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REVISION OF THE THERAPEUTIC PRODUCTS ACT (TPA): INCREASED MEDICATION SAFETY AND ADVANCED THERAPY MEDICINAL PRODUCTS

On 3 September 2025, the Federal Council published the dispatch regarding the partial revision of the Therapeutic Products Act (TPA) to be submitted to Parliament. The objectives are to: (i) promote digitalisation in the areas of prescription, dispensing and use of therapeutic products, (ii) enhance medicinal product safety in paediatrics, (iii) regulate access to medicinal products for novel therapies, and (iv) establish broad equivalence with EU law concerning veterinary medicinal products.

E-Prescription for Therapeutic Products

Prescriptions for medicinal products may already be issued electronically on a voluntary basis. The revision introduces a paradigm shift, whereby prescriptions must, generally, be issued electronically. Those authorised to prescribe will be required to issue prescriptions for therapeutic products in digital form. This serves to ensure seamless electronic transmission, improved legibility, a reduction in potential sources of error, and the prevention of falsifications and unauthorised multiple redemptions.

The ultimate objective is to enhance patient safety. The technical requirements for the electronic systems to be used will be developed by the Federal Council at a later stage and included in the Ordinance on Medicinal Products (VAM). The use of a system operated by the Confederation has been waived.

Healthcare professionals are responsible for ensuring that, when issuing and redeeming prescriptions, they use systems that guarantee data protection and data security in accordance with the Data Protection Act (FADP). In addition, they are required to record access, which goes beyond the general provisions of the FADP. A data protection impact assessment within the meaning of Art. 22 FADP may also be required.

At the patient's request, the prescription must also be issued in paper form (printed version of the e-prescription), whereby in all cases a machine-readable electronic signature is required. Handwritten signatures will no longer be permitted.

The (electronic) provision of a prescription already forms part of the service provider's obligations within the framework ofstate-of-the-art , healthcare provision. Therefore, no additional tariff-based remuneration is planned.

New E-Medication Plan

The revision introduces a legal basis for a mandatory electronic medication plan, which must be created or continuously updated by the attending healthcare professionals each time a medicinal product is prescribed, dispensed or administered. The medication plan lists the medications to be consumed and their administration. It serves to prevent incorrect usage, improve adherence to therapy and facilitate the exchange of information among healthcare professionals. In addition, it reduces medication errors and assists in the early identification of potential drug interactions.

The Federal Council will regulate the details and may provide for exceptions to the obligation to create or update the medication plan, or exceptions regarding the information to be disclosed (e.g., stigmatising medicinal products). The same technical requirements and standards

applicable to the electronic prescription will also apply to the medication plan.

Should the new obligation result in additional workload for healthcare providers, it will be the responsibility of the tariff partners to negotiate appropriate adjustments to the tariffs to ensure adequate remuneration.

Medication Safety in Paediatrics

The administration of medication to children presents a significant challenge, as there are only a few medicinal products specifically authorised for use in children, and medicinal products are therefore regularly used off-label. Furthermore, dosage calculations are complex, as they must be determined individually for each child based on age, weight, height and other relevant factors.

With the revision, inpatient paediatric institutions are, as a first step, required to implement a Clinical Decision Support System ("CDSS") for dosage calculation. This measure is intended to prevent calculation errors and enhance the safety of medicinal product administration. This obligation applies irrespective of whether or not the inpatient facility qualifies as a service provider within the meaning of the Health Insurance Act (HIA). It is also irrelevant whether the treatment is provided on an inpatient or outpatient basis. In the process of prescribing, dispensing or administering medication, a CDSS must be used at least once.

A CDSS generally qualifies as a medical device and must therefore comply with the requirements of the applicable medical device regulation.

The Federal Council has already announced that the obligation to use a CDSS shall also be introduced for outpatient facilities at a later stage. The Federal Council may extend the application to other specific population groups and provide for exceptions (e.g., emergency situations).

Healthcare professionals are responsible for ensuring that they use a CDSS which complies with data protection and data security in accordance with the FADP, and precludes the re-identification of patients.

The use of a CDSS is not to be considered in the tariffs, as such systems are already widely used. However, the acquisition and operating costs of the CDSS may be included in the tariff calculation. The negotiation of such matters remains the responsibility of the tariff partners.

Medicinal Products for Advanced Therapies

The revision introduces and regulates the category of medicinal products for advanced therapies in the TPA. For this purpose, Switzerland largely adopts the provisions of the EU regarding advanced therapy medicinal products ("ATMP"). This is intended to enhance competitiveness and compatibility between markets and to ensure simple and safe access to innovative and high-quality products.

ATMPs include, on the one hand, gene therapy medicinal products, somatic cell therapy medicinal products, biotechnologically processed tissue products and combinations of ATMPs with medical devices. On the other hand, the ATMP regulation fully removes the category of transplant products, previously contained in the Transplantation Act, from that act and incorporates it into the TPA. Consequently, transplant products are now also classified as ATMPs.

This creates a uniform regulatory framework for medicinal products, including ATMPs, and eliminates the previous parallelism between the TPA and the Transplantation Act.

However, with the new Art. 4 para. 1 lit. a^{undecies} Draft-TPA, Switzerland introduces a legal definition for ATMPs that deviates from that of the EU. The main differences are that Switzerland additionally includes veterinary medicinal products, mRNA vaccines and products of so-called cell and tissue engineering within the definition of medicinal products for advanced therapies.

The introduction of ATMPs leads to numerous amendments to the TPA (including adjustments to the requirements for marketing authorisation; specific requirements regarding the dispensing or use of ATMPs; expanded obligations for post-marketing surveillance, traceability, and record retention; authorisation requirements for clinical trials; inspection responsibilities of Swissmedic; amendments to the penal provisions), and in part, additional provisions are to apply (in particular for ATMPs manufactured from human organs, tissues, or cells, stem cells, or from animal organs, tissues or cells for use in humans).

Veterinary Medicinal Products: Broad Equivalence with EU Law

To secure the supply of veterinary medicinal products in Switzerland, the requirements for obtaining Swiss marketing authorisation are set to be reduced. Among other measures, the current temporal limitation on the authorisation of veterinary medicinal products will be abolished, so that such authorisations will now, as a rule, be granted for an unlimited period.

To maintain the ability to export animals and animal products to the EU, Switzerland is extending its existing measures against antibiotic resistances to also fight antimicrobial resistance. After the autonomous adoption of EU law, the prohibition of specific antimicrobial medicinal products was already implemented at the ordinance level. A statutory basis for this measure is now being formally established.

Finally, the legal definition of ATMP will also include veterinary medicinal products. This aims to ensure market access for novel and innovative therapies in veterinary medicine.

Parliamentary Deliberation Pending

The dispatch regarding the draft of the revised TPA was submitted to Parliament at the beginning of September. The timing for parliamentary deliberation of this matter is currently unknown.

Outlook and Recommendations

The present draft of the revised TPA provisions does not yet contain any transitional provisions, so the timeframe for the technical adjustments remains unclear. Nevertheless, early preparation is advisable.

Healthcare institutions and service providers should plan and budget for the procurement of the digital

infrastructures required for e-prescriptions, e-medication plans and CDSS. It is also necessary to examine the data protection-related characteristics of the selected solutions to ensure compliance upon commissioning.

The impact under health insurance law will depend on whether and how the remuneration structure and tariff positions are adjusted and negotiated within the framework of the new regulations. While the introduction of the new obligations may lead to increased costs, the anticipated improvement in patient safety is also likely to reduce costs.

Further Information

Press Release

Patial Revision of the TPA

Draft Act TPA

Dispatch to the changes of the TPA

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