BÄR & KARRER

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Ordinance on Integrity and Transparency in the Therapeutic Products Sector has been adopted

On 18 March 2016, the Swiss Parliament adopted the revised Therapeutic Products Act (revTPA). At the same time, the Swiss Parliament revised the provisions regarding discounts set out in the Federal Act on Health Insurance (KVG). The details of the revTPA and the revised provisions of the KVG are contained in a new Ordinance on Integrity and Transparency in the Context of Therapeutic Products (VITH) and a revision of the Ordinance on Health Insurance (revKVV) which the Federal Council adopted on 10 April 2019 based on the feedback received during the consultation process. The revised regulations will enter into force on 1 January 2020.

Overview

The key goals of the revised provisions of the TPA, the KVG and the KVV as well as of the VITH are to ensure that the prescription and supply of medical products is not influenced by financial benefits of any sort granted to health care providers (HCPs) while at the same time incentivising HCPs to negotiate discounts with suppliers or refunds since these may help to reduce health care costs and are, therefore, generally desired. The new legislation intends to achieve these goals with the following key principles:

– integrity in the choice of treatment

– transparency on discounts

– benefits for patients and insurers

– stricter criminal sanctions and enforcement

Key Principles in a Nutshell

Integrity in the Choice of Treatment

Article 55 para. 1 revTPA sets out the key principle that persons who prescribe, dispense, use or purchase prescription medicines and organizations who employ such persons may not claim, accept a promise or accept for themselves or in favour of a third party any undue benefit. At the same time, it is prohibited to offer, promise or grant any such person or organization any undue benefit.

The scope of article 55 para. 1 revTPA is limited to prescription drugs. The Federal Council did not make use in the VITH of its right to extend the scope to further therapeutic products, in particular medical devices.

Article 55 para. 2 revTPA defines in an exhaustive list those advantages which are not undue. It is particularly of note that rebates and refunds are explicitly not undue if they have no influence on the choice of treatment. The Federal Council did not specify the circumstances under which rebates and

refunds do not influence the choice of treatment. However, according to the Federal Office of Public Health's (FOPH) FAQ on the subject, at least benefits which are entirely passed on to the patient or his/her healthcare insurer have no influence on the choice of treatment.

Transparency on Discounts

According to article 56 revTPA, all discounts and refunds granted on therapeutic products must be recorded on the invoices as well as in the books of the selling and purchasing persons and organizations and disclosed to the FOPH upon its request.

In contrast to article 55 revTPA, article 56 revTPA generally applies to all therapeutic products irrespective of the stage at which discounts and refunds are granted within the supply chain. However, the Federal Council made use of its rights: (i) to limit the obligation of disclosure vis à vis the FOPH to the last stage within the supply chain, so only to discounts granted to persons or organizations who prescribe, dispense, use or purchase for such purpose therapeutic products (article 10 para. 1 VITH) and (ii) to exclude from the transparency obligation of article 56 revTPA therapeutic products which are deemed to have a low risk potential, such as medicinal products available on a retail basis and Class I medical devices (e.g. plasters, thermometers and walking aids) (article 10 para. 2 VITH).

Benefits for Patients and Insurers

According to article 56 para. 3 KVG, HCPs are obliged to pass on financial benefits granted to them (such as discounts and refunds) to the patient and/or the healthcare insurer.

According to the new article 56 para. 3bis revKVG, insurers and HCPs may agree that certain discounts do not have to be fully passed on. However, such agreements have to ensure that the majority (more than 50%) of the discounts or refunds are passed on and that the portion retained by the HCP is demonstrably used to improve the quality of treatment. These agreements need to be reported without delay to the FOPH and disclosed to it on its request.

With regard to the retained benefits, article 76b revKVV states that these should primarily be used for nationwide programmes to improve the quality of treatment. The parties to the agreement must, therefore, define methods of proof to establish what constitutes such improvement of treatment. Article 76c revKVV even provides that the reports by the insurer to the FOPH must also address the evaluation of the improvements achieved compared to the former quality of treatment. In addition, such evaluation must be conducted by an independent organization applying scientific methods. Considering these provisions as well as the examples mentioned by the FOPH, it appears doubtful that the provision or financing of equipment and instruments for individual HCP practices or services to HCPs qualify as such measures, even though it is possible to argue that they also have a positive impact on the treatment. At least the use of the retained part of the benefits for means for which the HCPs would be paid otherwise (e.g. by being able to invoice the cost thereof as a technical service (TL) under TARMED) or to cover costs that must be regarded as part of the ordinary costs of doing business (e.g. office refurbishment and the like) does in our view not qualify as an admissible measure for the improvement of treatment under the meaning of article 56 para. 3bis revKVG and articles 76b et seq. revKVV.

Furthermore, according to the explanatory report of the FOPH, the benefits retained by the HCP in accordance with article 56 para. 3bis revKVG need to be permitted under article 55 revTPA and also be in line with article 56 revTPA. In our view, article 55 revTPA does not provide for additional requirements to the ones set out in article 56 para. 3bis revKVG, i.e. the retained discounts and refunds which are demonstrably used to improve the quality of treatment are not undue since they have no influence on the choice of treatment (see article 55 para. 2 lit. d revTPA) and should therefore be permitted under article 55 revTPA.

According to article 76a para. 2 revKVV, which was not included in the consultation draft of the VITH, discounts and rebates which are already reflected in the calculation of the tariffs and prices of the corresponding service do not have to be reported separately in the invoicing process. According to the

explanatory report of the FOPH, this applies particularly to flat-rate tariffs. It therefore remains unclear whether and to what extent article 56 para. 3 and 3bis revKVG apply to inpatient services reimbursed according to Swiss DRG or outpatient services for which specific flat-rate tariffs have been agreed between the insurers and the health care providers (e.g. in the ophthalmology sector).

Finally, it is worthy of mention that the VITH in comparison to the consultation draft no longer requires manufacturers and sellers of therapeutic products to designate a responsible person who, among others, would have the duty to ensure that: (i) the placing on the market of therapeutic products complies with the VITH, (ii) the orders of the FOPH are immediately and fully complied with and (iii) all documents and information are delivered to the FOPH upon its request.

Stricter Criminal Sanctions and Enforcement

The criminal provisions of the TPA have been modified. According to article 86 revTPA, violations of the prohibition of undue material benefits (article 55 revTPA) qualify as a misdemeanor punishable with a custodial sentence of up to three years or a monetary penalty. Under current law, violations of the respective prohibition only qualify as a contravention sanctioned with a fine.

A violation of the transparency requirement relating to discounts and refunds (article 56 revTPA) will qualify as a contravention and will be punishable with a fine.

Currently, the Swiss Agency for Therapeutic Products Swissmedic is responsible for the implementation of the prohibition on advantages set out in article 33 TPA. Furthermore, it is the duty of the health insurers to enforce the disclosure requirement set out in article 56 of the KVG. With the new legislation, the overall responsibility for enforcement will rest with the FOPH with the intention to "allow more vigorous enforcement" (press release of the FOPH dated 10 April 2019).

Key Takeaways

The revTPA, the revised provisions of the KVG and KVV as well as the VITH intend to increase the integrity and transparency in connection with discounts and refunds granted in the health care sector and we expect increased enforcement activities by the FOPH.

However, a number of questions have been left open and the applicable provisions contain various exemptions and vague legal terms. Consequently, further clarifications will be required and legal advice should be sought in specific cases.

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