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Law & Politics in Switzerland

Ordinary Revision of the Therapeutic Products Act (2nd stage): More child-friendly medicines and simplified access to medicines

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Changes to the Therapeutic Products Act will improve public access to medicines and conditions for biomedical research and industry. The aim is to make it easier for complementary and herbal medicines to enter the market and increase the availability of a wider range of medicines suitable for children. There are also amendments to regulations on discounts and kickbacks, on self-medication, on good corporate governance, on medicinal products information, on market surveillance and on regulatory data protection.

The Therapeutic Products Act ("TPA"), which came into force in early 2002, has been revised twice, in two stages. The 1st stage, the early partial revision of the TPA, already entered into force in October 2010, so that the urgent problem of the supply of medicines in hospitals could be resolved. The 2nd stage of the revision of the TPA involves mainly the following areas:

Medicinal products for pediatric use

The revision of the TPA seeks to promote the production of medicinal products for pediatric use by increasing research, development and authorization for this type of medicinal product. The lack of medicinal products specifically designed and developed for treating children is a Europe wide problem. Thus, the revised TPA aims to improve the health and quality of life of children by ensuring that new medicines for children and medicines already on the market are fully adapted to their specific needs. In order to fill the gaps in research on this type of medicinal product, the TPA lays down new obligations for the pharmaceutical industry accompanied by rewards and incentives, especially an additional extension of the patent protection term of six months. Therefore, the regulation also contributes to the competitiveness of the Swiss pharmaceutical industry.

Simplified authorization procedure of complementary and herbal medicinal products

The Federal Council has drafted concessions in drug authorization procedures, particularly concerning complementary and herbal medicinal products. Medicinal products which were approved at the cantonal level at the time of entry into force of the TPA and which are still distributed may also benefit from the proposed changes. However, due to a special provision, the aforementioned medicinal products may continue to be placed on the market – as in the past – only in the concerned canton.

Discounts and kickbacks

Being revised is also the current system of non-cash benefits such as bonuses or free samples of products that manufacturers use in order to promote their products with physicians or pharmacists. The aim is to create more transparency and clarity on the admissibility of such discounts granted in prescribing, dispensing and use of medicines and medical devices. For example, rebates in kind will no longer be permitted. Additionally, physicians and pharmacists must also disclose their commercial links with manufacturers.

Distribution of medicinal products

Pharmacies and drugstores shall obtain additional authorization for the independent distribution of medicinal products; thus the self-medication under surveillance by a pharmacist or a druggist will be enhanced.

Druggists shall be allowed to independently distribute all non-prescription drugs in Switzerland. Pharmacists shall be allowed to dispense some of prescription drugs – without a prescription – provided a technical

consultation in person has occurred. This requires a review of the prior classification of drugs in the different distribution-categories by Swissmedic before these changes can go into effect.

Good Corporate Governance

With regard to the revision of the corporate governance, which is based on the adopted corporate governance report of the Federal Council of 13 September 2006, an efficient and uniform control and management of Swissmedic shall be achieved.

Medicinal products information

In line with Directive 2001/83/EC, the revised TPA aims to improve a regular updating of the professional and patient information because a comprehensive collection of medicinal products information is currently not ensured.

Market surveillance

Additionally, the revision of the TPA purposes to strengthen the market surveillance by extending the mandatory reporting, in particular the reporting of adverse medicinal products reactions.

Regulatory data protection

The new Swiss regulatory data protection system is intended to implement the EU's 8+2(+1) system. Even though the revised Swiss regulatory data protection system is projected to introduce harmonisation with the EU system, the new Swiss regime leaves noteworthy loopholes. For example, compared to the European law, the proposed revision does not consider the required data protection for new combinations or in cases of a change of classification of a medicinal product. In addition, the definition of the term "original preparation" by Swissmedic is still much stricter than the reference products that enjoy regulatory data protection under Directive 2001/83/EC.

Commentary

It is welcomed that druggists may distribute what today are distribution-category "C" drugs. Druggists are well trained and form an often overlooked backbone of the Swiss healthcare provision.

With the additional dispensing of Rx-drugs by pharmacists on the other hand the devil is in the details: Which drugs are suitable? What about the long sung tale by pharmacists that who prescribes shall not dispense? What about the situation in those cities and cantons of Switzerland, where doctors are not permitted to dispense drugs? Will we see a total treatment shift from doctors to pharmacists, and will doctors accept this?

Not addressed yet are some open questions concerning the (e-) mail order business. Long-term, one can expect that we will see mail order business permitted according to retail order permit system in Switzerland. A timely revision and precision on these issues would save the market a lot of court cases over the next years.

The planned revision of the Swiss regulatory data protection system seems to be a half-hearted approach. It should rather implement the complete set of EU provisions protecting the data submitted in support of an application for a new product.

Time schedule

The consultation document will be dealt with by the appropriate Commission at the beginning of 2013 at the earliest. The revised TPA is expected to come into force as of 1 January 2016.