OMCL Network of the Council of Europe
GENERAL DOCUMENT

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Sampling and Testing of Centrally Authorised Products – Procedure for Parallel Distribution Programme

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Concerned Network	EU/EEA OMCLs – EU/EEA Sampling Organisations

SAMPLING AND TESTING OF CENTRALLY AUTHORISED PRODUCTS

PROCEDURE FOR PARALLEL DISTRIBUTION PROGRAMME

Introduction

Parallel distribution is the distribution of a centrally authorised medicinal product from one Member State to another by a pharmaceutical company independent of the marketing-authorisation holder.

On 20 May 2004, notifications of parallel distribution of centrally authorised medicinal products became mandatory throughout the community, in accordance with Article 57(1)(o) of Regulation (EC) No 726/2004. The task of the European Medicines Agency (EMA) is to check compliance of products in the parallel distribution chain with the conditions laid down in Community legislation on medicinal products and in the marketing authorisation of the product. Parallel Distributed (PD) CAPs can be tested as part of the Parallel Distribution Programme. As part of this individual testing programme, each year a number of PD CAPs will be randomly sampled from the parallel distribution chain and checked. The number of products to be sampled and checked yearly should be maximum 10, unless otherwise agreed in writing.

This paper describes the operational procedure for post-authorisation sampling and checking of PD CAPs within the Parallel Distribution Programme. It contains a step by step description starting from the planning of the forthcoming test programme (year n-1) to the presentation of the overall CAP Agreement Report . It should be read in conjunction with the General procedure PA/PH/CAP (05) 49 in its current version.

Statements made in italics in this procedure are comments related to the steps described.

Subsequent actions to be taken based on the outcome of the testing lie within the responsibilities of the EMA.

Step 1: **Proposed Programme**

In August (year n-1) the EMA Secretariat prepares a proposed list of PD CAPs selected on the basis of the number of notifications for parallel distribution received by EMA. The list of products will be established following risk-based considerations and will then be distributed to the OMCL Network beforehand.

Out of this list, samples will be taken by samplers in year n depending on availability for 10 products (unless exceptional circumstances). If applicable, the most parallel distributed and the never sampled products should be prioritised. In special circumstances, for example if a risk of falsification has been identified, the EMA may provide a priority level for sampling.

As such, every year additional products will be selected and added to the existing list of products selected in the past; thus, the number of products included in each yearly programme will continuously increase with time, offering more chances to get a sample.

Step 2: **Final Adoption of the Programme for the Year n**

The final programme is normally adopted during the September (year n-1) meetings of the CHMP and CVMP.

The EMA Secretariat informs the EDQM, Intergovernmental Committees and Network Division (ICND) about the decision in a timely manner (list of products). The receipt of this list is confirmed by EDQM in writing.

Step 3: **Gathering of the Documentation and Information Package necessary to carry out the Yearly Programme**

Shortly after the adoption of the list of products, the EMA contacts the MAHs of the listed PD CAP products, asking them to provide EDQM by end year n-1 with the relevant information from the original application, as amended during the assessment of the application and by relevant variations (i.e. quantitative and qualitative composition of the finished product) including health and safety information about the finished product and special precautions to be taken during analysis and information on potential classification as controlled substance.

To help planning the future sampling phase, the companies are also asked to forward directly to EDQM a filled in and signed electronic voucher.
Section 1 of the Voucher is signed by the MAH or its agent and returned to the EDQM. By signing the Vouchers the MAH commits to rapidly replace the indicated amount of pharmaceutical units or less (whichever was practically sampled).
Section 2 of these documents is filled in by the EDQM, indicating the EDQM project number and the exact amount of pharmaceutical units needed.

Once the duly filled-in documents have been returned, they are kept at the EDQM until the initiation of the sampling operations.

The receipt of the documents is confirmed by EDQM to the MAH after having ensured that the documentation is complete. In case of outstanding replies, the EMA sends a reminder to the MAH.

Each PD CAP is identified by an internal EDQM code (PD_CAP 20xx/Y) and its EU number. The EDQM coding system allows distinguishing between different dosage forms or strengths of a single product, thus ensuring easy traceability.

Documentation is stored at EDQM, ICND, in an archive system in electronic format with restricted access.

In parallel, the EMA provides additional relevant information to the EDQM secretariat together with the list of PD products, such as the countries where the products are parallel distributed and the name and contact details of the parallel distributors.

Step 4: **Sampling**

The list of PD products and their marketing situation is distributed to the samplers by e-mail, so that they can check if products are available at the parallel distributor. Sampling operations can be performed from the time where the list of product is distributed until the end of September of the Year **n**.
Reminders will be sent out by the EDQM Secretariat twice a year to ensure that samplers regularly check if products are available at the parallel distributor. Every time a PD product is collected, the EDQM Secretariat will circulated an up-dated list.

Should a product be available at the parallel distributor level, the sampler will immediately inform the EDQM Secretariat, who will providethe Official Sampling Request electronically (i.e. e-Voucher and label check questionnaire),

The sampler/Member State's Agency completes Section 3 of the e-vVoucher when taking the samples and clearly identifies the quantity of packs (tablets/units) actually sampled. For the label check, a single pack should be collected and checked at the Parallel Distributor wholesaler premises.

Section 4 of the Voucher is then signed in his/her presence by the person responsible at the site where the samples are drawn (sampling location), confirming thus the quantity and type of samples drawn as well as the location.

The sampler immediately sends the completed Voucher directly to the MAH contact person or to the MAH's agent designated in Section 1.

Upon receipt, the MAH replaces the sampled product, in the number and pack size indicated in Section 3 of the Voucher, directly to the sampling location identified in Section 4 within one month unless another arrangement has been agreed with the sampling location.

For details on the conditions of transportation of samples, please refer to the "General procedure for Sampling and Testing of Centrally Authorised Products", PA/PH/CAP (05) 49 in its current version.

Each PD product indicated on the list can only be sampled once. If, for a given product, several samplers contact the EDQM at the same time, only one Official Sampling Request will be provided. The choice of the country will be taken so that an equal repartition of the sampling operations can be reached at the end of the year.

If the authenticity of the PD sample is questioned, additional units will be drawn in order to perform physico-chemical tests; for solid forms/tablets, approximately 30 units should collected, whereas for injectable forms 3 to 6 units would be enough. In parallel to the shipment of the Official Sample Request sent to the sampling contact person, EDQM also sends a request to the MAH to collect three different batches of a Control Test Sample (CTS), necessary reagents/standards - where applicable and additional relevant documents (i.e. Certificates of Analysis). If fewer batches are available, the tests can still be performed but the results will be "less consolidated".

Step 5: **Label check and reporting**

The packaging/ leaflet check is performed on each pack collected by the Sampler using the questionnaire provided by the EDQM Secretariat on the ACT Plateform.

The Anti Tampering Device (not mandatory for veterinary products) should be checked, and the efficiency of the Anti-Tampering Device should be assessed. If possible, the scan of the Unique Identifier (not mandatory for veterinary products) should be performed to check the status of the product in the European Medicines Verification System (EMVS) database. The status should be "active" in the database.

The sample and its filled in label check questionnaire are send back to the EDQM following the instructions given in the INFO008 sheet. After reviewing the questionnaire to ensure all cases have correctly been ticked by the sampler, the EDQM secretariat forward them to the EMA; this step corresponds to the "Reporting" phase.

A status of the programme is provided by the EDQM Secretariat during the CAP Annual Meeting of the Year n.

The EDQM Secretariat also report to the EMA the work performed in the Agreement Report of the Year n+1.

If the authenticity of the product is questioned, physico-chemical tests will be performed according to Steps 6 and 7.

Step 6: **Receipt and dispatching of all Samples, Reference Materials and Reagents – where applicable**

For detailed information, please refer to the "General procedure for Sampling and Testing of Centrally Authorised Products", PA/PH/CAP (05) 49 in its current version.

Step 7: **Testing and reporting**

If the authenticity of a PD product is questioned, the OMCL network is contacted by the EDQM Secretariat to find as quickly as possible a volunteer for testing.

All OMCLs from the different EEA Member States should be given the possibility to be involved and the choice should be made on a voluntary basis (keeping in mind individual technical competencies).

Testing is the responsibility of the participating OMCLs. For each product to be tested, an Individual CAP Testing Template is signed between the EDQM and the testing OMCL(s). This contract establishes the general terms governing the testing and includes the amount of the financial contribution that is provided to the OMCL(s) in order to support the costs incurred with the testing. The testing cannot be further sub-contracted, if not agreed in advance in writing by the two contract partners, i.e. the EDQM and the OMCL/Competent Authority.

Several options (based on different techniques available in OMCLs) could be used to test the authenticity of a product. The decision about the testing strategy would be taken on a case-by-case basis by the testing OMCL in view of the product to be tested and the instrumentation available. Different cases have been analysed and recommendations for testing strategies were summarised in the position paper An "aide-mémoire" for the testing of suspected illegal and counterfeit medicines, PA/PH/OMCL (06) 81 in its current version.
The report is due at the latest 65 working days after receipt of the test samples, the date of receipt being documented on the acknowledgement of receipt for the samples.

The participants provide a testing report, in a format of their choice, containing at least, the object of the study (i.e. name of the product, project N°, pharmaceutical form, number of samples tested, batch numbers…), the strategy/technique used, a summary of the test(s) performed, results obtained and a conclusion on whether or not there are any reasons to question the authenticity of the product.

It is not possible for OMCLs to definitively determine the authenticity of a product, because ultimately only the manufacturer is in possession of exhaustive information on how a specific batch has been produced (e.g. sources of ingredients and packaging materials). For that reason OMCLs are encouraged to highlight similarities and differences between the tested sample and the original product in their reports, on the basis of their observed results.

An abridged report compared with the regular programme is set up by the EDQM within one month after the receipt of the results for a given product. Reports are issued on an ongoing basis and are distributed to the EMA and all OMCLs.

Enforcement or any other follow-up measures are coordinated by the EMA in connection with the Rapporteur/Co-Rapporteur and where appropriate the testing OMCL(s). The EMA has the responsibility of the actions initiated as an outcome of the testing. A report on the outcome of the annual programme including follow-up measures initiated further to the testing is published by the EMA.

The EDQM reports about the status of the programme during the CAP Annual Meeting of the Year n and provides an overview of the work performed to the EMA in the Annual Report of the Year n+1.

History Sheet of Technical Post-Approval Changes

Title of document: PA/PH/CAP (18) 79 R3 - Sampling and Testing of Centrally Authorised Products – Procedure for Parallel Distribution Program

- The History Sheet of Technical Post-Approval Changes was added.

♥ **Date of becoming effective: November 2025**

Title of document: PA/PH/CAP (18) 79 R2 - Sampling and Testing of Centrally Authorised Products – Procedure for Parallel Distribution Program

- A new cooperation agreement between EDQM/EMA was signed at the end of 2023. As of 2025, the Parallel Distribution Programme remains as an individual programme, but the strategy was revised and only the packaging/leaflet check would be performed.
- The Anti-Tampering Device (not mandatory for veterinary products) should be checked, and the efficiency of the Anti-Tampering Device should be assessed. If possible, the scan of the Unique Identifier should be performed to check the authenticity of the sample.
- A physico-chemical testing would only be requested if the authenticity is questioned.

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