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Sampling and Testing of Centrally Authorised Products – Procedure for Generics Programme

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SAMPLING AND TESTING OF CENTRALLY AUTHORISED PRODUCTS

PROCEDURE FOR GENERICS PROGRAMME

Introduction

A generic medicinal product for human use is defined by Article 10 of Directive 2001/83/EC, as amended, as "a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, isomers, mixture of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form." The same definition applies to generic veterinary medicinal products (Article 18 of Regulation (EU) 2019/6, as amended). Human and veterinary reference medicinal products are defined as medicinal products authorised under Article 6 of Directive 2001/83/EC or Article 5 of Regulation (EU) 2019/6, respectively. A reference medicinal product can either be a centrally authorised medicinal product or be authorised through a Mutual Recognition/Decentralised or National procedure. Alternatively, a generic medicinal product of a centrally authorised reference medicinal product can be authorised through one of the four available procedures and thus might not necessarily be a CAP.

When a generic medicinal product as defined above has been authorised through the Centralised procedure, it might be included as such in the CAP Annual Programme. Under these circumstances, the "General procedure for Sampling and Testing of Centrally Authorised Products", PA/PH/CAP (05) 49 in its current version, applies.

Generic medicinal products authorised through the Centralised procedure can also be included in a specific CAP Generics Programme. The Generics Programme is an individual testing programme, which is part of the CAP Sampling and Testing programme, where Centrally Authorised Generic Products with the same or similar dosage form and containing the same Generic INNs, and ideally for which there is a developed common test method from previous testing experience in the OMCL network available, are sampled and tested. Three Generics programmes are usually run every year. It should be read in conjunction with the General procedure PA/PH/CAP (05) 49 in its current version.

This paper describes the operational procedure for post-marketing sampling and testing of Generics CAPs, when they are included in the Generics Programme. This only applies to chemical products. It contains a step-by-step description starting from the planning of the forthcoming test programme (year n-1) to the presentation of the Annual Report to the EMA (year n+1).

In the eventuality of Out-Of-Specifications results, appropriate verifications will take place according to the established procedures and using the registered methods for the sample in question, if different; any subsequent action is the responsibility of the EMA.

The establishments in this procedure do not prevent the OMCLs from liaising with their National Competent Authority within the framework of their regulatory activity.

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

Planning of the Forthcoming Programme

Step 1: **Proposed Programme**

A list of molecules for potential future generics programmes, drafted by the EMA Secretariat, is re-evaluated on a yearly basis in collaboration with the EDQM and the CAP advisory group members.
The three Generic INNs groups to be tested every year are agreed during CAP Advisory group meetings and the work programme is documented in the minutes thereof.

When the list is available, the EDQM Secretariat helps to identify volunteers (Scientific Advisor) for each Generic INN (e.g. survey sent to the OMCL Network), so that the workload can be equally split and ideally between as many OMCLs as possible. The OMCLs having previous experience in testing the same or a similar product - either in the CAP programme or in MRP/DCP/national programmes - would be given priority for being the Scientific Advisor, as feasibility studies might be skipped in these cases.

A draft timetable indicating the year of testing and the OMCL selected per each Generic INN is prepared by the EDQM and provided to the EMA Secretariat. The work programme is maintained and updates are presented during the CAP annual meetings. Proposed timelines are kept internally in order to have more flexibility and re-arrange the work programme in case the selected OMCL could not honored his participation at the predefined date.

For the purpose of programme planning and budgeting, the sampling and testing of each Generic INN Group will be organised as "yearly" programme, as set out in the following steps.

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

Based on the work programme agreed, the EMA prepare the list of products associated to the proposed Generic INNs which is normally adopted during the **February/March** (year n-1) meetings of the CHMP and CVMP.

Special care should be taken when the list of products is prepared, to identify co-marketed or duplicate products (i.e. identical manufacturing sites…), so that Generics Programme having the higher number of products from multiple sources are prioritised (i.e. as much different MAHs as possible).

The EMA Secretariat informs the EDQM of the decision in a timely manner (registered sources of a Generic CAP product and list of the trade name products with a given International Non–proprietary Name - INN, to be considered). The receipt of this list is confirmed by the EDQM in writing.

Step 3: **Preparatory phase**

Gathering of the Documentation and Information Package necessary to carry out the Yearly Programme

In **March** (year n-1), after confirmation of the annual list of products, the EMA contacts the MAHs of the listed Generic CAP products asking them to provide the EDQM within 5 weeks with the current quality parts of the Common Technical Document (2.3 Quality overall summary and 3.2.S & 3.2.P of the Module 3 Quality), including health and safety information about the active substance, 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 the EDQM the present and prospective market situation of the product up to the end of the year n (EEA Member States where the product is or will be marketed plus estimate of stocks available for low volume products), together with additional information on special distribution pattern (other than the usual channel) of the product in the various member states.

In addition, a written statement that "the methods and specifications provided directly to the EDQM for the control of the active ingredient and the finished product are those currently approved in the original application as amended by any subsequent relevant variations" has to be included.

The receipt of the documents is confirmed by the 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. The updating of the market situation for a product included in an ongoing programme lies within the responsibility of the EDQM which will request the necessary information directly from the MAH.

The MAH is asked to automatically supply any Module 3-related documentation that may have been amended by a variation and approved after the date of submission of the initial information package to the EDQM.

The MAHs should ensure that all relevant complete and up-to-date detailed Standard Operating Procedures (SOPs) in English for the tests (also considering associated procedures) as well as the full validation is provided to the EDQM. The EDQM shall contact the MAH should suitable level of details not been achieved.

Each Generic CAP is identified by an internal EDQM code (CAP 20xx/Y) and its EU number. The EDQM coding system makes it possible to distinguish between different trade name products, thus ensuring easy traceability of the test samples.

Documentation is stored electronically at the EDQM, in specific IT folders with restricted access.

For each Generics CAP programme, all registered CAP products ("registered sources") for a given INN, plus the reference medicinal product are included in the list of products.

- **Preparation of the "INN test Protocol"**

As the necessary documentation and information are received, the EDQM compiles all the quality documents and transfers them to the Scientific Advisor (**at latest before summer of the year n-1**). The Scientific Advisor is asked to fill in an acknowledgment of receipt of confidential documents.

On the basis of the documentation available, the Scientific Advisor will prepare an "INN Test protocol" including the parameters and methods selected for the testing of the active substance – when applicable, and the finished products. The Scientific Advisor shall give a rationale/justification regarding the choice of the test parameters for the active substance and/or for the finished products.

The methods to be used for the testing of generics products and related APIs are proposed by the testing OMCL according to past experience with the molecule and can be Ph. Eur., MAH and/or in-house methods specifically developed. It is the OMCL responsibility to ensure that the testing methods are accurate for the purpose of the testing campaign of the INN generic products. To this end, feasibility studies can be performed in the laboratory; product samples and materials can be requested to the MAHs if needed, upon request to the EDQM Secretariat.

The CAP generics programmes involve a high workload, handling of toxic products, and difficulties in obtaining samples. These challenges make it necessary to optimise the testing process, while preserving the balance between not having exhaustive controls and having sufficient data to check the quality of the products.

Various strategies that could be applied to optimise the Generics programme are based on the feasibility study, selection of parameters/products, and combining/coordination of studies. The feasibility study could either use expertise-based efficiency or be conducted right before the testing. The selection of parameters/products could take into account the handling of toxic and anticancer products, the optimisation of limited sampling (for manufacturing parameters), or the bracketing/matrixing approach. The combination/coordination of studies could benefit from the synergies of different studies.

By the end **of the year n-1** at latest, the Scientific Advisor should provide a draft test protocol, the pharmaceutical forms and strengths selected for the testing as well as an estimation of the amount of pharmaceutical dosage units required for the testing. The Scientific Advisor should also define and identify the Common Test Sample and the relevant non-commercially available reference materials, if possible.

The final "INN test Protocol" should be ready by **the end of the 1st semester of the year n**.

Sampling preparation

On the basis of the market availabilities received from the MAHs, a Sampling questionnaire is set up for each Generics programme.

The Sampling Questionnaire consists of a table indicating the Member States where the products are marketed, a proposal for sampling country(ies) and the estimated number of units to be sampled. General information regarding the products (such as EU numbers and special storage conditions) is also provided in the questionnaire. As soon as the draft test protocol is finalised, by **the end of the year n-1** at latest, the EDQM distributes this Questionnaire to the nominated contact persons of each National Authority, and requests confirmation within 1 month regarding the availability on their respective market of the products tentatively allocated to each of them. A first estimation of the sample size may be

given for information. In case of problems of availability of a given product in one country, sampling will be allocated to another Member State.

Samples are to be collected along the distribution chain by the competent national services of, as a general rule, three EEA Member States[1]: the choice of the countries is made by the EDQM taking climatic conditions of the different Member States into account and with the aim of sharing the sampling workload equally among the countries. Sales volumes are also taken into consideration. As far as possible, samples should be taken from all areas of the distribution chain (wholesaler, pharmacy, hospital or veterinarian as applicable).

In general, 3 market samples are withdrawn from the EEA market per generics product. Within each sampling country, samples should originate from a single batch to ensure comparability and adequacy of the results of the different tests performed (3 different batches / 1 batch per sampling country).

The sample size is a case-by-case decision depending on the number of pharmaceutical dosage units needed per test procedure, the number of presentations of the dosage forms to be tested, the availability of the product, the size of the market, the clinical use of the product etc. The general rules may be adapted on a case-by-case basis to take into account the specific market situation (e.g. product available in a single member state only).

After receipt of the responses, the EDQM establishes the final Sampling Plan.

The actual sampling phase should be initiated by the **end of the 1st semester of the year n** in order to start the active testing phase in the **2nd semester of year n at latest**.

Year n

Step 4: **The Sampling and Testing Programme**

Step 4A1: **The electronic vouchers**

For each trade name product, an e-voucher for rapid sample replacement is sent to the legal contact person of the MAH or to its agent for signature with a deadline of 2 weeks for returning them to the EDQM. The EDQM indicates in Section 1 of the e-voucher the name of the product, its strength, its pharmaceutical form, its EU number, the EDQM unique project number and the maximum amount of pharmaceutical dosage units required for the testing programme based on the parameters selected by the Rapporteur/Co-Rapporteur in their recommendations. Section 2 of the e-voucher is completed and signed by the MAH or its agent and the originals are returned to the EDQM. By signing the e-vouchers the MAH commits to rapidly replacing the indicated number of pharmaceutical units or fewer (whichever was sampled in practice). The EDQM issues the Vouchers for all products and sends them to the relevant MAHs in late **November**/beginning **December of year n-1**. Once the duly e-vouchers have been returned, these are kept at the EDQM until initiation of the sampling operations.

[1] Because of the reduced size of its market, Liechtenstein is not included among the sampling locations.

Step 4A2: **Sampling**

Market samples

Once the signed e-vouchers are returned, Official Sampling Requests e-mails are sent by the EDQM to the nominated contact persons in the sampling Member States. E-vouchers are designed to enable replacement by the MAHs of the collected units. The Sampling Form, the electronic voucher and the Delivery Terms and Conditions sheet can be downloaded from the ACT platform using the link provided in the Official sample request e-mail.

Each sampling Member State chooses an appropriate site within the distribution chain as closely as possible to patients on its national territory. Samples should preferably be drawn from a retail pharmacy or a hospital pharmacy. If not, sampling should be performed at wholesalers. Sampling at MAH warehouse level shall be performed only as the last resort. The choice of sampling location is dependent on the availability of the required product(s) and on the number of packs requested by the EDQM for appropriate testing in accordance with the pack size(s) available. The sampler/Member State's Agency completes and signs Section 3 of the e-voucher when taking the samples and clearly identifies the quantity of packs (tablets/units) actually sampled. Section 4 of the e-voucher is then completed and signed 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.

Note: In order to avoid supply problems for life threatening products, the sampling contact person will, if necessary, ask the sampling location to increase stocks by the amount of pharmaceutical units to be sampled in advance of the sampling operation. In this case, the sampler should ensure that the samples are drawn from the original stock and not from the replacement stock.

The sampler sends the completed e-voucher to the MAH contact person or to the MAH's agent designated in Section 1. The samples drawn are transmitted to the EDQM under the required conditions of transport, together with the completed Sampling Form (which includes essential information regarding sampling and a label check) for traceability purposes and a copy of the filled in e-voucher – accompanying documentation should be uploaded on the ACT platform (i.e. "paper versions" of these documents should only be provided as last option). The instructions indicated on the conditions of delivery sheet must be taken into consideration.

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

Drug substance

A request for samples from the MAH is done on the basis of a list of the last 5 active substance batches used in the manufacture of recent finished product batches. This list will be provided by the MAH. The EDQM Secretariat will select one batch from the pool and request the adequate quantity of substance from the MAH.

Other sampling strategies for active substances might be envisaged, such as the sampling of the active substance at the relevant active substance or finished product manufacturing sites by EEA GMP inspectors. Another alternative approach could be to request material from active substance batches matching with the finished product batches drawn for testing. This requires a longer preparatory phase which would then need to be considered during the planning of the programme.

Common test sample and reference materials

An Official Sample Request e-mail is also sent to the MAH in order to collect a Control Test Sample (CTS) and all necessary non-commercially available reagents and standards. It is the Scientific Advisor who decides which product(s) to be used as CTS(s) and which are the necessary non-commercially available reagents and standards to be used.

The MAH is asked to fill in electronically a Sampling Form that contains the list of samples needed and to provide the accompanying documentation (i.e. CoAs, SDS sheet…) by uploading these documents on the ACT platform. Normally a deadline of eight weeks for sampling is given.

The EDQM states in the sampling request that testing will be performed according to a Test Protocol developed for this specific purpose within the OMCL Network.

Step 4A3: **Receipt of all Samples, Reference Materials and Reagents**

All incoming samples are registered and stored within the DRSL-Items (Division of Reference Standards and Samples) at the EDQM according to an EDQM internal procedures.

The Sampling Contact Person or the MAHs are informed of the good reception of the samples/materials per e-mail by DRSL-Items.

The storage conditions of the samples on their way from the manufacturer / sampling organisations to the EDQM must be verified and documented sufficiently: to this end, the electronic Sampling Form completed by the sampler/MAH should be made available on the ACT platform when samples are returned to the EDQM at latest.

Step 4A4: **Sample Preparation and Labelling**

The samples are labelled by DRSL-Items and prepared for dispatching to the testing OMCL following a defined timetable. Storage conditions for the samples, reference materials and special reagents are clearly indicated in an attached table which includes further important information on all sent materials such as batch numbers, expiry dates, etc.

Step 4B1: **Preparation of Individual CAP Testing template**

Individual CAP Testing templates defining the terms of collaboration between the testing OMCLs and the EDQM are issued by the EDQM and sent to the relevant OMCL for each INN Generics programme. These contracts have to be signed by an authorised representative of each party. The Individual CAP Testing template defines the agreed practical conditions for testing and reporting (duration of the testing phase and funding) and cross refers to the INN Test protocol and Results Data Sheet (see step below). An electronically signed original is kept

at the EDQM. At the same time persons responsible for testing are informed about the expected time schedule of the testing phase.

Step 4B2: **Elaboration of Results Data Sheets**

Based on the test protocol established by the Scientific advisor, the EDQM designs the **Results Data Sheet** (RDS), specific to each INN Generics programme. They actually consist in a template for the OMCLs to report their testing results. The RDS indicates clearly how many independent tests/assays are to be carried out as well as the number of replicates within each independent test/assay. For each test to perform, the RDS contains tables to be filled in by the testing OMCLs with their system suitability and analytical results.

Step 5: **Dispatching Samples / Results Data Sheets**

Samples are dispatched by the EDQM according to a defined timetable. The Scientific advisor is informed in a notification e-mail about the shipment of the samples and is sent electronically the Results Data Sheet and accompanying documentation.

The participating OMCL confirms the safe receipt of the samples, standards and data sheets and acknowledges any relevant information such as the storage conditions, handling etc. For that purpose, when the shipment takes place, a delivery note is sent to the recipient, together with an Acknowledgment of receipt form. The filled in Acknowledgement of receipt form is sent back to the Dispatch unit by the OMCL after having received the samples. A copy of this filled in acknowledgement of receipt is also addressed per e-mail to the Scientific Officer responsible of the project.

Upon reception, OMCLs are also requested to perform a visual check of the materials received to ensure that they conform to the expectations. Particular attention is paid to the products requiring specific temperature conditions. Any deviation from the expected appearance is reported on the acknowledgement of receipt returned to the EDQM who will initiate the appropriate investigations.

Step 6: **Testing Phase**

Testing is the responsibility of the participating OMCL. A Cooperation Agreement (framework contract) 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 provided to the OMCL(s) to support the costs incurred in the testing. Testing cannot be further subcontracted, if not agreed in advance in writing by the two contracting partners, i.e. the EDQM and the OMCL/Competent Authority. Any information concerning observations or changes in the test protocol will be communicated to the EDQM.

Step 7: **Results Data Sheets Completed**

The Scientific advisor completes and sends back the Results Data Sheets together with type chromatograms and any comments in due time. Each trade name product should comply with their respective approved specifications.

The report is due 40 working days after receipt of the test samples by the latest, the date of receipt being documented on the acknowledgement of receipt for the samples. An extension of the testing period may be granted on a case-by-case basis when numerous tests are requested for a given product and/or when testing of the active substance is included in the testing protocol.

Where clarifications are required, the EDQM directly contacts the person responsible for testing at the OMCL.

The analyses performed using the Common INN Test Protocol should be seen as quality screening. In the event of out-of-specification (OOS) situations, further action is needed in accordance with the procedure in place for handling OOS results and in particular retesting using the MAH-approved method.

Step 8: **Testing Reports**

For each Generics INN Group tested, within one month after the receipt of all the results the EDQM will issue:

- abridged CAP Testing Reports for each MAH involved in the programme,
- an Overall CAP Summary testing report.

Testing Reports are issued on an ongoing basis and are distributed to the relevant samplers, EMA and all OMCLs. When all results are compliant, the abridged CAP Testing reports only contains an executive summary part (i.e. general administrative information concerning the tested products, information about the sampled batches, the tested parameters, and the general outcome of the testing for this product). If issues are encountered during the testing, additional information is included in the report; the results obtained for the concerned parameter are reported together with relevant comments and conclusions in an Annex of the report. The recommendations from the testing OMCL/EDQM about the follow-up actions to be initiated can be annexed to the report, if necessary.

The EMA distributes the Testing Reports to the MAHs for information or comments.

The EMA will then distribute all Testing Reports to the (Co-)Rapporteurs for information, comments and follow actions, where applicable.

The **Overall CAP Summary testing** report is composed of an executive summary part, a core report (detailed information regarding the management of the project within the EDQM and the results obtained by the testing OMCL for individual parameters tested together with the relevant comments and conclusions) and Annexes, where applicable. The Overall CAP Summary testing report is only distributed to the EMA and the OMCLs, together with the testing recommendations of the OMCL with respect to the selection of test parameters in case of retesting are provided (internal purpose).

Step 9: **Follow-up actions**

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 responsibility of the actions initiated as an outcome of the testing. A report on the outcome of the annual generics programmes including follow-up measures initiated further to the testing is published by the EMA.

Step 10: **Annual status report at Annual Meeting**

The EDQM reports about the status of the programmes during each yearly CAP Annual Meeting (focus on Year n+1).

In addition, the EDQM shall provide the EMA no later than 1st of December of year n a written update indicating which activities planned for year n were not performed as planned. This will be used by the EMA for budget planning purposes.

Year n+1

Step 11: Annual **Reports to EMA/OMCLs**

An Agreement Report and a Final Financial Report are submitted to the EMA by 31st March of the year n+1, to provide an overview of the previous year's testing programme and the summary of the costs associated to these activities, respectively. In case some projects are not finalised by the date, an extension of the deadline can be proposed by the EDQM, which must be endorsed by the EMA. Any outstanding activities not reported in the Agreement Report and Final Financial Report of the year n, shall be reported by the EDQM in the Agreement and Final Financial Reports of the year n +1, following written agreements between both parties.

A Global Report to the EMA, the OMCLs and the Samplers is released by the end of November of the year n+1. It provides an overview of the products sampled and tested during the CAP programme, as well as information about the different partners that have contributed to this programme.

General Remarks

- **Discussion and Optimisation**

The improvement of the general scheme is the responsibility of both the EMA and the EDQM based on experience gained during current application of the present procedure. To this end, the CAP Advisory Group is consulted.

History Sheet of Technical Post-Approval Changes

Title of document: PA/PH/CAP (12) 32 17R - General Procedure for Sampling and Testing of Generic Centrally Authorised Products

6th Edition: (2024):

- Streamline and optimise CAP Generic Market Surveillance programmes.
- Selection of future Generics programmes.

♥ **Date of becoming effective** *(month and year)*: **January 2025**

Title of document: PA/PH/CAP (12) 32 16R - General Procedure for Sampling and Testing of Generic Centrally Authorised Products

5th Edition: (2022):

- Revision following the use of electronic documentation instead of paper versions.
- Suppression of the Sampling Information Notices.

♥ **Date of becoming effective** *(month and year)*: **January 2023**

Title of document: PA/PH/CAP (12) 32 R14 - General Procedure for Sampling and Testing of Generic Centrally Authorised Products

4th Edition: (2018):

- Restructuring of the whole procedure according to the new strategy adopted for the sampling and testing of Generics products.

♥ **Date of becoming effective** *(month and year)*: **December 2018**

Title of document: PA/PH/CAP (12) 32 11R - General Procedure for Sampling and Testing of Generic Centrally Authorised Products

3rd Edition: (2014):

- Overall editorial revision of the document.
- Introduction: Inclusion of details about the selection of products included in the programme.
- Step 1: Inclusion of details on programme establishment.
- Step 3A1: Inclusion of details about documents to be provided by the MAHs.
- Step 3A2: Inclusion of details about the number of OMCLs participating in the programme.
- Step 3B1: Inclusion of details about the nomination of the Scientific Advisor in the event of there being no candidates.
- Step 3B2: Requirements for the used reference materials.

♥ **Date of becoming effective***(month and year)*: **December 2014**

Title of document: PA/PH/CAP (12) 32 9R - General Procedure for Sampling and Testing of Generic Centrally Authorised Products

2nd Edition: (2013):

- Introduction: Inclusion of details related to the EDQM/OMCLs testing contract: eventual need of national regulatory action.
- Step 3A2: Inclusion of details on group establishment.
- Step 3B1: Inclusion of details about the nomination of the Scientific Advisor.
- Step 3B2: Inclusion of details about the duties of the Scientific Advisor: selection and procurement of the materials necessary for the feasibility check; assistance of the EDQM and checking of relevant quality parameters of non-commercially available reference materials prior testing.
- Step 5C1: Amendment of the timeline to send out the Testing Questionnaire.
- Step 9: Information that a financial contribution is provided to the testing OMCL(s) and inclusion of the Cooperation agreement.

♥ **Date of becoming effective***(month and year)***: December 2013**

Title of document: PA/PH/CAP (12) 32 6R - General Procedure for Sampling and Testing of Generic Centrally Authorised Products

1st Edition: (2012): new programme.

♥ **Date of becoming effective** *(month and year)***: November 2012**