



Standard operating procedure

Title: Sampling and testing of centrally authorised products		
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1. Purpose

To enable the management of the programmes of sampling and testing of centrally authorised products in a consistent way.

2. Scope

This SOP applies to the Compliance and Inspection Sector only, and should be read in conjunction with the documents listed under section 6.

3. Responsibilities

It is the responsibility of each Head of Sector to ensure that this procedure is adhered to within their own sector. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

4. Changes since last revision

Updated to reflect the new organisational names in the Agency and the new corporate identity. The process map and the procedure have been slightly reworded for better clarity. The following steps have been changed: Steps 4 and 4.1 have been moved and are now step 6 and 7 to reflect actual procedure. Deleted steps: step 7 because it is an external activity and step 8 because it is not relevant.



5. Documents needed for this SOP

Template letter to Rapporteurs requesting testing recommendations for human products (X:\Templates\Others\Compliance and Inspection\S&T\Request Recommendations Human)

Template letter to Rapporteurs requesting testing recommendations for veterinary immunological products (X:\Templates\Others\Compliance and Inspection\S&T\Request Recommendations Vet Immunological)

Template letter to Rapporteurs requesting testing recommendations for veterinary chemical products, (X:\Templates\Others\Compliance and Inspection\S&T\Request Recommendations Vet Chemical)

Template letter to Marketing Authorisation Holder requesting documentation (X:\Templates\Others\Compliance and Inspection\S&T\Request Documentation)

6. Related documents

Sampling and Testing of Centrally Authorised Products - Objectives and description of the Programme (EMA/INS/S&T/5291/2005)

Operational Units/Inspections/Samptest/c_Procedures/m_General Procedures

Development of risk based approach for the selection of products (EMA/INS/S&T/120857/2008)

Operational Units/Inspections/Samptest/c_Procedures/m_General procedures

Cooperation Agreement between EMA and EDQM for Sampling and Testing of Centrally Authorised Products (EMA/274375/2007)

Operational Units/Inspections/Samptest/a_Contracts EMA-EDQM/a3_Agreement (2008-2012)

Annual Agreement Letter template

X:\Templates\Others\Compliance and Inspection\S&T

SOP/INSP/2011 Reports circulation and follow-up procedure

SOP/INSP/2016 Sampling and testing of centrally authorized products – financial procedures

7. Definitions

AAL: Annual Agreement Letter

AR: Assessment report

CAP: Centrally authorised product

CHMP: Committee for Medicinal Products for Human Use

P-CI: Compliance and Inspection Sector in the Patient Health Protection Unit

CR: Co-Rapporteur

CTD : Common technical document

CTR : CAP testing report

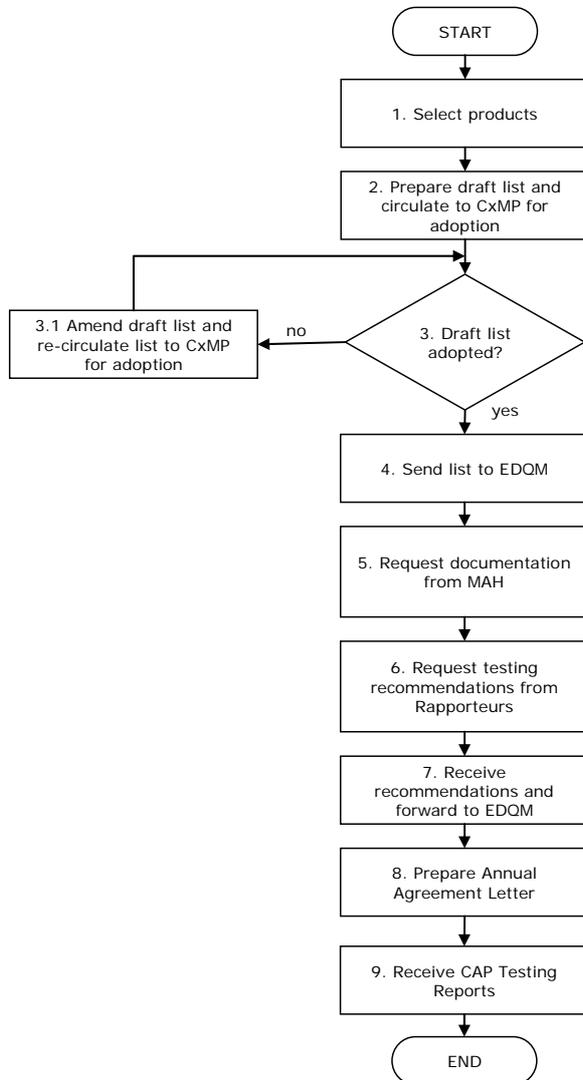
CVMP: Committee for Medicinal Products for Veterinary Use

CxMP: CHMP and CVMP

EDQM: European Directorate for the Quality of Medicines and HealthCare, Strasbourg

DREAM: Document Records Electronic Archive Management
GMP: Good Manufacturing Practices
LoQ: List of Questions
MAH: Marketing authorisation holder
R: Rapporteur

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
1	Select the CAPs to be tested in a given year. The list is prepared in year n-1 for the programme in year n. The selection is carried out on the basis of the indications contained in document EMA/INS/S&T/5291/2005, and on the basis of specific documents on risk-based approach for the selection of products (EMA/INS/S&T/81176/2007 and EMA/INS/S&T/75010/2009).	Scientific Administrator
2	Prepare draft list of CAPs based on selection in step 1 to be included in the annual sampling and testing programme and circulate list to CxMP Secretariat.	Assistant
3	Is list of CAPs to be tested adopted? List adopted: go to Step 4 List not adopted: go to Step 3.1	Assistant
3.1	Amend list and re-circulate to CxMP for adoption. The list should be adopted latest in March year n-1.	Assistant
4	Send adopted list to EDQM by 31 March in year n-1. For the financial agreement see SOP/INS/2016.	Assistant
5	Request documentation (specifications/testing methods/etc.) from MAH (year n-1). Send a letter to the MAH of each product and ask them to send the documentation and information requested to EDQM, and send a copy of the cover letter and statement to P-CI. 5 weeks deadline to reply.	Assistant
6	Request testing recommendations from Rapporteurs (year n-1). If testing recommendations are not available: <ul style="list-style-type: none"> from the Day 80 AR for human new applications after the responses received to the LoQ between Day 121-125 for veterinary new applications send a letter to the Rapporteurs of each product and ask them to record their testing recommendation on the template attached to the letter and return it to the P-CI. 4 weeks deadline to reply.	Assistant
7	Receive recommendation from Rapporteur, save them in DREAM and forward them to EDQM.	Assistant
8	Finalise the list of products, prepare the AAL and send it to EDQM for signature by 1 August in year n-1. Receive signed AAL from EDQM by 1 September in year n-1.	Assistant
9	Receive CAP Testing Reports from EDQM during year n. On an on-going basis the EDQM provide to the EMA electronic copies of the reports for each product tested. File copies of the product reports in DREAM. For Reports circulation and Follow-up actions see SOP/INSP/2011.	Assistant

10. Records

Electronic copies of documents related to each programme are filed in electronic folders in DREAM under: Operational Units/Inspections/Samptest/e.Programmes/YYYY.