

1 How is the export country for parallel-imported medicinal products defined if the products have been authorised in the EU by the EMA according to the centralised procedure (CP)?

When completing the form, the EU country that should be declared as the export country is the one in which the medicinal product packs are procured.

2 When must the test samples be submitted to the laboratory (OMCL)?

The samples must be sent to the OMCL simultaneously, i.e. not more than three days before or three days after the submission of the application documentation.

3 How many test samples must be submitted? Revised in May 2025

In principle, one sample pack per dosage strength and per export country must be submitted. Moreover, care should be taken to ensure that the shelf-life of the samples submitted covers the duration of the authorisation process. Depending on the dosage form, dosage strength, number of individual doses contained in each pack and/or the duration of the process up until the end of the formal control, Swissmedic may have to request further samples.

4 If measures*) according to the guidance document *RMP ICH E2E Information for submission HMP* have been implemented for the original medicinal product (first applicant), do these have to be adopted for the parallel-imported medicinal product too? New, 1 June 2025

*) particularly the following:

- Pharmacovigilance plan with the measures described in it (for example, risk-specific questionnaires (specific / targeted follow-up questionnaires))
- Risk minimisation measures (e.g. appropriate warnings in the Information for healthcare professionals and Patient information, packaging material design, additional measures such as patient information cards, officially ordered information material)

Yes

5 If the packaging of the original medicinal product (first applicant) has mobile technologies on it, do these have to be adopted for parallel-imported medicinal products too? New, 1 June 2025

Yes, in accordance with the guidance document *Mobile technologies*.

6 What is the procedure for labels on the folding carton of the parallel imported medicinal product if there are mobile technologies on the folding carton of the foreign packaging? New, 1 June 2025

Any mobile technologies on the foreign packaging must not be visible.

7 Is it permitted to affix extra labels to the primary packaging of parallel-imported medicinal products, or to the blister packs, in addition to the existing foreign labels, for example to provide translations of the information into the official Swiss languages? New 15 April 2026

Under the simplified authorisation procedure, the primary packaging of parallel-imported medicinal products is not assessed or approved by Swissmedic and is accepted in the version used in the country of export. Information on primary packaging that is important for correct use but that patients in Switzerland will not understand must be explained in the "Other information" or "What else needs to be observed" sections of the IHP or PI (see Guidance document Import of a human medicinal product according to Art. 14 para. 2 and 3 TPA (parallel import)).

Since a possible influence of an extra label on the medicinal product cannot be ruled out (e.g. due to the migration of components from the adhesive or ink to the container), and in order to avoid delimitation issues, Swissmedic does not accept such extra labels on primary packaging, irrespective

of the format (blister packs, tubes, bottles, etc.) or the material of the primary packaging, and irrespective of the specific areas of the primary packaging to be covered by the affixed label.