Bär & Karrer Briefing
March 2016

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The Revision of the Therapeutic Products Act has been Adopted

The National Council and the Council of States have adopted the revised Therapeutic Products Act during the federal parliament's spring session of 2016. In particular, the provisions on the prohibition of undue material benefits, the acceptance and use of discounts as well as the statutory regulation of minimum requirements regarding medical prescriptions were highly controversial. The necessary implementing ordinances will now be drafted, and the public consultation is planned to be initiated in spring 2017. Once the public consultation will be completed, the effective date of the revised statute and its implementing provisions will be determined.

Overview

On November 7, 2012 the Federal Council presented its draft of the revision of the Therapeutic Products Act (TPA) to the federal parliament. While the core elements of the Federal Council's draft were accepted by the National Council and the Council of States, some issues remained highly controversial until the very end. Particularly, the problems surrounding discounts granted on medicines almost led to a failure of the revision. After a conciliation, the final draft of the Therapeutic Products Act has been adopted by the National Council and the Council of States during the spring session of 2016.

The revision aims for improving the human and animal health in the field of therapeutic products. To this end, the revision wants to improve supervision and transparency of the market. Moreover, the revision is part of the federal government's master plan to foster biomedical research and technology.

Major Amendments in a Nutshell

Prohibition of Undue Material Benefits

The present art. 33 TPA regarding material benefits will be replaced by the new art. 55 et seqq. TPA. The prohibition of undue material benefits will only apply to prescription drugs. The Federal Council may, however, extend the scope of the provision to other categories of therapeutic products.

Additionally, the list of exceptions has been amended: Besides material benefits of modest value, contributions to research and advanced training, compensation in return for services of equal value as well as discounts and refunds on therapeutic products which do not affect the choice of treatment, will no longer be considered undue material benefits. During the conciliation, the present statutory rule stating that discounts must have a direct effect on the prices (art. 33 para. 3 lit. b TPA) has been abrogated.

The requirement of the Health Insurance Act (AHI) according to which discounts have to be passed on

to the consumer has also been amended: In the future, insurers and health care providers may agree not to pass on discounts entirely. However, the majority of the discounts, i.e. at least 51% according to the parliamentary debate, must be passed on to the consumer. The other part of the discounts have to be used to improve the quality of treatment.

As a consequence of the new transparency requirement, all discounts and refunds granted on the purchase of therapeutic products (i.e. for all drugs and medical devices) must be disclosed in the buyer's and in the seller's documents and invoices as well as in their accounting records. The competent authorities may require that this documentation as well as the agreement on the amount of the discounts to be passed on according to the AHI be communicated to them.

Additional Incentives for Research Activities

A 10 year document protection period will be granted for new indications of authorized active substances, if significant clinical benefits compared to existing therapies can be expected, and if the new indication is supported by extensive clinical studies.

While the market exclusivity period according to EU law has not been adopted, a 15 year document protection period for orphan drugs will be granted upon request.

Regarding paediatric drugs, the amendments to the Act on Patents for Inventions (PatA) provide the possibilities to either grant an independent supplementary protection certificate for the period of 6 months, or to extend an existing supplementary protection certificate.

Prescription and Dispensing of Drugs

Pharmacists will be allowed to dispense certain prescription drugs without medical prescription. The Federal Council will set out the drugs and indications concerned as well as the scope of the required documentation in the implementing ordinance.

Statutory minimum requirements for medical prescriptions were rejected during the conciliation. Instead, the Federal Council will determine these requirements after consultation of representatives of the medical professions concerned.

The new art. 9 para. 1 lit. g PatA exclude actions in the course of medical activities, which relate to an individual person as well as to medicines, from the scope of patent protection. It is thus guaranteed that physicians or pharmacists may prescribe or dispense the medicines they consider most appropriate without running the risk of a patent infringement. This provision is particularly relevant in cases of prescription or dispensing of a generic drug for the treatment of an indication which is still covered by a patent.

Stricter Criminal Sanctions

The criminal provisions of the TPA regarding pharmaceutical crime have also been amended. First of all, art. 86 TPA was redrafted to include acts which typically put a person's health at risk. In addition, the amendment of art. 86 TPA qualifies violations of the prohibition of undue material benefits as a misdemeanor which can be punished with a custodial sentence or a monetary penalty. Under current law, violations of this prohibition only qualify as a contravention sanctioned with a fine.

Furthermore, the new art. 86 TPA includes counterfeiting, falsifying and mislabeling of therapeutic products as well as placing of such products on the market.

A violation of the transparency requirement regarding discounts and refunds will qualify as contravention and will be punished with a fine.

Conclusion and Outlook

To some extent, the final version of the revised TPA is a trade-off where the particularly sensitive issues were shifted to the ordinance level. Whether the original aims can eventually be achieved, for instance regarding the prohibition of undue material benefits, will depend on the implementing provisions which remain to be drafted.

Provided that there will be no popular referendum against the revised TPA, the necessary ordinances will now be drafted under the label "Therapeutic Products Ordinance Package IV". The public consultation regarding this package is planned to be initiated in spring 2017. Only after completion of the public consultation, the effective date of the revised TPA and its ordinances will be determined.

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