Life Sciences

Swiss Therapeutic Products Act Revision: A Step Forward in Digitalization

At the beginning of September 2025, the Swiss Federal Council published the dispatch for the partial revision of the Therapeutic Products Act (TPA). The revision aims to promote digitalization regarding prescription, dispensing, and use of therapeutic products, enhance medication safety in pediatrics, regulate access to novel therapies, and align Swiss law with EU law for veterinary medicinal products.

Prescriptions for therapeutic products, which could previously be issued electronically on a voluntary basis, must now generally be issued electronically. The revision introduces a paradigm shift, whereby those authorized to prescribe will be required to issue prescriptions in digital form, ensuring seamless electronic transmission, improved legibility, reduced errors, and prevention of falsifications or unauthorized multiple redemptions. The goal is to enhance patient safety. Technical requirements for electronic systems will be developed by the Federal Council and included in the Ordinance on Medicinal Products (VAM). Healthcare professionals (HCPs) must use systems that guarantee data protection and security in accordance with the Federal Data Protection Act (FADP) and must record access. The previously envisaged use of a technical system mandated by the Swiss Confederation is no longer required. A data protection impact assessment may also be required. At the patient's request, a printed version of the e-prescription must be provided, but always with a machine-readable electronic signature; handwritten signatures are no longer permitted. No additional tariff-based remuneration is planned for e-prescriptions.

The revision also introduces the legal basis for a mandatory electronic medication plan, which must be created or updated by HCPs each time a medicinal product is prescribed, dispensed, or administered to a patient. The plan lists medications and their administration, aiming to prevent incorrect usage, improve adherence, and facilitate information exchange among HCPs. It also reduces medication errors and helps identify potential drug interactions early. The Federal Council will regulate details and may provide exceptions (e.g., for stigmatizing medicinal products). If the new obligation increases workload, the tariff partners must negotiate appropriate adjustments.

Administering medication to children presents significant challenges due to the limited availability of authorized medicinal products, frequent reliance on off-label use, and the complexity of dosage calculations. Inpatient pediatric institutions must implement a Clinical Decision Support System (CDSS) for dosage calculation, irrespective of whether they qualify as a service provider within the meaning of the Health Insurance Act (HIA) and regardless of whether the treatment is provided on an inpatient or outpatient basis. This measure aims to prevent calculation errors and enhance safety. The CDSS must comply with medical device regulations and data protection laws. The Federal Council may extend this obligation to outpatient facilities and other groups. The use of a CDSS is not to be considered in the tariffs, but acquisition and operating costs may be included in tariff calculations. The Federal Council has announced plans to extend the CDSS requirement to outpatient facilities and potentially to other population groups.

The revision introduces and regulates the category of advanced therapy medicinal products (ATMPs), which largely adopts the respective EU provisions, but expands the definition to include veterinary medicinal products, mRNA vaccines, and cell/tissue engineering. Transplant products are now also classified as ATMPs, creating a unified regulatory framework. The amendments will impact a broad range of areas, including marketing authorization, ATMP dispensing and use, post-marketing surveillance, traceability and record retention, clinical trials, Swissmedic inspections, and sanctions.

Finally, for veterinary medicinal products, the requirements for a Swiss marketing authorization are reduced, and authorizations will generally be unlimited in duration. Measures to combat antimicrobial resistance are strengthened to maintain export capability to the EU. The scope of ATMPs now includes veterinary medicinal products, supporting market access for novel and innovative therapies in veterinary medicine.

The draft is now before the Swiss Federal Parliament, with deliberation timing still uncertain. It currently lacks transitional provisions, leaving the timeline for technical adjustments unclear. Nonetheless, healthcare institutions should begin planning and budgeting for the necessary digital infrastructure and ensure compliance with data protection. The impact on health insurance law and tariffs will hinge on future negotiations.

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