Stepping into the future: A closer look at the third revision oft the Therapeutic Products Act (TPA / HMG)

By Celine Weber
MLaw, Attorney at Law
Managing Associate
Phone +41 58 658 56 17
celine.weber@walderwyss.com

On 8 December 2023, the Federal Council has opened the consultation procedure on the third revision of the Therapeutic Products Act (TPA; in German: "Heilmittel-gesetz", HMG). The amendments clearly aim at promoting innovation and the digitalisation of the healthcare sector. The draft revision comprises changes in the following areas[1] :

I. Advanced therapy medicinal products (ATMPs)

To account for new therapies referred to as «advanced therapy medicinal products» (ATMPs), the EU has enacted the Regulation (EC) No. 1394/2007, regulating:

- gene therapy medicinal products,
- somatic cell therapy medicinal products,
- tissue engineered products and
- a combination of ATMPs and medical devices.

In the proposed revision of the TPA, Switzerland will adopt the EU legislation to the extent possible. The amendments include, inter alia:

- the exclusion of the previously existing category of transplant products from the scope of the transplantation legislation and the transfer to the therapeutic products legislation; these products will fall under the definition of ATMP;
- a legal definition of ATMPs;
- a list of provisions that do not apply to the manufacture and dispensing of ATMPs;
- the possibility of using unauthorized ATMPs;
- the requirements for the approval of ATMPs;
- the possibility for Swissmedic to define specific requirements for the dispensing or use of an ATMP in order to protect health when authorizing it;
- specification of the authorization requirements for clinical trials with ATMPs;
- requirements regarding surveillance, traceability and a retention obligation.

These provisions aim to ensure patients' access to innovative and high-quality therapies, while creating a comparable level of safety and increasing competitiveness and compatibility between the EU and the Swiss market.

II. Mandatory electronic prescriptions for therapeutic products

The revised TPA contains various amendments to promote digitalisation in the healthcare sector.
Electronic prescriptions of medicinal products and medical devices, which is already enshrined in law on a voluntary basis, is to become mandatory in the future according to the draft revision. Issuing, transmitting and redeeming prescriptions electronically is intended to guarantee better legibility and thus help increase patient safety, prevent counterfeit prescriptions and unauthorised multiple prescriptions. However, patient self-determination and the free choice of pharmacy shall continue to be guaranteed.

III. Mandatory electronic medication plan

Pursuant to the draft revision, healthcare professionals (HCPs) will be obliged to create an electronic medication plan when prescribing, dispensing or using medicines and to carry out and document medication reconciliation. HCPs will have

to update the medication plan on an ongoing basis. Patients shall receive the medication plan electronically or in printed form upon request.
The amendments aim to increase drug safety, transparency and adherence to treatment as well as to enhance the exchange of information between all HCPs providing treatment.

IV. Mandatory use of electronic systems for calculating drug dosages in pediatrics

Since only very few medicinal products are specifically authorised for children and dosages must be calculated individually for each child based on, inter alia, age, weight and height, medicating children involves a considerable risk. Therefore, the draft revision stipulates that the use of electronic systems for calculating individual dosages will be mandatory in institutions that provide inpatient pediatric treatment. The aim is to avoid calculation errors as far as possible and thus to increase the safety of medicinal products used for children. The Federal Council may provide for exceptions for medicinal products with low risk potential. Furthermore, the Federal Council may extend the obligation to use electronic systems for calculating dosages to institutions that provide exclusively outpatient pediatric treatment (such as pediatric medical practices) and to public pharmacies.

V. Veterinary medicinal products

Considering the revision of the EU legislation on veterinary medicinal products, the draft revision provides for necessary amendments to ensure the security of supply of veterinary medicinal products in Switzerland and to maintain the exportability of animals and animal products to the EU.

VI. Thoughts

The stakeholders are asked to diligently assess the impact of the proposed revision. All in all, the draft aims to strengthen the fundamental pillars of the TPA/HMG (i.e., high quality, safety and efficacy of therapeutic products) within the context of a rapidly evolving scientific and digital landscape. Swiss life sciences regulatory law is predominantly shaped by international standards. However, in cases where Switzerland can offer a legal framework that is more streamlined, less repetitive, and simpler than those in other jurisdictions, it should do so – in alignment with its tradition of straightforward legislation. The consultation process is an initial opportunity to refine the auspicious first draft.

Endnotes

1 Relevant documents, including the "Amendment of the TPA" and the "Explanatory report on the amendment of the TPA", can be found at www.bag.admin.ch/bag/en/home.html > Medicine & research > Medicinal products & medical devices > Therapeutic Products Act: Partial revision (2023) (last visited on 17.01.2024).