

Healthcare compliance: integrity and transparency

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The sale of medicines differs from the sale of most other goods because the person who decides on the purchase is often not the person who pays for it. The doctor prescribes, the patient takes the medicine and an insurer or a public health system pays. This structure creates a risk that financial incentives offered to the prescriber influence decisions to the detriment of patients and payers. All developed health systems therefore regulate the relationship between the industry and health professionals more strictly than ordinary commercial relationships. In Switzerland, the relevant rules are found in the Therapeutic Products Act, in its implementing ordinances and in the codes of the industry associations.¹

The revision of the Therapeutic Products Act that entered into force on 1 January 2020 reformulated the integrity rules. Article 55 TPA prohibits persons who prescribe, dispense, use or purchase prescription medicines, and the organisations that employ them, from soliciting or accepting undue advantages. It also prohibits offering or granting such advantages to them. Advantages of modest value that are relevant to medical or pharmaceutical practice are permitted, as are support for research, teaching and further training under certain conditions and compensation for equivalent services. Article 56 TPA requires that price reductions and rebates be disclosed in the supporting documents and in the accounts. The Ordinance on Integrity and Transparency in the Therapeutic Products Sector (VITH) specifies these rules, and the Federal Office of Public Health has been responsible for enforcing them since 2020.²

The industry adopted its own rules earlier. The Pharma Code of scienceindustries regulates the promotion of medicines to professionals, while the Pharma Cooperation Code regulates cooperation with health professionals and healthcare organisations. Since 2016 the companies that have signed the Pharma Cooperation Code have published the payments they make to individual doctors and institutions, unless the individual

objects to publication. The Swiss rules follow the Disclosure Code of the European Federation of Pharmaceutical Industries and Associations (EFPIA), which was adopted in 2013 and integrated into the EFPIA Code of Practice in 2019. The disclosure covers fees for services, sponsoring of congress attendance and donations to institutions. The data are published annually on the websites of the companies and, in Switzerland, on a central platform.³

In the United States, the corresponding rules are much more stringent and are backed by heavy sanctions. The Anti-Kickback Statute makes it a criminal offence to offer or pay remuneration intended to induce the prescription of products reimbursed by federal healthcare programmes. A claim tainted by such a kickback is considered a false claim under the False Claims Act, which allows private whistleblowers to bring actions on behalf of the government and to receive a share of the recovery. The Physician Payments Sunshine Act, part of the Affordable Care Act of 2010, requires manufacturers to report payments to doctors and teaching hospitals, which the Centers for Medicare & Medicaid Services publish in the Open Payments database. The Basel groups' American subsidiaries operate under these rules, which have significantly influenced the design of the global programmes.⁴

The practical result is that interactions with health professionals have become a highly formalised process. Consulting contracts with doctors require a documented need, a selection based on expertise and fees at fair market value. Speaker events must have a scientific purpose and take place in appropriate venues. Sponsorship of congress participation must be transparent and is often channelled through the organising society. Patient support programmes and market research are subject to their own rules. Many groups have introduced central systems for approving and recording such interactions, which allow them to produce the disclosure reports and to document compliance with the different national rules. This administrative apparatus is itself a source of employment in Basel, because the global platforms are often managed from the headquarters.⁵

1 Notes

1. Federal Act on Medicinal Products and Medical Devices of 15 December 2000 (Therapeutic Products Act, TPA/HMG, SR 812.21). To be verified. ↩
2. Articles 55 and 56 TPA in the version in force since 1 January 2020; Ordinance of 10 April 2019 on Integrity and Transparency in the Therapeutic Products Sector (VITH, SR 812.214.31). On the

enforcement responsibility of the Federal Office of Public Health, see its guidance on integrity and transparency. To be verified. ↩

3. Pharma Cooperation Code (PKK) of scienceindustries, adopted 2013, first disclosure in 2016 for the reporting year 2015; EFPIA Code of Practice (consolidated 2019, as amended). On the Swiss central disclosure platform, see the information of scienceindustries. To be verified. ↩
4. Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); False Claims Act, 31 U.S.C. §§ 3729–3733 (qui tam provisions in § 3730); Physician Payments Sunshine Act, section 6002 of the Patient Protection and Affordable Care Act of 2010, 42 U.S.C. § 1320a-7h. To be verified. ↩
5. On the internal processes of pharmaceutical companies for interactions with health professionals, see the codes of conduct and the policies on professional practices published by Roche and Novartis on their websites. To be verified. ↩

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