Human Medicines Division
EMA/184151/2024

Business process description

Title: Certificates of medicinal products		
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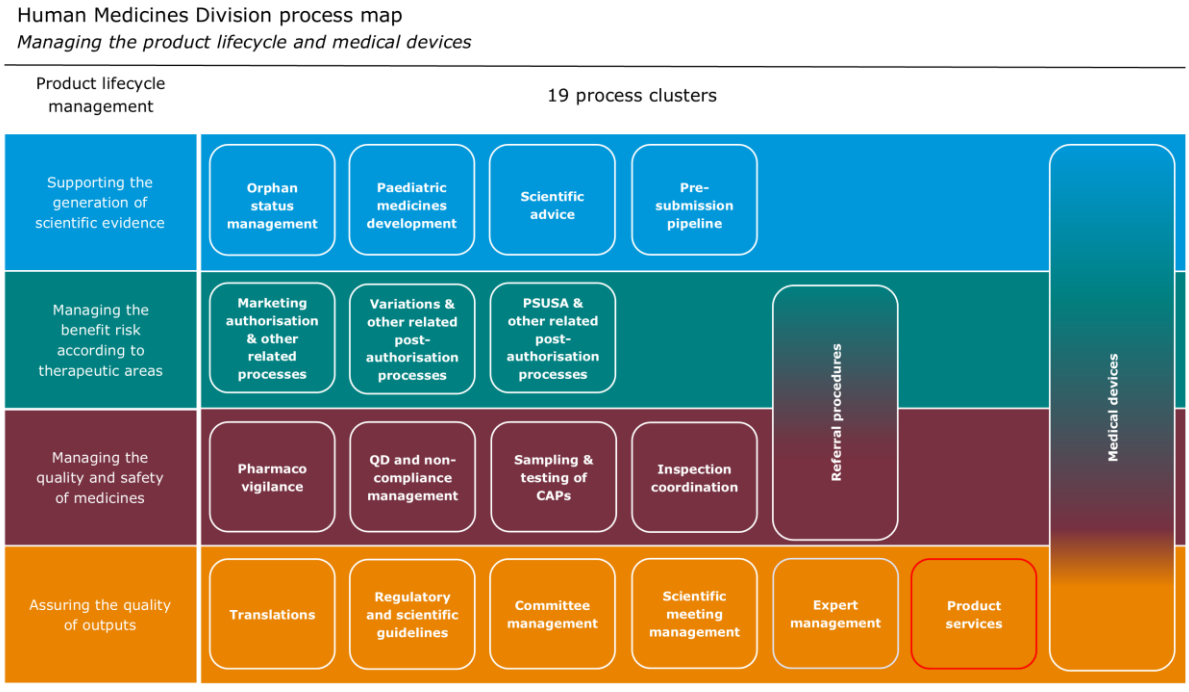
1. Introduction

The purpose of this document is to describe the high-level & end-to-end process for the certification of medicinal products for human and veterinary use, which confirms the medicine's marketing authorisation status and its compliance with GMP standards.

The certificates of medicinal products process belongs to the product services process cluster. The product services 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.



Certificates of medicinal products process:

It describes the process of the EMA issuing certificates on behalf of the EC for products either authorised by the EC through the centralised procedure, or for products for which a centralised application has been submitted to the EMA, as well as for products for use outside the EU.

2. Changes since last revision

New business process description

3. Related documents

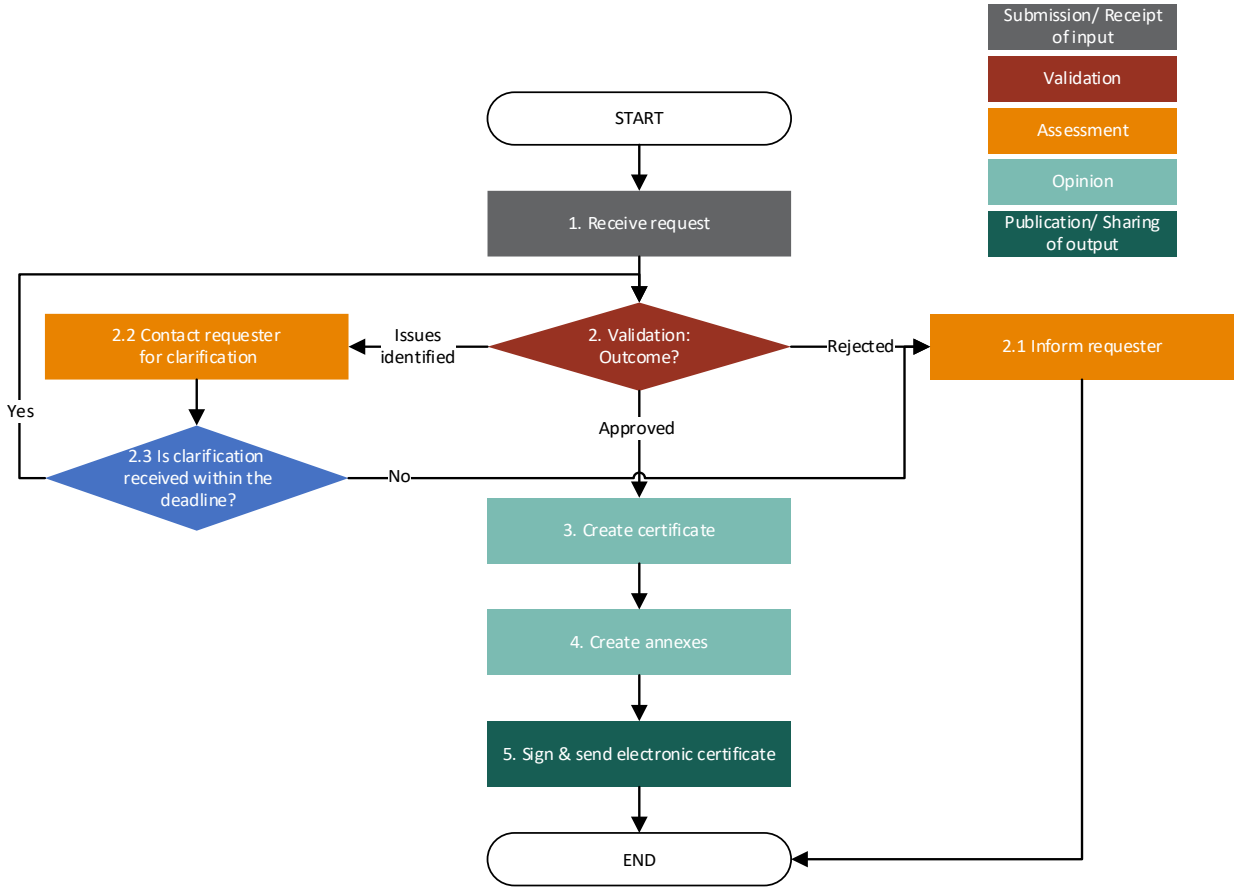
Relevant information:

- Instructions on how to submit a request for certificates of medicinal products
- Information note on the format and validity features of electronic certificates for medicines issued by the European Medicines Agency
- Information package for certificates of medicinal products issued by the European Medicines Agency (EMA)

4. Abbreviations/Definitions

CAPs	Centrally authorised products
CMP	Certificate of medicinal product
EC	European Commission
EMA	European Medicines Agency
GMP	Good Manufacturing Practice
MA	Marketing authorisation
MAH	Marketing authorisation holder
PSUSA	Periodic safety update report single assessment
QD	Quality defect
Requester	Holder of (applicant for) the community marketing authorisation or any other organisation with the permission of the MAH/MA applicant requesting certificates from the Agency

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.	**Receive request** • Receive CMP request for the standard or urgent procedure through the web interface
2.	**Validation: Outcome?** • If the validation is approved, go to step 3 • If the validation is rejected, go to step 2.1 • If there are issues identified, go to step 2.2
2.1	**Inform requester** for reason of rejection and then the process ends
2.2	**Contact requester** by e-mail to ask **for clarification** (go to step 2.3)
2.3	**Is clarification received within the deadline?** • If yes, go to step 2 • If no, go to step 2.1
3.	**Create certificate** • Compile and check information to create the certificate
4.	**Create annexes** • Check the variation to be used and create the annexes
5.	**Sign and send electronic certificate**