UST-21 version 7 Reporting of Selected Medicinal Products and Batch Release onto the Market

This Guideline supersedes the previous version 6 of Guideline UST-21 as of 01 April 2021.

The Guideline is published on the basis of and in compliance with the provision of Section 102(1) of Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended.
The Guideline is legally binding.

Subject-matter of the Guideline

Pursuant to Section 102(1) of Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended, (hereinafter referred to as the "Act on Pharmaceuticals"), the marketing authorisation holder shall be obliged to submit to the State Institute for Drug Control (hereinafter referred to as "SÚKL") samples of each batch of the bulk and/or finished medicinal product for examination prior to the placement of the batch of the selected medicinal product into circulation in the Czech Republic. The marketing authorisation holder shall do so via a batch report for the selected medicinal product as specified the annexes to this Guideline. Batch samples shall be submitted for examination regardless of the country of origin and regardless of the quantity to be distributed. This obligation shall be applicable to the following groups of medicinal products:

- live vaccines;
- immunological medicinal products used in the primary immunisation of children or other risk groups;
- immunological medicinal products used in public health immunisation programmes;
- new immunological medicinal products or immunological medicinal products manufactured using new or altered kinds of technology or those which are new for a particular manufacturer, during a transitional period;
- blood derivatives (i.e. industrially manufactured medicinal products derived from human blood).

The obligation to submit samples of each batch of the bulk and/or finished medicinal product to SÚKL for examination prior to their placement onto the market is implied by the provision of Section 32(4)(a) of the Act on Pharmaceuticals and the Marketing Authorisation of the concerned medicinal product.
Mandatory reporting shall be applicable also to medicinal products belonging to any of the aforementioned medicinal product groups that are placed onto the market within the scope of a specific therapeutic programme. In such a case, the obligations stipulated by Section 102 of the Act on Pharmaceuticals shall be the responsibility of the submitter of the specific therapeutic programme.

Competencies of SÚKL's organisational units

The area of batch release is within the powers of the Biological Method Unit of SÚKL's Department of Laboratory Control. The batch release request (in the form of the report) shall be submitted by the marketing authorisation holder or the specific therapeutic programme submitter together with the required supporting documentation and samples of the medicinal product via data mailbox[1], in writing, personally through SÚKL's mailroom, or electronically with an electronic signature to the following e-mail address: batchrelease@sukl.cz.

[1] Data mailbox is a special-type electronic repository serving for the purposes of electronic document exchange between public authorities and natural or legal persons. The statutory obligation to have a data mailbox applies only to public authorities and to legal persons incorporated in the Czech Companies Register.

SÚKL's Laboratory Control Department is part of the European OMCL (Official Medicines Control Laboratories) network whose members are official control laboratories of the EU/EEA countries (i.e. EU Member States, Norway, Iceland, Liechtenstein, and Switzerland which has concluded a mutual recognition agreement with the EU that includes also recognition of batch releases by official control laboratories). In batch release, the Laboratory Control Department follows the procedures of Official Control Authority Batch Release (hereinafter referred to as the "OCABR") available from Batch Release for Human Biologicals: vaccines, blood and plasma derivatives | EDQM - European Directorate for the Quality of Medicines.

A product in respect of which the marketing authorisation requires batch release by a state control authority may not be placed onto the market in the Czech Republic without prior approval from SÚKL.

Procedure applicable to batch release onto the market in the Czech Republic

Batch reports for selected medicinal products shall be submitted by the marketing authorisation holder or the specific therapeutic programme submitter.
SÚKL agrees that the report may be submitted by a representative (e.g. a distributor) of the marketing authorisation holder or of the specific therapeutic programme submitter. The obligations implied by the Act on Pharmaceuticals shall be borne by the marketing authorisation holder or by the specific therapeutic programme submitter.

1. **Selected medicinal products with an EU OCABR certificate – administrative release with recognition of the EU OCABR certificate issued by another European OMCL network laboratory:**

Required supporting documentation:

a) The reporting shall be done using the "Batch Release Request" form (Annex 1 hereto), where the following details shall be specified: product code, authorised product name and name supplement, batch number and expiry (date) shown on the final packaging, manufacturer, marketing authorisation holder (if other than the manufacturer), number of packages intended for placement onto the market in the Czech Republic;
b) Marketing Information Form (MIF) – a form with the identification data of the manufacturer and of the manufactured batch (Annex 2 hereto);
c) Batch release protocol for the finished medicinal product, signed by the qualified person; and
d) OCABR certificate certifying the release of the batch of the finished medicinal product or its component by another European OMCL network laboratory (i.e. a control laboratory of an EU/EEA country (i.e. EU Member States, Norway, Iceland, Liechtenstein) or Switzerland (which has concluded a mutual recognition agreement with the EU that includes also recognition of batch releases by official control laboratories) via the procedure applicable to batch release of vaccines and blood derivatives by a control authority (OCABR clarification provisions to Art. 114 of Directive 2001/83/EC). In compliance with the provision of Section 102(2) of the Act on Pharmaceuticals, SÚKL accepts the conclusion of the attest (OCABR certificate), if the OCABR certificate is available for the batch, and in such cases it shall not perform its own laboratory control (i.e., shall not require any further documentation or batch samples).

2. **Selected medicinal products without OCABR certificate – release with laboratory control and issuance of the EU OCABR certificate:**

Required supporting documentation:

a) The reporting shall be done using the "Batch Release Request" form (Annex 1 hereto), where the following details shall be specified: product code, authorised product name and name supplement, batch number and expiry (date) shown on the final packaging, manufacturer, marketing authorisation holder (if other than the manufacturer), number of packages intended for placement onto the market in the Czech Republic; if relevant: a request for the issue of OCABR certificate and the number of packs sent for laboratory testing;

b) Marketing Information Form (MIF) – a form with the identification data of the manufacturer and of the manufactured batch (Annex 2 hereto);
c) Batch release protocol for the finished medicinal product, signed by the qualified person, including the completed tests and their results, acceptable value ranges, and test result evaluations; and
d) Samples of the medicinal product observing tightly the instructions for selected vaccine and blood derivative release specified in individual Product Specific Guidelines (Batch Release for Human Biologicals: vaccines, blood and plasma derivatives | EDQM - European Directorate for the Quality of Medicines). The samples of the finished medicinal product submitted for control purposes shall be sent by the marketing authorisation holder or, where applicable, the specific therapeutic programme submitter, observing the prescribed storage conditions (cooling chain observance); upon request, the marketing authorisation holder/specific therapeutic programme submitter shall be able to provide documentary evidence of the storage conditions.

3. Repeated release of further quantities of the batch:

Required supporting documentation:

The completed "Batch Release Request" form (Annex 1 hereto), OCABR certificate, and MIF shall be submitted also in case the batch of the selected medicinal product has been already released upon the first placement onto the market in the Czech Republic (upon repeated import of the same batch).

4. Reimbursement of costs:

The costs of batch release of the selected medicinal product shall be established on the basis of the scope of activities associated with the batch release referred to under guideline UST-29 "Administrative fees, reimbursements of costs of expert activities, reimbursements of activities associated with the provision of information and reimbursements of other activities". In case of repeated batch release for the same applicant, no cost reimbursement shall be required. The payment of the fee for administrative release shall not be required for medicinal products within the scope of specific therapeutic programmes, either.

5. Notice of the State Institute for Drug Control on the release of the batch to circulation:

Seven days of meeting the requirements governing batch assessment (i.e. of the delivery of the Request, including the required annexes, and proof of payment of cost reimbursement), the marketing authorisation holder or its representative or, where applicable, the specific therapeutic programme submitter, shall receive – in their data mailbox or by e-mail (if the entity does not have a data mailbox) - SÚKL's notice of the release of the batch of the medicinal product to circulation or request for the provision of additional information and samples for examination.
Where SÚKL performs laboratory examination of the batch of the medicinal product, the marketing authorisation holder or its representative or, where applicable, the specific therapeutic programme submitter shall receive the result of the laboratory control with the notice of batch release to circulation via data mailbox or e-mail no later than within 60 days of the provision of the samples and supporting documentation. The original of the EU OCABR certificate shall be sent to the marketing authorisation holder or its representative or, where applicable, to the specific therapeutic programme submitter, by post in documentary form or in electronic format with an electronic signature. In case of noncompliant laboratory results, the marketing authorisation holder or, where applicable, the specific therapeutic programme submitter shall receive a notice of declined release of the batch to circulation.

Annexes

Annex 1 – Batch Release Request
Annex 2 – Marketing Information Form (MIF)