

To Swiss Medtech Members

Information on transparency requirements under the Therapeutic Products Act (TPA) and the Ordinance on Integrity and Transparency in the context of Therapeutic Products (OITTP): Discounts and Rebates

The Therapeutic Products Act (TPA) regulates the management of medicinal products and medical devices in Switzerland; in particular, their approval, manufacture, distribution, safety, and protection against improper use. The Ordinance on Integrity and Transparency in the context of Therapeutic Products (OITTP) is an extension of the TPA and specifies requirements regarding integrity and transparency. Together, the TPA and OITTP are intended to ensure that therapeutic products and medical devices are placed on the market under safe, effective, and fair conditions.

The OITTP is currently under revision to align regulations with therapeutic product market conditions, particularly regarding medical technologies. The aim is to consider international standards and ensure greater transparency and integrity in the healthcare sector. Swiss Medtech is actively involved in incorporating the industry's perspective into the process. The official consultation of the OITTP revision is planned for 2025. Existing regulations will remain unchanged until the new provisions come into force.

All companies or stakeholders operating in the therapeutic products sector are responsible for ensuring compliance with statutory provisions, including obligations relating to transparency and disclosure under the Health Insurance Act (HIA) and the Health Insurance Ordinance. The following overview summarises the most relevant provisions, with particular reference to discounts and rebates.

Provisions for transparency Art. 56 TPA in accordance with Art. 10 and 11 OITPP

- All discounts and rebates related to the purchase of therapeutic products must be indicated on the receipts and invoices, as well as in the account books of the selling and purchasing individuals and establishments, and be disclosed to the competent authorities upon request
- Class I medical devices are not subject to this regulation
- Manufacturers or distributors of therapeutic products subject to provisions on integrity and transparency must appoint a contact person responsible for providing all required documents and information to the Federal Office of Public Health (FOPH) upon request
- All agreements reached with professionals and establishments under the scope of the Ordinance must be archived for ten years following their last usage
- A record must be kept of all professionals and establishments who have received benefits as defined in the OITTP
- Fines of up to CHF 50,000 may be imposed for violating the provisions for transparency.

Disclosure of discounts

The TPA does not specify a specific form for discounts on invoices, receipts, or in account books. The minimum requirement is that the format be clearly recognisable to both the recipient and the enforcement authority.

The FOPH is maintaining its existing policy that if manufacturers' invoices explicitly state the standard price, the discount granted, and the actual price paid, it is assumed that the manufacturer has undertaken all possible measures to fulfil the corresponding requirements (see Swissmedic Journal 11/2003, pp. 980-984, 11/2012, p. 1054).

Standard prices

The standard price is determined by the vendor (and may be reviewed by the authorities). It is the vendors' duty to clearly and comprehensibly indicate all discounts granted (in addition to the standard price) on invoices, receipts, and in the account books (Art. 56 TPA). Purchasers can then also record the discounts in their account books. Discounts may be specified per product.

In the absence of government pricing regulations, prices shall be determined by market principles.

The FOPH assumes that companies are free to define systems and methods to determine standard pricing. The vendor's list price for a specific product (i.e. not the product price for one specific purchaser) may be used as the standard price. If the supplier does not have a list price and offers the product to different purchasers at different prices, the highest price offered to a purchaser for the same product in Switzerland shall be applied. If an averaged price is used, the company is responsible for ensuring transparency by disclosing discounts granted in accordance with the OITTP.

Applicable are discounts awarded by vendors to purchasers within Switzerland. Furthermore, only prices offered at the last stage of distribution (i.e. limited to discounts and rebates for individuals or establishments which prescribe, dispense, use or purchase therapeutic products for this purpose) are affected.

Volume discounts / Graduated discounts

Volume discounts and graduated discounts are as a rule permissible. It is essential that the discount is indicated transparently in accordance with the OITTP.

Year-end discounts / Rebates

As soon as a rebate is granted, it must be recorded and itemised accordingly on the invoice (rebate awarded), and in the account books. The recipient is then obligated to pass it on in accordance with the Health Insurance Act / Health Insurance Ordinance. A statement of end-of-year discounts or a reference to the contractual basis under which end-of-year discounts are provided is not required on individual invoices issued throughout the year, as long as the rebate has not yet been awarded. In the spirit of transparency, a corresponding reference could be made (e.g. «End-of-year discounts are granted at year-end»).

Payment of transport costs

If not included in the standard price, any assumption of transport costs by the vendor (in particular in the case of direct sales) shall be viewed as a discount and must be indicated as such.

Affected individual and establishments

All individuals and establishments involved in the last stage of distribution (which excludes manufacturers or wholesalers to patients, or manufacturers to wholesalers) are subject to the provisions on transparency. The Federal Council may amend the Ordinance at a later date to apply transparency provisions to other levels of trade.