Human Medicines Division
EMA/268846/2024

Business process description

Title: Sampling and testing of CAPs		
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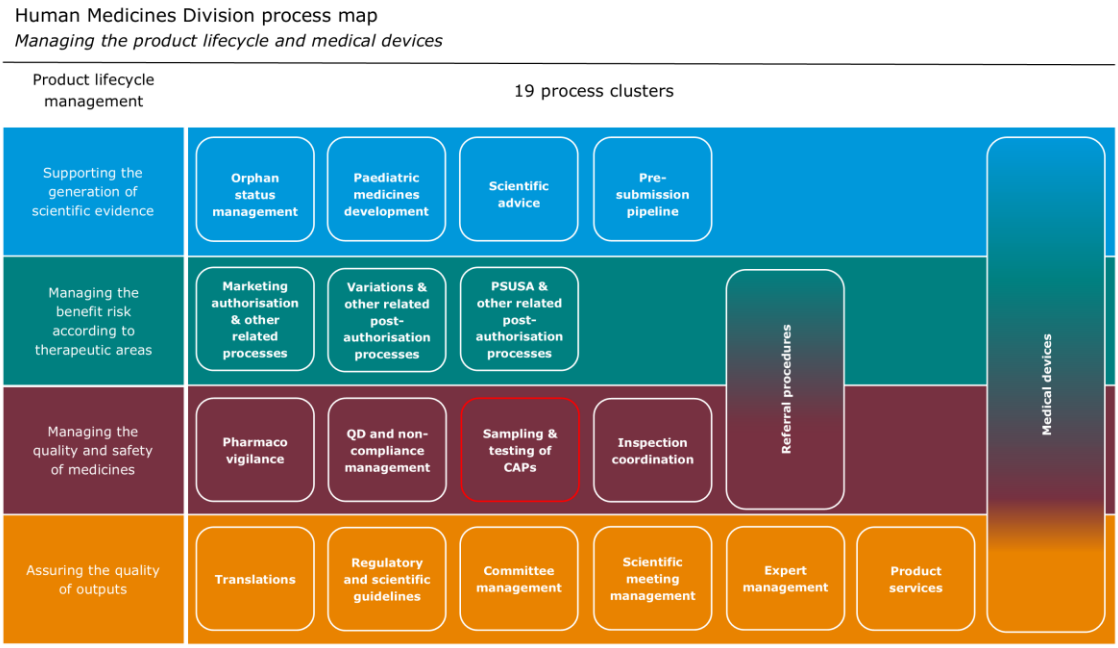
1. Introduction

The purpose of this document is to describe the high-level & end-to-end process of the sampling and testing programme of CAPs coordinated by the European Medicines Agency to ensure public and animal health protection. The sampling and testing of CAPs process describes the pre-authorisation and post-authorisation testing as well as reporting activities and it applies to Human and Veterinary medicinal products in scope.

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.



2. Changes since last revision

New business process description

3. Related documents

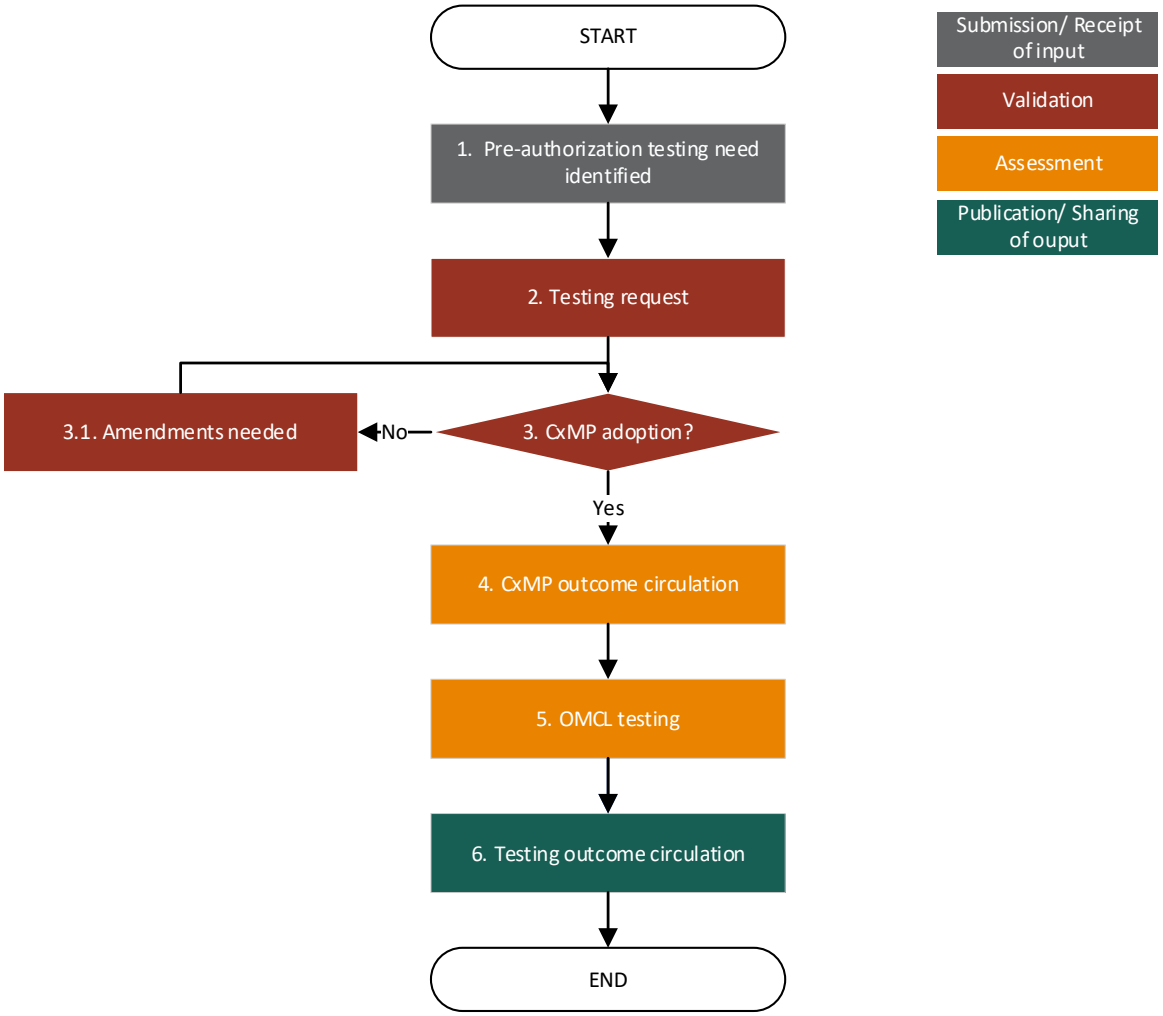
- CAP Sampling & Testing Programme
- Sampling and Testing of Centrally Authorised Products
- Sampling and testing | European Medicines Agency (europa.eu)

4. Abbreviations/Definitions

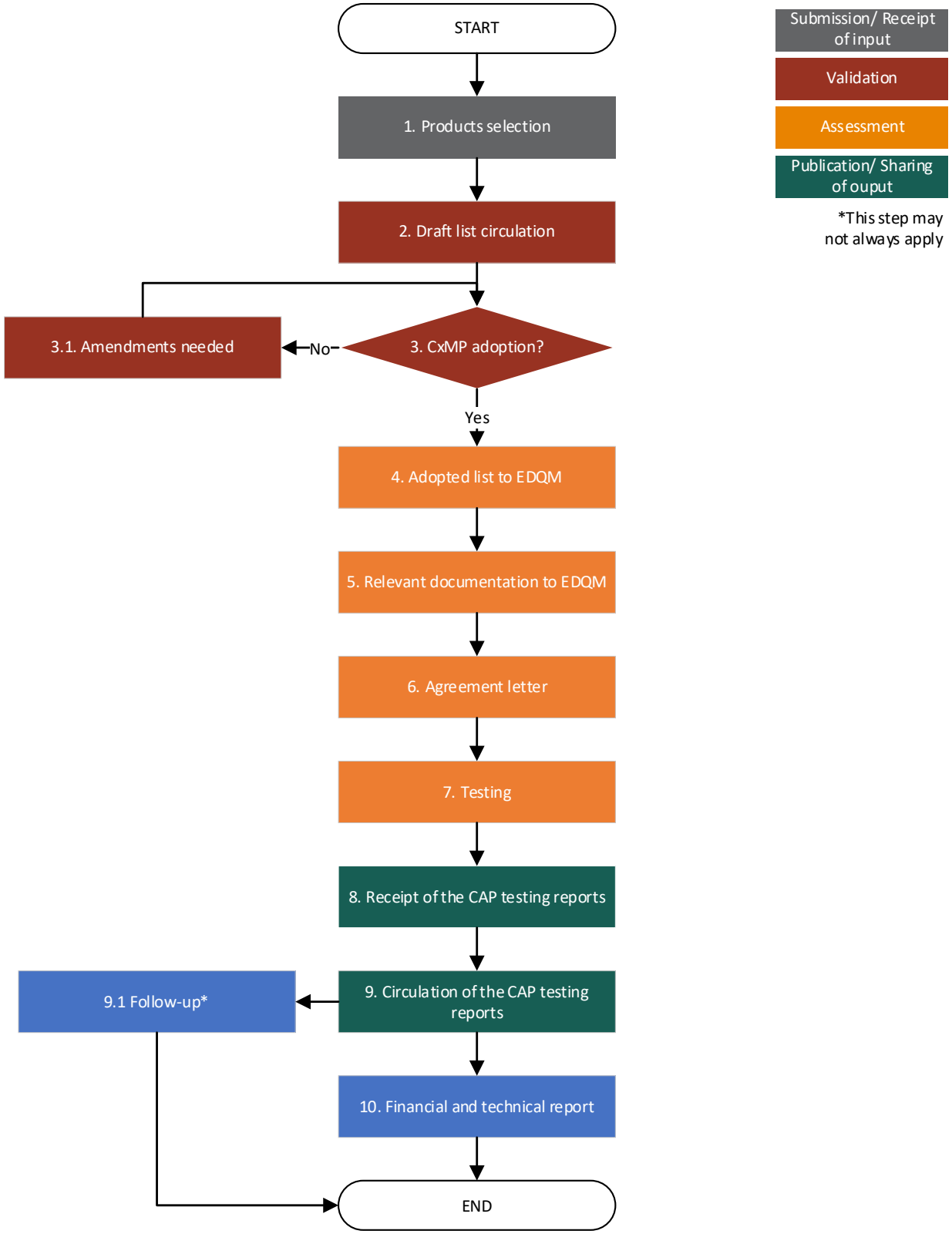
CAPs	Centrally authorised products
CHMP	Committee for Human Medicinal Products
CVMP	Committee for Veterinary Medicinal Products
CxMP	CHMP (Committee for Human Medicinal Products) or CVMP (Committee for Veterinary Medicinal Products)
EDQM	European Directorate for the Quality of Medicines and Healthcare
EMA	European Medicines Agency
MAH	Marketing authorisation holder
OMCL	Official Medicines Control Laboratory
PSUSA	Periodic safety update report single assessment
QD	Quality defect

5. Process map(s)

5.1 Pre-authorisation



5.2 Post-authorisation



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

6. Procedure

6.1 Pre-authorisation

Step	Description
1.	**Pre-authorisation testing need identified** • (Co-)rapporteurs identify the need for a pre-authorisation testing during the assessment of a procedure (e.g. initial marketing authorization application) and send the request to EMA
2.	**Testing request** • Request (co-)rapporteurs to provide the completed form "Committee of medicinal products testing request" which includes the details of the request (e.g. product, samples, tests to be carried out, OMCL assigned if applicable, deadline for reporting) • EMA may support the (co-)rapporteurs in the assignment of an OMCL if needed
3.	**CxMP adoption?** The test requests for human medicines are sent to CHMP and for veterinary medicines to CVMP for adoption. Is the pre-authorisation test request adopted by CxMP? • If yes, go to step 4 • If no, go to step 3.1
3.1	**Amendments needed** • Liaise with the (co-)rapporteurs to amend the pre-authorisation testing request as needed • Re-send the testing request to CxMP for adoption Go to step 3
4.	**CxMP outcome circulation** • Inform (co-)rapporteurs of the CxMP outcome for the request • Send the pre-authorisation testing letter to the applicant/MAH
5.	**OMCL testing** • The applicant/MAH provides the samples, materials and relevant documentation to the testing OMCL/designated laboratory. EMA may liaise with the applicant/MAH as needed to support the OMCL or the designated laboratory. • The OMCL/designated laboratory conducts the testing

Step	Description
6.	**Testing outcome circulation** • The OMCL/designated laboratory provides the CAP testing results to the (co-)rapporteurs and/or EMA, which will be then used for the assessment of the procedure that triggered the pre-authorisation testing request

6.2 Post-authorisation

Step	Description
Year n-1	
1.	**Products selection** • Select the CAPs to be tested in a given year. The list is prepared in year n-1 for the programme in year n.
2.	**Draft list circulation** • Circulate draft list of CAPs for inclusion in the sampling and testing programme to the EDQM and the CAP Advisory Group for their endorsement
3.	**CxMP adoption?** The list for human medicines is sent to CHMP and for veterinary medicines to CVMP for adoption. Is the list of CAPs adopted by CxMP? • If yes, go to step 4 • If no, go to step 3.1
3.1	**Amendments needed** • Amend the list as needed • Re-send to CxMP for adoption Go to step 3 *Note: The list should be adopted no later than July of year n-1*
4.	**Adopted list to EDQM** • Send final adopted list of CAPs to EDQM
5.	**Relevant documentation to EDQM** • Request the MAH to provide the relevant documentation (specifications/testing methods/etc) to EDQM • Request the (co-)rapporteurs to provide the testing recommendations • EMA to send the testing recommendations to EDQM

Step	Description
6.	**Agreement letter** • EMA to prepare the agreement letter which contains the selected products to be tested in year n as agreed with EDQM, the CAP Advisory group and any relevant stakeholder as applicable • Send final agreement letter to EDQM for review and signature. This should be signed by EMA and EDQM before October n-1.
Year n	
7.	**Testing** • The MAH provides the samples, materials and relevant documentation to the EDQM or to the OMCL/designated laboratory, as agreed by EDQM • The OMCL/designated laboratory conducts the testing
8.	**Receipt of the CAP testing reports** • The EDQM provides electronic copies to EMA of the reports for each product tested during year n
9.	**Circulation of the CAP testing reports** • CAP testing reports are sent to the MAH and (co-)rapporteurs by EMA for comments
9.1	**Follow-up** • EMA liaises with MAH and (co-)rapporteurs as needed to ensure follow-up actions are addressed *Note: This step may not always apply. Depending on the nature of the follow-up actions, other processes could be triggered (e.g. submission of a variation, defective product report, etc.).*
Year n+1	
10.	**Financial and technical report** • The EDQM provides the financial and technical report and EMA reviews it to process payments