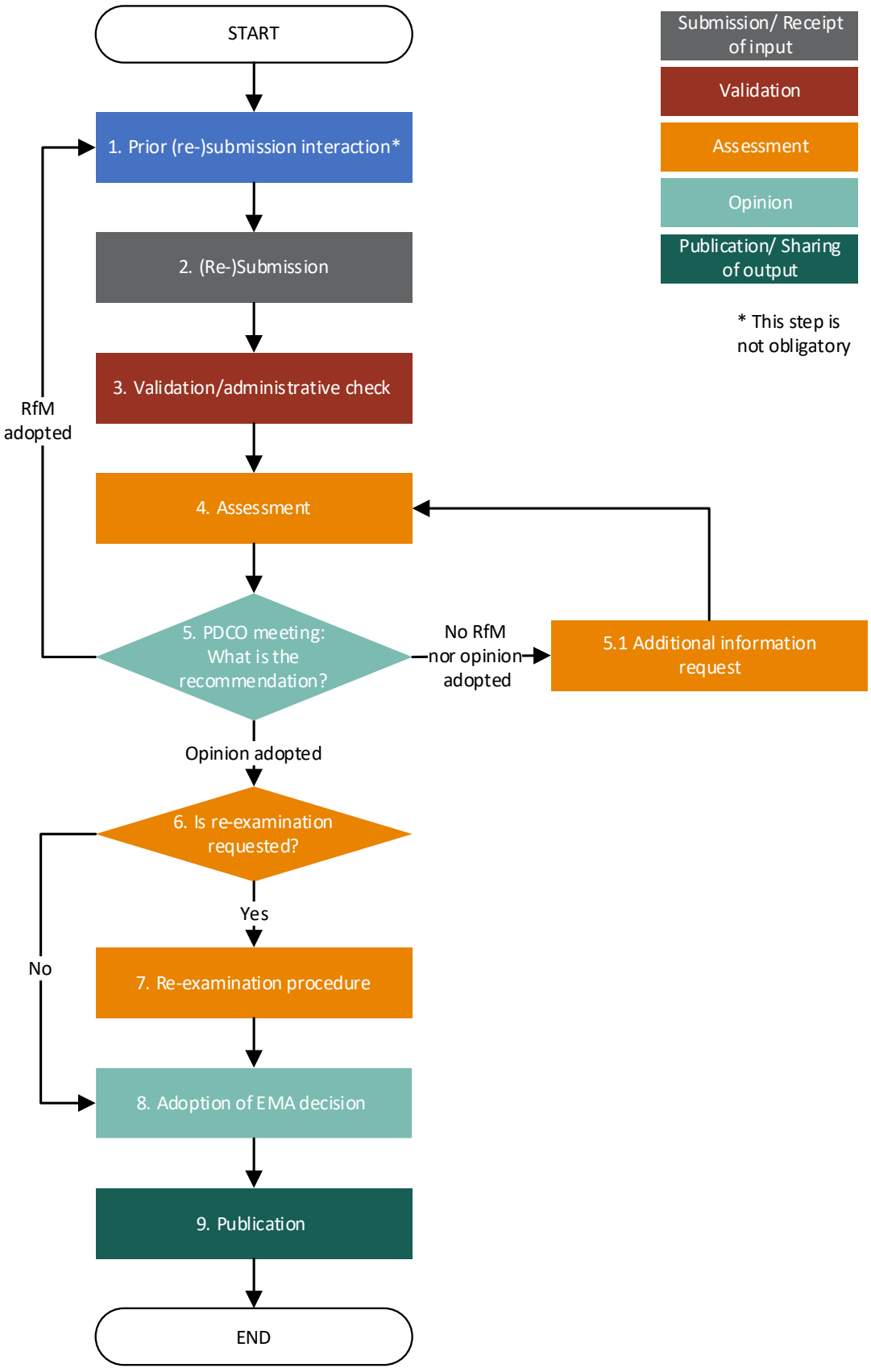
3. Related documents

- Paediatric medicines: applications and procedures
- Procedural advice on paediatric applications
- Rules of procedure of the Paediatric Committee (PDCO)
- Roles and responsibilities of members and alternates, rapporteur and peer reviewers, experts and observers of the Paediatric Committee (PDCO)

4. Abbreviations/Definitions

CAPs	Centrally authorised products
EMA	European Medicines Agency
PDCO	Paediatric Committee
PSUSA	Periodic safety update report single assessment
QD	Quality defect
RfM	Request for modification
SAG	Scientific advisory group
WG	Working group
WP	Working party

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.	**Prior (re-)submission interaction** • Receive a pre-submission interaction request before submission or a clarification request before re-submission *Note: This step is not obligatory*
2.	**(Re-)Submission** Receive the (re-)submission for an application for the following paediatric procedures: • Paediatric investigation plan • Product-specific waiver • Modification of an agreed paediatric investigation plan • Compliance check of a paediatric investigation plan
3.	**Validation/administrative check** • Validate the submission and/or perform an administrative check • Identify the need for experts/WPs/WGs/SAGs/committees' involvement *Note: Once the validation/administrative check is positively concluded, the procedure (re-)starts.*
4.	**Assessment** • Co-ordinate the assessment of the application
5.	**PDCO meeting: What is the recommendation?** • If a PDCO opinion is adopted, send the outcome to the applicant and go to step 6 • If a RfM is adopted, send the outcome to the applicant (clockstop) and go to step 1 • If neither a RfM nor an opinion is adopted, go to step 5.1 *Note: The PDCO opinion and the RfM must be adopted within the legal deadline*
5.1	**Additional information request** • Request additional information from the applicant/WPs/WGs/SAGs/committees/etc. (go to step 4)
6.	**Is re-examination requested** by the applicant? • If yes, go to step 7 • If no, go to step 8
7.	**Re-examination procedure** • The PDCO adopts a final opinion, and the outcome is sent to the applicant
8.	**Adoption of EMA decision**

Step	Description
9.	**Publication** • Publish the EMA decision on the EMA website