

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.

Human Medicines Division process map

Managing the product lifecycle and medical devices

Supporting the generation of scientific evidence

Managing the benefit risk according to therapeutic areas

Managing the quality and safety of medicines

Managing the quality of outputs

Managing the quality of outputs

Paediatric medicines development

Scientific advice

Scientific advice

Presubmission processes

PSUSA & other related post-authorisation processes

PSUSA & other related post-authorisation processes

Pharmaco vigilance

QD and non-compliance management

Sampling & testing of CAPs

Inspection coordination

Scientific meeting authorisation processes

From Carbon Coordination

Scientific meeting authorisation processes

Sampling & testing of CAPs

Translations

Regulatory and scientific guidelines

Regulatory and scientific meeting management

Scientific meeting management

Scientific meeting management

Product services



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
- <u>Information note on the format and validity features of electronic certificates for medicines</u> 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

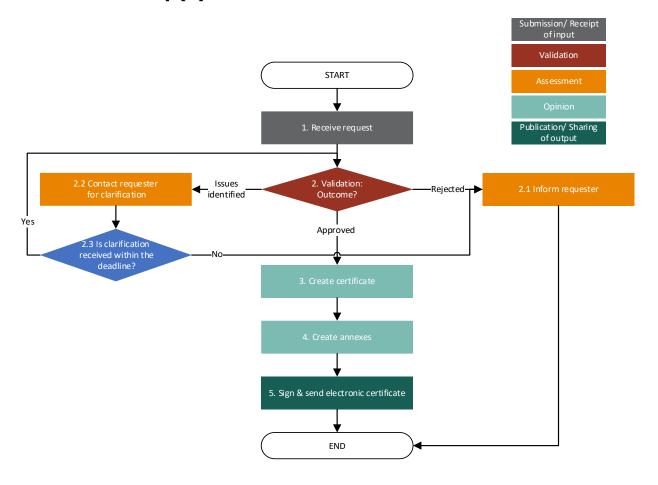
QD Quality defect

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	