

The change in responsibility for immunological veterinary medicinal products from the IVI (currently responsible) to Swissmedic on 1 January 2023 will result in some changes for you as marketing authorisation holders. Extensive information has already been provided in advance at the VMP Round Table and the Regulatory & Beyond event.

In this letter, we would like to provide you with the following additional advance information:

Official batch release

From 1 January 2023, official batch release will be handled by Laboratory Unit 1 OCABR of the OMCL laboratory. Updated application forms and the information brochure on **Official Control Authority Batch Release (23_VZ_03)** will be available from 16 December 2022 on our website ([Official Control Authority Batch Release \(swissmedic.ch\)](https://www.swissmedic.ch)). However, please note that applications for OBPR and notifications of IVMPs using the application form (Marketing Information Form, MIF) can only be submitted from 1 January 2023.

Submission of samples

No submission of samples is envisaged for official batch release (notification and OBPR for IVMPs). This will therefore cease from 1 January 2023.

Swissmedic will receive inspection samples from the IVI's inventory. If not all authorised preparations are covered, Swissmedic will request a second inspection sample for the preparations concerned.

Specifications

Please submit a PDF file of the specifications last authorised by the IVI for each authorised preparation by the end of 2022 via e-mail to notification@swissmedic.ch.

eGOV OCABR portal

Submission of applications for batch assessment or notification are made via the eGOV OCABR service ("portal"). We will also issue release certificates after completion of batch assessment via the portal. Your administrators will receive information sheets and contracts for the service from our IT department in early December 2022.

Submission of e-mail addresses for notification

Once the documents you submitted via the portal have been checked, you will receive an automatically generated confirmation from our LIMS system to the e-mail addresses you specified. Please send your e-mail addresses (max. 3) to notification@swissmedic.ch.

Invoicing

In future, fees will be invoiced monthly and will be based on the Swissmedic Fees Ordinance (FeeO-Swissmedic; SR 812.214.5). They comprise:

Notification of a batch: CHF 200 (Annex I section. VI no. 1 FeeO-SMC)

Batch assessment OBPR: Fee based on the work involved, usually CHF 1,000 (Art. 4 FeeO-SMC)

Current "special rules" with the IVI regarding batch assessment

Special rules will cease to apply on 31 December 2022.

Dates for last submission to the IVI, first submission to Swissmedic

In agreement with the IVI, please note the following dates:

Last submission for OBPR (received by post) to the IVI: Monday, 19 December 2022

Last submission for notification (received by post) to the IVI: Thursday, 22 December 2022

First submission to Swissmedic via the eGOV OCABR service: **1 January 2023**, processing from **3 January 2023**