The Last Piece of the Puzzle: Preventing Financial Influences on Healthcare Professionals' Therapeutic Decisions

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The Swiss Act on Therapeutic Products (TPA) has undergone a comprehensive revision with regard to the regulatory framework of medicinal products. The bulk of the revised provisions entered into force on January 1, 2019. The last batch of new rules regarding financial benefits flowing from the industry to healthcare professionals (HCPs) has recently been adopted by the Swiss Federal Council but will enter into force only on January 1, 2020.

It has taken quite some time to replace the infamous Art. 33 TPA regarding "promises and acceptance of material benefits". On January 1, 2020, the last remnant of the "old" TPA will finally be superseded by two new provisions (Art. 55 and 56 TPA) as well as an entirely new ordinance issued by the Swiss Federal Council on April,10 2019.

The name of the ordinance (Ordinance on the Integrity and Transparency with Regard to Therapeutic Products; OITT) is partially misleading, as it in fact applies only to financial benefits in connection with drugs and not medical devices. A last-minute proposal to include medical devices in the revised scheme was blocked by a majority of the Swiss Parliament in March 2019 to avoid jeopardizing the transposing of EU regulations for medical devices and in vitro medical devices into Swiss law. The Federal Council retains the competence to extend the regulatory scheme to medical devices but has not exercised that power to date. It remains to be seen whether the name of the OITT is a prelude for what's to come in terms of extending the regulation.

Companies battling with the old scheme will be happy to learn that the OITT now defines a "discount". For medicinal products, which are listed with an officially authorized ex-factory price, a discount is "notably" every margin below this ex-factory price. For drugs that are not listed, the price usually paid by wholesalers ("standard price") replaces the ex-factory price. This is intended to simplify matters as compared to the old Art. 33 TPA.

However, as always, the devil is in the detail. The commentary to the OITT issued by the Federal Office of Public Health (FOPH) indicate that "notably", as used in the definition for "discount", might mean that prices only marginally above the ex-factory price will already be considered as containing a discount (e.g. distribution costs are not taken into account).

Furthermore, the OITT sets new transparency standards with regard to discounts (and reimbursements) received by HCPs in the procurement of medicinal products. . However, such financial benefits do not have to be disclosed if they have already

been taken into account when fixing the prices for treatments, as is the case for all inpatient services covered by the Swiss Diagnostic Related Groups.

Finally, companies manufacturing or distributing medicinal products have to implement a compliance system for the new rules. This includes the obligations to

- designate a responsible person for the exchange of information with the FOPH
- file all the contracts and agreements with HCPs and organizations (e.g., hospitals) regarding the procurement of medicinal products and store them for at least 10 years
- establish a directory of all HCPs and organizations receiving financial advantages covered by the OITT

In addition to the OITT, new provisions in the Ordinance on Health Insurance (Art. 76a – 76c) contain rules governing the transfer of financial benefits to patients and health insurers and the agreements with health insurers regarding partial transfers of such benefits.

The new legislation is much more detailed than the current one. It has been strongly influenced by Swissmedic's enforcement activities in the past 16 years. However, the authority responsible for enforcing the new rules will no longer be Swissmedic but FOPH. We expect that the FOPH, on the basis of the new law, will increase the enforcement activities especially with regard to the transparency rules.

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