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?

In principle, two sample packs 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.

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