Provisional interpretation of the term "emergency" in the context of Art. 49 MPLO to overcome acute supply shortages

It has not been possible to ensure the normal supply of medicinal products in Switzerland for a long time, or it has only been possible with a very great effort on the part of the professionals concerned.

The report from the Federal Office of Public Health (FOPH) on shortages in the supply of medicinal products dated 1 February 2022 contained a catalogue of measures to improve the supply situation that were subsequently reviewed in more detail and proposed for implementation if they were found to be suitable (see the final report of the interdisciplinary working group published by the Federal Council on 22 August 2024).

Measure 10 refers to the simplification of imports of unauthorised medicinal products in accordance with Article 49 of the Ordinance on Licensing in the Medicinal Products Sector (MPLO).

Art. 49 MPLO stipulates that a medical professional who holds a cantonal dispensing licence may import a ready-to-use human medicinal product that is not authorised in Switzerland without a licence provided the medicinal product has been authorised in a country with a comparable control system for medicinal products and no medicinal product that might be used as an alternative is authorised or available in Switzerland.

However, importation is only permitted for a specific patient and in small quantities. According to the legal rulings, a "small quantity" is considered to be the quantity of an unauthorised medicinal product that affected patients/customers need for around one month (see Straub, Basel Commentary on the Therapeutic Products Act, 2nd edition, Art. 20, numbers 8-9b and 14 [in German]). As a result, the current interpretation means that a) the importing medical professional must be in possession of the customer's order before the product is imported, and b) any form of storage of unauthorised medicinal products is not permitted.

The only exception is made for medicinal products for emergencies. Emergency medicinal products are not subject to the restriction to individual patients; storage is also possible in this case. This exception was introduced in the legislation primarily to enable hospitals to import antidotes. Swissmedic and the cantonal authorities have accordingly interpreted the terms "emergency" and "emergency medicinal product" very restrictively to date.

The implementation order approved on 21 August 2024 by the Federal Council now makes provision for Art. 49 MPLO to be modified such that, should a serious supply shortage occur, wholesalers with a specific licence from the competent authority may import and distribute large quantities of medicinal products in order to meet the needs of the population. However, it appears necessary to revise the Act and/or the Ordinance.

As an interim solution to overcome acute supply shortages, the cantonal pharmacists in Switzerland have decided, with the agreement of Swissmedic and the FOPH, to reinterpret Art. 49 and the term “emergency” contained in it as follows:

An emergency is understood to be any situation in which the treatment of an acute condition with a medicinal product that is authorised in Switzerland but not available must be started as soon as possible. Emergency medicinal products are medicinal products that must be administered immediately in such situations.

The importing medical professional is responsible for determining which medicinal products comply with this definition in the given individual case, and must be able to explain and justify their decision. The existence of a doctor's prescription at the time of dispensing is a prerequisite in all cases. The import is subject to a requirement for detailed record-keeping. The importing medical professional must also transparently document and demonstrate that the medicinal product cannot be supplied in Switzerland; it is sufficient to show that the medicinal product cannot be supplied by the wholesaler to whom orders are usually sent.

Emergency medicinal products in this sense may be imported in accordance with Art. 49 MPLO without reference to a specific patient and may be kept in stock by the medical professional. The quantity required for one month may not be exceeded.

The imported, unauthorised medicinal products may only be dispensed to the pharmacist’s own customers; it is still not permitted to dispense them to other medical professionals. Only service providers who are authorised to import medicinal products (wholesalers with Swissmedic licence S.2.3.4.3 to import products not authorised in Switzerland on behalf of the ordering medical professional) may group orders. The products may not be stored by the wholesaler.

If the medicinal product authorised in Switzerland becomes available again, the imported medicine may only continue to be sold for a maximum of one month.

The product will be reimbursed by the mandatory health insurance in accordance with Art. 69b or 71c HIO. This means that medicinal products with indication(s) and active substance(s) identical to and delivery forms comparable to medicinal products contained in the List of Pharmaceutical Specialities can be imported and the effective costs can be reimbursed if their supply can temporarily not be ensured (Art. 69b HIO). Imported medicinal products that are not contained in the List of Pharmaceutical Specialities can only be reimbursed in individual cases following approval of the costs by the health insurance provider.

The position paper issued by the Cantonal Association of Pharmacists, KAV 0015 Import of unauthorised ready-to-use medicinal products by practising doctors and pharmacists and hospital pharmacies, remains applicable to all other situations. The provisions governing controlled substances as stipulated in the Narcotics Act and the associated ordinances also remain unaffected.

For the Cantonal Association of Pharmacists

The President

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