ABT NEWS

Adaptation of the guidance document for parallel import in accordance with the Therapeutic Products Act (TPA) (effective from January 1, 2025)

According to an announcement by Swissmedic, the revised guidance document for the import of a human medicinal product in accordance with Art. 14 para. 2 and 3 of the Therapeutic Products Act (TPA) (parallel import) came into force on January 1, 2025. The new clarifications and explanations emphasize that the importer of a parallel-imported medicinal product must meet the same safety and quality requirements as the marketing authorization holder of the original medicinal product throughout the entire period of authorization. This includes the implementation of market surveillance measures that may be ordered for the original medicinal product due to safety signals or quality defects and that must also be applied to the parallel imported medicinal product.

The new provision in Art. 14 para. 3 TPA simplifies the import of medicinal products from countries whose authorization system is equivalent to the Swiss one (see Art. 14 para. 2 TPA). At present, these are the EU and EFTA-EEA member states, Australia, Japan, Canada and the USA. Swissmedic is authorized to issue simplified rules for the labeling and information of parallelly imported medicinal products. These simplified rules can be found in Art. 28 ff. of the Therapeutic Products Licensing Requirements Ordinance ("TPLRO").

It should be emphasized that the new rules can only be applied to medicinal products that are authorized in both the country of export and Switzerland and that essentially meet the same requirements as the medicinal product already authorized in Switzerland (original preparation). The new guidance then clarifies that the transfer of the authorization for a parallel imported medicinal product is subject to the guidance document on the transfer of the authorization.

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