Life Sciences

Five Years of Switzerland's Revised Integrity, Transparency and Discounts Framework: Current Status and Emerging Enforcement Trends

BÄR & KARRER

Dr. Oliver M. Brupbacher
(*Partner, Basel*)
oliver.brupbacher@
baerkarrer.ch

Prof. Dr. Markus Schott
(*Partner, Zurich*)
markus.schott@
baerkarrer.ch

On January 1, 2020, the revised Swiss integrity, transparency and discounts (ITD) regime in the therapeutic products sector came into force. This included updates to the Therapeutic Products Act, the Federal Act on Health Insurance and the related Ordinance, plus the introduction of the Ordinance on Integrity and Transparency in Relation to Therapeutic Products. As we mark its fifth anniversary, this column examines the status of the Swiss ITD regime and the recent increase in enforcement activities.

The primary objective of the revision was to ensure that the prescription and supply of medical products remain uninfluenced by transfers of value (ToVs) granted to healthcare professionals (HCPs) and organizations (HCOs). The new legislation fosters integrity in treatment decisions, transparency regarding discounts, benefits for patients and insurers, as well as stricter criminal sanctions and enforcement measures.

To this end, persons who prescribe, dispense, use or purchase prescription medicines, along with organizations employing such individuals, are prohibited from claiming, accepting promises or receiving undue ToVs for themselves or on behalf of a third party. Simultaneously, it is forbidden to offer, promise or grant any undue ToVs to these individuals or organizations. The statute provides an exhaustive and very strictly limited list of ToVs that are not considered undue, notably including fair market value compensation for services rendered, sponsorships, and certain contributions for educational purposes. Additionally, ToVs that are fully passed on to the patient or their healthcare insurer are deemed to have no influence on treatment choices and are permitted.

Discounts and refunds granted on therapeutic products must be recorded on invoices and in the books of both selling and purchasing entities and disclosed to the Federal Office of Public Health (FOPH) upon request. This obligation applies only to the final stage of the supply chain and excludes certain low-risk therapeutic products.

HCPs must pass on financial benefits, such as discounts and refunds, to patients and healthcare insurers. Generally, agreements can be made to retain a portion of discounts (less than 50%), provided they are used exclusively and demonstrably to improve treatment quality. Such agreements must be reported without delay to the FOPH and disclosed upon request.

Violations of the prohibition on undue ToVs qualify as misdemeanors, punishable by custodial sentences of up to three years or monetary penalties. Violations of the transparency requirements related to discounts and refunds are considered contraventions and can lead to a fine. The FOPH is responsible for enforcement.

While transparency obligations generally apply to all therapeutic products (i.e., medicinal products and medical devices), integrity provisions currently apply only to prescription medicinal products and HCPs/HCOs. Although the legislator plans to revise the integrity regime to include certain medical devices (with consultation planned for this year), Switzerland does not currently regulate ToVs for such therapeutic products and non-HCPs/non-HCOs specifically. Importantly, the general anti-bribery provisions of the Swiss Penal Code still apply to auxiliaries in a principal-agent relationship, such as HCPs and HCOs procuring products on behalf of patients. Additionally, industry and medical profession (self-)regulation in Switzerland imposes limitations on ToVs that are sometimes broader and stricter than the statutory provisions for therapeutic products.

While enforcement of the revised ITD regime in the Swiss therapeutic products sector has generally been slow (not helped by COVID-19 pandemic which absorbed significant resources at the FOPH), the FOPH introduced a new whistleblowing platform in February 2025. This platform allows private individuals, particularly patients at medical practices or hospitals, pharmacy customers, and employees of pharmaceutical companies, wholesalers and pharmacies, to report concrete and substantiated suspicions of breaches of integrity and transparency provisions, as well as the obligation to pass on benefits, anonymously if desired.

In essence, this appears an opportune moment for actors in the Swiss therapeutic products sector to re-assess their ITD standards and processes to prepare for potentially increased enforcement activities by the FOPH. As the current regulation still leaves several questions unanswered and contains various exemptions and vague legal terms, seeking legal advice in specific cases is advisable.

In the Firm

• Leading the Way in Life Sciences and Healthcare Law

Bär & Karrer has a broad and leading life sciences and healthcare practice with 14 partners and 15 associates many of whom have significant industry experience, including as in-house counsel in pharma companies. The practice is expanding and covers all relevant topics, including:

- Regulatory
- IP (patents)
- Licensing and Contracting
- R&D
- M&A
- Litigation and arbitration, including patent disputes
- Internal investigations and crisis management

Our leadership in this field is reflected by our strong client base. Bär & Karrer is renowned for advising leading Swiss and international life sciences, biotech and medtech companies, public and private institutions, and international healthcare groups, such as hospitals and care homes on a range of industry-specific Swiss law matters, including large transactions, regulatory work, drug distribution and marketing, as well as various agreements, litigation and investigation.

• Accolades

Bär & Karrer and its partners are consistently ranked as a top-tier firm in life sciences and healthcare by leading legal directories like Chambers and Legal 500. We were awarded "Impact Deal of the Year" at the LMG Life Sciences Awards EMEA in 2022 and 2023 for our role in the USD 11.7 billion sale of Vifor Pharma to CSL Limited. Furthermore, Bär & Karrer received recognition as the "Healthcare & Life Science Law Firm of the Year" at the 2023 Legalcommunity Awards.

Brandschenkestrasse 90, 8002 Zurich
www.baerkarrer.ch