



Division Laboratories (OMCL)

OFFICIAL CONTROL AUTHORITY BATCH RELEASE (OCABR) OF VACCINES AND BLOOD PRODUCTS

Schweizerisches Heilmittelinstitut
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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 vaccines and blood products and plasma pool testing by the Division Laboratories (OMCL) of Swissmedic.

2 General information

2.1 Official control authority batch release

In accordance with Article 17 of the Swiss Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 15 December 2000 (Status as of 1 August 2020, if the manufacturing of a medicinal product requires specific measures - notably to ensure its safety - a release must be obtained for each batch from the Swiss Agency for Therapeutic Products before it is placed on the market. In accordance with Articles 18 to 21 of the Swissmedic Medicinal Products Authorisation Ordinance, (AMZV), of 9 November 2001 (Status as of 1 July 2020, batch release notably applies to:

- a. medicinal products manufactured from human blood or human plasma;
- b. vaccines;
- c. animal serums for use on humans.

The Agency may specify that further products are subject to official control authority batch release when this is necessary in order to ensure the safety of medicines.

When granting the authorisation to place a medicinal product on the market, the Agency stipulates whether or not it 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 from the Agency, in advance, a release for every batch to be placed on the market in Switzerland.

2.2 The Division Laboratories (OMCL) of Swissmedic

The Official Medicines Control Laboratory (OMCL) of Swissmedic (hereinafter referred OMCL) is an ISO/IEC 17025 certified control laboratory for chemical, physical and bacteriological analysis of medicinal substances. The scope of the Division OMCL (laboratory) 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 the individual batches of vaccines and blood products based on the Medicinal Products Authorisation Ordinance (AMZV). The basis for its decision consists of the results of the analytical examination of the products, the assessment of the manufacturing documentation and the analytical plasma pool testing for products made from human blood.

The OMCL releases a batch by issuing a certificate stating that the relevant quality specifications have been fulfilled. The certificate can also be issued based on a batch release issued by a foreign authority.

If the requirements for a batch release are not met, the OMCL issues a refusal for the batch to be released 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).

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 12 June 1999 concerns 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 that are subject to official control authority batch release in Switzerland and at least one EU member state, and that have already been examined and released by the OMCL of an EU Member State require no additional sample testing by the OMCL by fully recognising the EU OMCL batch release. According to the agreement, all that is required is a notification of the batch by the authorisation holder to the OMCL. In return, the batch release certificates issued by the OMCL are recognised by the EU Member States. The diagram (1) below summarises the processes for batch releases and notifications in accordance with the bilateral agreement.

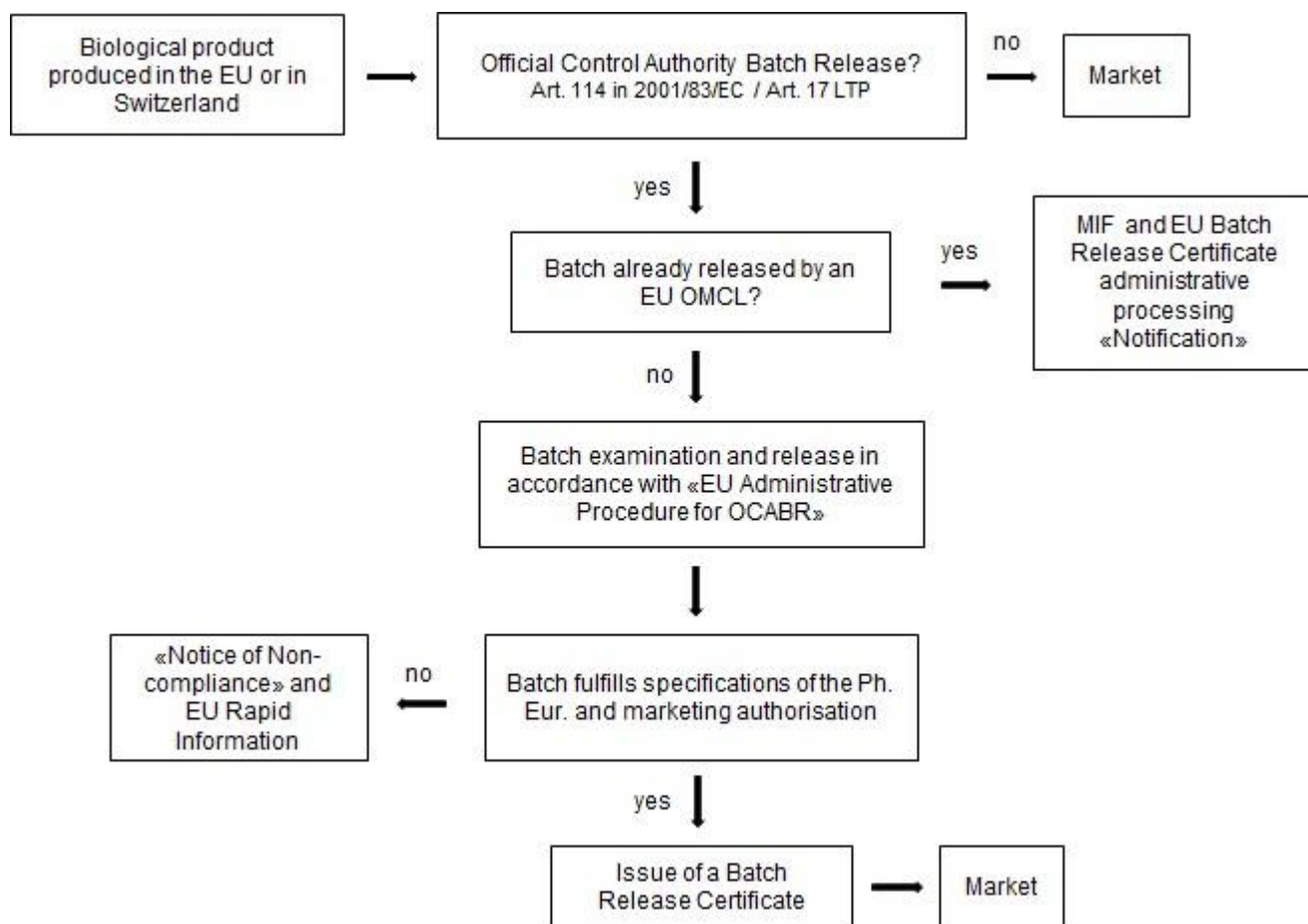


Diagram 1: Processes for batch release and notifications in accordance with the bilateral agreement

For batch releases, notifications and plasma pool testing within the framework of the MRA, the OMCL uses the EU Administrative Procedure for Official Control Authority Batch Release. 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 related to batch release, for notifications and for 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 clients of the OMCL by circular letter.

3.2 Batch release

The authorisation holder must submit the batch documentation and the samples to the OMCL at the same time as the **Request for batch release**. Documentation is submitted electronically via the **eGov Service OCABR** ("portal"). When submitting the samples, shipment and labelling must be in compliance with point 3.5 (below) "Labelling and reception of samples". As soon as the application, samples and all 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 clients concerned accordingly.

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 by means of a parallel procedure. For such a 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 concludes the assessment as soon as the complete batch documentation from the manufacturer is received.

The parallel procedure can save the authorisation holder time with regard to batch releases, but also means that there is a risk that the holder may need to withdraw the batch because of noncompliance with the specifications during the analytical testing that it carries out. For batches examined within the framework of the Mutual Recognition Agreement (MRA), the OMCL must, in such cases, inform the members of the EU/EEA OCABR network of the withdrawal in accordance with the EC Administrative Procedure for Official Control Authority Batch Release.

3.3 Notifications

For the notification of a batch in accordance with the MRA, the OMCL needs the completed **Market information form** (MIF) and a copy of the EU batch release certificate from the authorisation holder. Notifications have to 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 the EU Administrative Procedure for Official Control Authority Batch Release. For Swissmedic this is the only way of checking whether the specifications in the certification of analysis comply with authorisation requirements in Switzerland. If the authorisation holder confirms by writing, that the specifications authorised in Switzerland and in the EU are equivalent, the OMCL may agree that the submission of a certificate of analysis can be omitted.

The authorisation holder receives an acknowledgment of receipt from the OMCL by e-mail within 7 days following reception of the documents, confirming that the batch may be placed on the market in

Switzerland. Acknowledgments of receipt are sent electronically to the authorisation holder. Therefore, the authorisation holder must record a recipient e-mail address or addresses to 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 upon with the OMCL.

3.4 Plasma pool testing

The OMCL agrees on the number of samples for plasma pool testing with its clients. The samples must be sent to the OMCL with the **Request for testing of plasma pool**. Point 3.5 "Labelling and reception of samples" (below) must be fulfilled. 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 uses the OCABR guideline "Protocol for Approval of Plasma Pools".

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

3.5 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 be taken into consideration in particular:

- Cooled 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, a further dispatch of correctly labelled and / or dispatched samples will be requested.

Non-compliant samples cannot be used for testing.

Such samples will be destroyed or, on request by the client, returned at the client's expense.

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

3.6 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 refused batch releases or a plasma pool. If required, the OMCL provides samples of these documents to clients. The transmission of documents for customers takes place electronically via the portal.

3.7 Test reports for batch releases

In order for it to be possible for a batch release test report to be submitted 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.

3.8 Batch release certificates and notices of noncompliance

For batches tested according to the EU Administrative Procedure for OCABR by virtue of the Mutual Recognition Agreement, 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 serums, 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. In case of a non-compliance, a preliminary notice is addressed to the authorisation holder. An explanation on rights of appeal is then appended to the notice of noncompliance.

3.9 Notifications

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

3.10 Certificates on plasma pool testing

For each plasma pool tested, the OMCL issues a certificate in accordance with the EU Administrative Procedure for OCABR.

3.11 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 of 14. September 2018 (GebV-Swissmedic, Status as of 1 January 2019). 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 framework 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.

3.12 Publications

The batches that are released (control authority batch release and notifications) are published on the Swissmedic website (www.swissmedic.ch).

3.13 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. It is important for the division to maintain transparency for its clients.

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 forwards 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.

3.14 Client needs, issues and complaints

The needs, issues and complaints raised by clients are recorded on an ongoing basis, independently of whether they are received orally or in written form by the OMCL. 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 of blood products and vaccines, the specialists on this subject are the primary dialogue partners:

Scientific Expert OCABR	Scientific Expert OCABR
Dr. Katja Bögli	Dr. Michael Sängler
Tel.: 058 463 44 24	Tel.: 058 462 95 19
E-mail: katja.boegli@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 dialogue 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

4.2 Address

Swissmedic, Swiss Agency for Therapeutic Products
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 Hallerstrasse 7
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4.3 Site map location Freiburgstrasse 139, 3008 Bern

