# Revision of the Therapeutic Products Act and the Therapeutic Products Ordinance Package IV

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On 18 March 2016, the Swiss Parliament adopted the revised Therapeutic Products Act ("revTPA"). Some of its new provisions as well as the corresponding ordinances will already come into force at the beginning of 2018, whereas the majority of the implementing regulations will come into force at the beginning of 2019 only (Therapeutic Products Ordinance Package IV). On 21 June 2017, the Federal Council has instructed the Federal Department of Home Affairs ("FDHA") to start a consultation phase on the revised ordinances of both the Federal Council and the Swiss Agency for Therapeutic Products ("Swissmedic").

The consultation phase will end on 20 October 2017.

The current second phase of the Swiss healthcare law's revision pursues different aims and concerns the following subjects: an extended application of the simplified authorization procedure as well as additional incentives for scientific research, especially in the area of pediatric medicine. Moreover, drug safety shall be increased and in different areas transparency shall be raised. Finally, by amending the rules on pecuniary benefits, corruption shall be prevented.

**1. Simplified Authorization Procedure**

Based on the National Council's initiative, art. 14 para. 1 abis – aquater revTPA are introduced. These provisions make it possible for additional medicinal products to receive marketing authorization through the simplified authorization procedure, provided that this is compatible with the requirements on quality, safety and efficiency, and neither Switzerland's interests, nor international obligations, are opposed. In this regard, it is distinguished between "well established use", "traditional use", and medicinal products that are already approved in a canton. The respective new implementation regulations can be found in Art. 17a et seqq. of Swissmedic's Ordinance on the Simplified Authorization of Medicinal Products and the Authorization of Medicinal Products by Notification ("VAZV", German abbreviations used in this text if no English translation officially available) as well as in ciph. 1 of the Appendices 4 to 5.3 of the Ordinance on the Requirements for the Authorization of Medicinal Products ("AMZV").

## 2. Incentives for Scientific Research

Swissmedic grants extended first applicant's dossier protection of 15 years with regard to important medicinal products for the treatment of rare diseases (art. 11b para. 4 revTPA). Upon request, a special first applicant's dossier protection of 10 years can be granted for medicinal products that are intended specifically and exclusively for pediatric use, provided that no dossier protection has been granted for a medicinal product authorized by Swissmedic with the same active substance and for the same specific pediatric use (art. 11b para. 4 revTPA).

In the course of the TPA's present revision, changes were also made to the Federal Patents Act ("PatA") and the Patents Ordinance ("PatV"). The amended PatA provides for an extension of six months of the already existing Supplementary Protection Certificate as well as the newly created pediatric Supplementary Protection Certificate. The Federal Department of Justice and Police carries out a separate consultation phase for the PatV's amendments, which ends on 20 October 2017 contemporaneously.

## 3. Drug Safety

The incentives for the promotion of scientific research are contrasted with various new or extended obligations regarding the medicinal products' safety of use. On one hand, art. 54a revTPA provides for a pediatric evaluation concept ("PEC"). According to this new provision, the pediatric population group must be involved from the outset in the development of new medicinal products. Art. 5 para. 4 lit. b of the Ordinance on Medicinal Products ("VAM"), however, stipulates an exemption to the general obligation to conduct a PEC insofar as the medicinal product concerned is used solely for the treatment of adults' diseases. Furthermore, art. 5 para. 3 VAM provides that a PEC already assessed by a foreign authority is taken into account by the Swiss authorities. The respective new implementation regulations can be found in art. 5, 9 para. 5, 11 para. 3 and 5, 30 para. 4 and 83 para. 1 VAM as well as in art. 2 lit. c and 13 para. 2 AMZV.

On the other hand and to fill potential gaps between the knowledge status at the time of authorization and at the time of market surveillance, a pharmacovigilance plan is newly introduced, which must include an assessment of the risks and, insofar as necessary, a plan for their systematic recording, investigation and prevention (art. 11 para. 2 lit. a ciph. 5 revTPA).

In addition, the reporting obligations regarding adverse reactions to or adverse events in connection with medicinal products pursuant to art. 59 TPA were expanded to include also health care professionals who are entitled to use or dispense medicinal products.

Finally, art. 59 para. 6 revTPA mandates the Federal Council to define the rules of Good Vigilance Practice, taking into account the internationally recognized directives and standards. In Appendix 3 to the VAM, references to various relevant directives and standards can be found.

## 4. Raised Transparency

Thanks to the revised provision in art. 67 revTPA, Swissmedic's various competences with regard to public information are clarified. For example, Swissmedic shall publish various information on the medicinal product and on the authorization holder in respect to applications for authorization, extensions of indication or extensions of the authorization, as well as in respect to the granting of authorizations and their revocation as well as in respect to the withdrawal of applications for authorization or indication extension of a medicinal product. In addition, the publication of the first applicant's dossier protection duration is introduced.

Based on art. 67b revTPA the Federal Council is also entitled to publish in a database the results of clinical trials that have been carried out during the development of a medicinal product. In addition, the VAM provides for the publication of a summary of the relevant trial results by marketing authorization holders, whereby the holders are allowed to make reference to internationally established public registries and databases of clinical trials. The relevant new implementation regulations can be found in art. 70 et seqq. as well as in Appendix 5 of the VAM.

## 5. Self-Medication

In the course of the amendment of the regulation on self-medication, the Federal Council has restructured the dispensing categories in accordance with art. 23 et seqq. revTPA (see art. 40 et seqq. VAM). Category C is abolished and the majority of medicinal products formerly assigned to this category are re-assigned to Category D (dispensing after expert advice). Medicinal products that cannot be assigned to Category D due to safety concerns are re-assigned to Category B (dispensing on medical prescription). The respective implementation regulations can be found in art. 45 et seqq. and Appendix 2 of the VAM.

## 6. Pecuniary Benefits

In order to ensure the incorruptibility of physicians and pharmacists, the regulation supported by the Council of States, whereupon the rules on pecuniary benefits shall apply to medicinal products subject to prescription only, has prevailed (art. 55 para. 1 revTPA). Therefore, pecuniary benefits regarding both medical devices and medicinal products not subject to prescription are only subject to the generally applicable corruption provisions of the Swiss Criminal Code. Art. 55 para. 2 lit. a-e revTPA newly define exceptions by prescribing cases that are not considered to qualify as a relevant pecuniary benefit. An extension of the integrity requirement to other categories of medicinal products as foreseen in art. 55 para. 3 revTPA is currently not intended. The details are laid down in the newly created Ordinance on Integrity and Transparency in the Field of Therapeutic Products ("VITH").

Art. 86 para. 1 lit. h revTPA defines criminal sanctions with regard to breaches of art. 55 revTPA. It remains to the courts to decide in the individual case, whether – as assumed during the discussions in Parliament – the mentioned criminal law provision of the revTPA will take precedence over the generally applicable corruption provisions set forth in the Criminal Code (art. 322ter et seqq. of the Criminal Code).

The mandatory passing on of price concessions set out in art. 56 para. 3 of the Federal Law on Health Insurance ("KVG") was relativized by Parliament. The insurer and the medical service provider may agree on a partial passing on of the price concessions if the withheld benefits are evidently used for the treatment's quality improvement (art. 56 para. 3bis revKVG). The relevant implementation regulations are laid down in art. 76a and 76 VITH.

**7. Conclusions**

The TPA's revision brings relevant changes with regard to the simplified authorization procedure and introduces new incentives in the field of research, in particular based on the extended first applicant's dossier protection. In addition, the revised TPA also provides for new obligations, such as the PEC or the reporting obligations for health care professionals who are entitled to dispense medicinal products.

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