PARTIAL REVISION OF THE THERAPEUTIC PRODUCTS ACT – PACKAGE 3B (*HMG 3B*)

On 19 June 2026, the Federal Council launched a consultation procedure (*Vernehmlassung*) on a legislative proposal for a further revision of the Therapeutic Products Act (TPA; CC 812.21).

The proposal (*HMG 3b*) is part of a larger reform package and primarily covers the following five areas:

- Reform of the mail-order sale of medicinal products;
- Introduction of a supervisory levy in the medical devices sector;
- Measures to address medicinal product shortages;
- Clarifications regarding the dispensing of individual quantities of medicinal products; and
- Expansion of the competencies of chiropractors.

The consultation procedure runs until 16 October 2026.

BACKGROUND

The reform project is primarily driven by recurring shortages of essential medicinal products and the objective of reducing regulatory barriers while making Switzerland's pharmaceutical supply system more resilient.

It is the second part of an ongoing revision of the TPA started in 2025 with the proposal of so-called Advanced Therapy Medicinal Products (ATMP), electronic prescriptions and medication planning, electronic dosage calculations for pediatric medicines, and veterinary medicinal products (*HMG 3a*), cf. our briefing of September 2025.

KEY CHANGES

PARTIAL LIBERALISATION OF MAIL-ORDER LICENCING

The Federal Council intends to revise the existing rules governing the mail-order sale of medicinal products with the objective of modernising distribution channels while maintaining medicinal product safety.

Specifically, the bill proposes the following key changes:

- At present, only category E, i.e., a limited range of over-the-counter (OTC) medicinal products, can be dispensed via mail order without prescription (cf. Art. 32 para. 2 TPA). In contrast, category D medicinal products, i.e., a range of non-prescription OTC medicinal products which can only be dispensed upon professional consultation, must have a prescription for dispensing via mail order even though such products are otherwise non-prescription products (i.e., if sold in brick-and-mortar stores). Under the proposed legislation, the prescription requirement would be lifted for this category of medicines.

- Similarly mail-order sales of non-prescription in-house preparations and Formula officinalis medicines (prepared according to standardised formulations in a pharmacy or drugstore) would be permitted without a prescription on two conditions: (1) an initial in-person contact at the point of sale must have taken place, and (2) the sale can be exclusively to the business's own customers.

- In addition, it would be permitted to dispense certain prescription-only medicinal products of category B via mail order without prescription under simplified conditions following an in-depth assessment by a pharmacist.

- At present, a licence to operate a public-facing brick-and-mortar pharmacy is required for the operation of a mail order business. Under the new legislation, a license to operate a drugstore (*Drogerie*) would be sufficient.

INTRODUCTION OF SUPERVISORY LEVY FOR MEDICAL DEVICES

The proposal further introduces a new supervisory levy in the medical devices sector to partially cover (increased) costs of regulatory oversight and market surveillance.

The planned fee is based on the existing model in the pharmaceutical sector and would apply to manufacturers and importers of medical devices.

The fee would be levied on the manufacturing, development or acquisition costs of medical devices placed on the market in Switzerland and capped at 15 per mille of such costs. The total revenue from the fee would not exceed 10 per mille of the proceeds from all medical devices sold during the respective tax year.

MEASURES TO ADDRESS SUPPLY SHORTAGES

To further strengthen supply chain resilience, particularly for low-cost standard therapies such as antibiotics and medicines used to treat chronic conditions, the proposal also includes regulatory simplifications designed to:

- Facilitate market access for medicinal products;
- Improve the availability of essential medicines during shortage situations; and
- Provide pharmacies with expanded competencies to manufacture or prepare medicinal products in the event of supply disruptions.

Specifically, the following key changes are planned as part of HMG 3b revision:

- At present, in case of a temporary shortage of authorised medicines, Swissmedic may authorise the import of *identical* medicinal products that are not authorised in Switzerland for a limited time or in limited quantities. This regulation would be expanded to allow the import of *equivalent* medicinal products in case of an existing or impending shortage.

- In case of an existing or impending shortage, Swissmedic would be entitled to issue a general ruling (*Allgemeinverfügung*) allowing public pharmacies and hospital pharmacies, and – in respect of certain high-risk diseases – the army's pharmacy to manufacture medicinal products with known active substances for the prevention and management of shortages and to place them on the market without a marketing authorisation.

- Swissmedic would further be charged with providing for a simplified marketing authorisation procedure for medicinal products with known active ingredients and a long history of use.

CLARIFICATION OF INDIVIDUAL DISPENSING OF MEDICINAL PRODUCTS

The proposal also aims to establish a more consistent legal basis for dispensing medicinal products in quantities smaller than the original package size and tailored to a patients' needs, extending not only to antibiotics but also to other groups of medicinal products.

According to the proposal, such individual dispensing would be permitted provided:

- Only original packages containing more units than are required for a specific treatment are authorised, or – although an original package containing the required number of units is authorised – it is not available at the point of sale; and
- Only the dispensing entity's own customers or patients are served.

It is further proposed that the Federal Council may define additional requirements and may make the individual dispensing of medicines mandatory for certain authorised dispensers.

EXPANSION OF CHIROPRACTORS' COMPETENCIES

The revision of competencies of chiropractors seeks to strengthen the profession's position and reduce existing disparities in competencies compared with other university-trained medical professionals, in particular regarding prescribing and dispensing rights.

With the proposed regulation, chiropractors would be entitled to prescribe prescription-only medicinal products, and pharmacies would be permitted to dispense products prescribed by chiropractors accordingly.

KEY TAKEAWAYS

From a regulatory perspective, the proposal combines targeted deregulation (mail-order sales, market access for known medicines, medicinal product supply in case of shortages, individual dispensing, competencies of chiropractors) with new supervisory financing mechanisms (medical devices). For affected industries, this could create both business opportunities and new compliance and cost risks, if ultimately implemented by parliament.

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