Division Laboratories (OMCL)

OFFICIAL CONTROL AUTHORITY BATCH RELEASE

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
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1 Introduction

This brochure provides clients with information and details regarding the requirements and procedures relating to the official control authority batch release of human vaccines and blood products, immunological veterinary medicinal products and plasma pool testing by the Division Laboratories (OMCL) of Swissmedic.

2 General information

2.1 Official control authority batch release

If the manufacturing of a medicinal product requires specific measures, particularly to ensure its safety, release must be obtained from the Swiss Agency for Therapeutic Products for each batch prior to distribution. This is in accordance with Article 17 of the Swiss Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 15 December 2000. In accordance with Articles 18 to 21 of the Swissmedic Medicinal Products Authorisation Ordinance (AMZV) of 9 November 2001, batch release particularly applies to:

a. medicinal products manufactured from human blood or human plasma;

b. vaccines;

c. animal sera for use on humans.

The Agency may subject additional products to official control authority batch release if this is necessary to ensure the safety of medicines.

Immunological veterinary medicinal products are also covered by official batch release. As of 1 January 2023, the responsibility for release of this category of medicines has been transferred from the Institute for Virology and Immunology (IVI) to Swissmedic.

When granting the marketing authorisation, the Agency stipulates whether or not the medicinal product is subject to official control authority batch release. The Agency publishes a list of medicinal products that are subject to such batch release before they may be placed on the market. This list can be found on the Swissmedic website (www.swissmedic.ch).

In accordance with Article 19 of the AMZV, the authorisation holder must obtain prior release from the Agency for every batch to be placed on the Swiss market.

2.2 The Division Laboratories (OMCL) of Swissmedic

The Official Medicines Control Laboratory (OMCL) of Swissmedic (hereinafter referred to as OMCL) is an ISO/IEC 17025 certified control laboratory for chemical, physical and biological analysis of medicinal substances. The scope of the OMCL accreditation is shown on the website of the Swiss Accreditation Service (SAS), at www.sas.admin.ch (Section "Accredited bodies", Accreditation no. STS 0158).

The OMCL consists of three laboratory units. Laboratory unit 1 is responsible for official control authority batch release (OCABR).

The OMCL issues or refuses the release of individual batches of medicinal products mentioned in 2.1, based on the Medicinal Products Authorisation Ordinance (AMZV). The decision is based on results of the analytical examination of the products, assessment of the manufacturing documentation and analytical plasma pool testing for products made from human blood.

The OMCL releases a batch by issuing a certificate, if the relevant quality specifications have been fulfilled. The certificate can also be issued based on batch release by a foreign authority (see section *3.5 Notifications*).

If the requirements for batch release are not met, the OMCL issues a refusal for the batch and a Notice of Non-Compliance.

As a result of the bilateral agreement with the EU, the OMCL is an active member of the EU/EEA network for Official Control Authority Batch Release (OCABR network) and from 1 January 2023 of the Veterinary Batch Release Network (VBRN).

2.3 The bilateral agreement with the EU

The mutual recognition agreement (MRA) between the Swiss Confederation and the EU/EEA in relation to conformity assessment of 21 June 1999 allows for the mutual recognition of official control authority batch release for industrially manufactured products made in Switzerland or the EU (Chapter 15 and the Explanatory Notes thereto). This means that medicinal products intended for the Swiss market, which are subject to official control authority batch release in Switzerland and at least one EU member state and which have already been examined and released by the OMCL of an EU member state, require no additional sample testing by the OMCL, and EU OMCL batch release is fully recognised. According to the agreement, only a notification of the batch by the authorisation holder to the OMCL is required. In return, the batch release certificates issued by the OMCL are recognised by the EU member states. Batches manufactured outside the EU/EEA area are excluded from this agreement.

For batch releases and notifications of human vaccines and blood products and plasma pool testing within the framework of the MRA, the OMCL applies the "EU Administrative Procedure for Official Control Authority Batch Release". For batch releases and notifications of immunological veterinary medicinal products within the MRA, the "EU Administrative Procedure for Official Batch Release of Immunological Veterinary Medicinal Products in Application of Article 128 of Regulation (EU) 2019/6" applies. The procedure and the product-specific guidelines can be found at the website of the European Directorate for the Quality of Medicines and Health Care (EDQM) at www.edqm.eu.

2.4 Plasma pool testing

Plasma pool testing for medicinal products made from human blood is part of the batch release process and serves to verify the viral safety of the products. This examination is also described in the monograph "Human plasma for fractionation (0853)" in the European Pharmacopoeia (Ph. Eur.).

3 Requirements and processes for batch release, notifications and plasma pool testing

3.1 Application forms

The application forms for batch release, notification and plasma pool testing can be found on the Swissmedic website (www.swissmedic.ch).
Changes to the application forms will be communicated to the OMCL clients by circular letter.

3.2 eGOV Service OCABR

Documentation is submitted electronically via the **eGov Service OCABR** (hereafter "portal").

3.3 Batch release of human blood products and vaccines

The authorisation holder must submit the batch documentation and the samples to the OMCL at the same time as the ***Request for Batch Release***. When submitting the samples, shipment and labelling must comply with point *3.7 Labelling and reception of samples*. Once the application, samples and complete documentation is available to the OMCL, the assessment of the batch is normally completed within 30 days.

If irregularities are noted, or if examinations requiring considerable resources are necessary, the assessment may take longer. In such cases, the OMCL will inform the affected clients.

The authorisation holder may withdraw an application for batch release for a batch that is in the assessment process at any time, by providing written justification for the withdrawal. In such cases, the OMCL will charge for any expenses already incurred.

By agreement with the OMCL, batches can also be tested in a parallel procedure. For this procedure, the authorisation holder submits samples to the OMCL together with the ***Request for Batch Release,*** before it has completed its own analytical testing. The OMCL also begins testing the samples and completes the assessment as soon as the complete batch documentation from the manufacturer is available.

The parallel procedure can speed up batch release for the authorisation holder, but entails the risk that the holder may need to withdraw the batch because of non-compliance with the specifications during the analytical testing. For batches examined within the framework of the MRA, the OMCL is in this case obliged by the "EC Administrative Procedure for Official Control Authority Batch Release" to inform the members of the EU/EEA OCABR network of the withdrawal.

3.4 Batch release of immunological veterinary medicinal products

The OMCL carries out **Official Batch Protocol Review (OPBR)** for batch release of immunological veterinary medicines. The authorisation holder submits the **Request for Batch Release (IVMP)** together with the batch documentation from the manufacturer. Submission of samples is not required for batch release by OBPR. As soon as the OMCL has received the complete application and all documents, the assessment of the batch is usually carried out within 10 working days.

3.5 Notifications

For the notification of a batch according to the MRA, the OMCL requires the completed ***Market Information Form*** (MIF) and a copy of the EU batch release certificate from the authorisation holder. For immunological veterinary medicinal products, the complete batch documentation (Summary Protocol) is also required. In consultation and after prior agreement by the OMCL, use of a company's own MIF is possible. Notifications must be submitted electronically via the portal. Since Swissmedic has no access to the specifications authorised in the EU, the OMCL also requests the authorisation holder to submit a certificate of analysis for the batch, although this is not foreseen within "EU Administrative Procedure for Official Control Authority Batch Release". For Swissmedic this is the only way of verifying whether the specifications in the certificate of analysis comply with authorisation requirements in Switzerland. If the authorisation holder of human medicines confirms in writing that the specifications authorised in Switzerland and in the EU are equivalent, the submission of a certificate of analysis can be omitted.

Within 7 working days following reception of the documents, the authorisation holder receives an confirmation from the OMCL that the batch may be marketed in Switzerland. The confirmation is sent electronically to the authorisation holder. Therefore, the authorisation holder must register one or more recipient e-mail addresses with the OMCL.

A notification via the OMCL is only possible when the industrial production of the product takes place within the EU/EEA. For products from outside Europe that have nevertheless obtained an EU/EEA OMCL batch release, the OMCL may issue a batch release without carrying out its own sample testing. In such cases, the extent of the manufacturing documentation to be submitted must be agreed with the OMCL.

3.6 Plasma pool testing

The OMCL agrees with its clients on the number of samples required for plasma pool testing. The samples must be sent to the OMCL with the ***Request for Testing of Plasma Pool***. Point *3.7 Labelling and reception of samples* must be followed. An application for plasma pool testing may be submitted independently of a batch release application. Documentation is submitted electronically via the portal. For plasma pool testing, the OMCL employs the OCABR guideline "Protocol for Approval of Plasma Pools“.

If plasma pool testing has already been completed within batch release by an OMCL of the EU/EEA network and if the corresponding certificates have been issued, the OMCL does not carry out its own testing. The certificates should, in such cases, be added to the batch documentation.

3.7 Labelling and reception of samples

It falls within the responsibility of the client to ensure that all samples reach the OMCL in perfect condition. The following points must particularly considered:

- Cooled / frozen samples and dry ice shipments must be clearly labelled as such, and arrive at the OMCL in the corresponding condition.
  Plasma pool samples must reach the OMCL in a frozen state.
- Every individual receptacle must be labelled and clearly identifiable. The following minimum requirements must be fulfilled:

Blood products and vaccines:	product name and batch number on each primary receptacle
Plasma pools:	plasma pool number on each tube

If these requirements are not fulfilled, further correctly labelled and / or dispatched samples will be requested.

Non-compliant samples cannot be used for testing. They will be destroyed or, on request, returned. The corresponding expense will be charged.

Dispatched samples may be delivered to Hallerstrasse 7 between 8.00 - 12.00 and 13.30 - 17.00 (Friday: 16.00). Postal and courier services must be informed accordingly. Direct deliveries to the location Freiburgstrasse 139 must be arranged with the OMCL in advance.

3.8 Documents for the clients

The following documents are issued to clients by the OMCL: test reports for batch releases, batch release certificates, certificates for plasma pool testing, notices of non-compliance in the case of refusal of a batch releases or plasma pool. If required, the OMCL provides samples of these documents to its clients. The transmission of documents for customers takes place electronically via the portal.

3.8.1 Test reports for batch release

To enable submission of batch release test report to other entities within an international framework, it is provided in English. The first section describes the samples analysed. The second section shows the test results. Tests carried out beyond the scope of accreditation are specially marked as such. Test reports also include a comment if a test has been carried out by a subcontractor on behalf of the OMCL.

If a client waives receipt of the test reports, this must be notified to OMCL.

3.8.2 Batch release certificates and notices of non-compliance

For batches tested according to the MRA, under "EU Administrative Procedure for OCABR" or "EU Administrative Procedure for Official Batch Release of Immunological Veterinary Medicinal Products in Application of Article 128 of Regulation (EU) 2019/6", the OMCL issues certificates referring to the Swiss Law on Therapeutic Products and EU legislation. For batches that are not tested within the framework of the MRA (e.g. animal sera, for which no product-specific guidelines exist), the OMCL issues certificates that refer to the Swiss Law on Therapeutic Products only. For a notice of non-compliance, reference is made to Swiss and EU legislation or Swiss legislation only, as appropriate. Following a preliminary notice to the authorisation holder, an explanation on rights of appeal is appended to the notice of non-compliance.

3.8.3 Notifications

In the case of batches subject to notification (market information), the authorisation holder is sent an acknowledgement of receipt by e-mail.

3.8.4 Certificates on plasma pool testing

For each plasma pool tested, the OMCL issues a certificate in accordance with the "EU Administrative Procedure for OCABR". When required, certificates referring to Swiss legislation only can be issued.

3.9 Costs

The costs for batch releases, notifications and plasma pool testing are defined in the Regulation of the Swiss Agency for Therapeutic Products on its Fees (GebV-Swissmedic). Fees are also payable if a batch is not released or is withdrawn by the authorisation holder. The resources required for extraordinary evaluations within the scope of batch release (e.g. assessment of one-time exceptions) are invoiced at a rate of CHF 200.- per hour, as "fee according to expenditure". This service is subject to VAT.

3.10 Publications

The human medicinal product batches that are released (control authority batch release and notifications) are published on the Swissmedic website (www.swissmedic.ch). Swissmedic can refrain from publication in specific cases. Released batches of immunological veterinary medicinal products are not published.

3.11 Provision of information

In order to promote collaboration with clients, the OMCL provides comprehensive information regarding its work, its processes and the legal principles applied.

A client may request information on the current status of any tasks submitted to the laboratory at any time.

The OMCL provides information on the principles and the references used within its testing methods and shares any doubts relating to measurements when issuing the results. On request, and depending on the situation, the laboratory permits clients to consult the specific test guidelines and validation documents.

For enquiries regarding test reports, please always quote the test report number.

The OMCL provides no information relating to other clients' products.

3.12 Client needs, issues and complaints

The needs, issues and complaints raised by clients are recorded on an ongoing basis, independently of whether OMCL receives them orally or in writing. Issues raised and complaints are handled at regular discussions, and analysed in order to identify possible common causes. Based on this analysis, the OMCL constantly strives to achieve improvements and integrates them within its work processes.

Depending on the importance or severity of an issue or complaint, the client receives an oral or written response.

4 Organisation

4.1 Contact persons

For questions concerning official control authority batch release, the specialists on this subject are the primary contact partners:

Scientific Expert OCABR	Scientific Expert OCABR
Dr. Mirjam Kühne	Dr. Michael Sänger
Tel.: 058 469 50 28	Tel.: 058 462 95 19
E-mail: mirjam.kuehne@swissmedic.ch	E-mail: michael.saenger@swissmedic.ch

For questions concerning laboratory analysis, the head of the laboratory unit 1 or his deputy are the primary contact partners:

Head of Laboratory Unit 1	Deputy Head of Laboratory Unit 1
Dr. Michael Gilgen	Nicolas Stüdle
Tel.: 058 463 41 69	Tel.: 058 481 48 36
E-mail: michael.gilgen@swissmedic.ch	E-mail: nicolas.stuedle@swissmedic.ch

E-mail for general enquiries: notification@swissmedic.ch

4.2 Address

Swissmedic, Swiss Agency for Therapeutic Products

Division Laboratory (OMCL)

Laboratory unit 1 (OCABR)

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