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Switzerland
Life Sciences

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This country-specific Q&A provides an overview of life sciences laws and regulations applicable in Switzerland.

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Switzerland: Life Sciences

1. Please briefly summarize your country's legislative framework for medicinal products (including biologicals), medical devices, food, and food supplements

According to Swiss nomenclature, the term therapeutic products covers medicinal products as well as medical devices.

- Medicinal products are products of chemical or biological origin which are intended or claimed to have a medicinal effect on the human organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and disabilities. They include prescription as well as over-the-counter products.
- Medical devices are products, including instruments, apparatus, equipment, in vitro diagnostics, software, implants, reagents, materials and other goods or substances, that are intended or claimed to have a medical use and whose principal effect is not obtained with a medicinal product.

Therapeutic products in Switzerland are mainly governed by the Therapeutic Products Act (TPA) and the related ordinances, including the Medicinal Products Licensing Ordinance (MPLO), the Ordinance on Medicinal Products (OMP), the Ordinance on the Requirements of Marketing Authorization of Medicinal Products (OMAMP), the Ordinance on the Simplified Marketing Authorization Procedures, the Ordinance on Advertising of Medicinal Products (OMPA), the Ordinance on Medical Devices (MedDO), the Ordinance on In Vitro Diagnostic Medical Devices (IvDO; both the MedDO and the IvDO are largely modelled after the Regulation (EU) 2017/745 on medical devices [EU-MDR] and the Regulation (EU) 2017/746 on in vitro diagnostic medical devices [EU-IVDR])), the Ordinance on Integrity and Transparency in the Therapeutic Products Sector (TPITO). Switzerland's medical reimbursement of therapeutic products is governed by the Federal Health Insurance Act (HIA) and the related Ordinance (HIO). Depending on the circumstances, sector-specific regulations may apply, in particular in the fields of transplantation (Transplantation Act [TransPA] and related ordinances) and reproductive medicine (Reproductive Medicines Act and related ordinances). Certain raw materials for medicinal products are also subject to Swiss chemicals law. For clinical trials with therapeutic products see Question 7 below.

Foodstuffs (food and food supplements) are defined as all substances or products that are intended, or may reasonably be expected, to be consumed by humans in a processed, partly processed or unprocessed state.

Foodstuffs are mainly governed by the Federal Act on Foodstuffs and Utility Articles (FSA) and the related ordinances, including the Ordinance on Foodstuffs and Utility Articles (FSO), the Food Additives Ordinance (FAO), the Novel Foods Ordinance (NovFO), the Ordinance on Genetically Modified Foodstuffs, the Ordinance on Food of Plant Origin, Mushrooms and Table Salt (FPO-O), the Ordinance on the Addition of Vitamins, Minerals and Other Substances to Foods, the Ordinance on Foods for Persons with Special Nutritional Needs, the Ordinance on the Maximum Levels of Contamination, and the Ordinance on Information about Foods. Certain raw materials for foodstuffs may also be subject to the Swiss chemicals and biocides regulation.

2. With regards to medicinal products and medical devices, how is the regulatory process structured in your jurisdiction from R&D through market approval until post-marketing vigilance, and what rules does it follow? Please briefly describe.

At the R&D stage, the regulatory process may be distinct for research involving microorganisms and research involving humans. The research with microorganisms may involve activities involving genetically modified, alien, or pathogenic organisms that require containment in closed systems and fall under the Ordinance on Handling Organisms in Contained Systems (ContainO). Before starting any activity with organisms in a contained system, a detailed risk determination and a risk classification assessment must be carried out by a project leader to determine the safety level, the required safety measures and the notification and authorisation procedures. If research with microorganisms involves human biological samples, the HRA may also apply. Another important prerequisite for developing marketable products in the life sciences industries is research involving humans. In human research, there are two types of research projects. With regards to the regulatory framework for clinical trials see below in Question 7. The second type of research involving human subjects is

called "other (non-clinical) human research project" and falls additionally under the Ordinance on Human Research except for Clinical Trials.

An authorisation to place medicinal products on the Swiss market requires an application (Article 11 TPA) and a detailed examination by the Swiss Agency for Therapeutic Products (Swissmedic), the national authorisation and supervisory authority for drugs and medical products in Switzerland. The applicant must hold a mandatory licence, which is issued by Swissmedic for an unlimited period of time and under the condition of possible periodic inspections (Articles 5, 18, 28 and 34 TPA). Depending on the characteristics and the application of the medicinal product in question, different authorization procedures may apply. However, the ordinary procedure applies for first authorizations of new active pharmaceutical ingredients (APIs) and major deviations (Article 9 para. 1, Articles 11 et seq. TPA; see Question 21 below for other authorization procedures for medicinal products). The period of validity for a marketing authorisation for medical products in Switzerland is five years. The authorisation is subject to subsequent renewal upon application (Article 16 para. 2, Article 16b para. 1 TPA). Swissmedic has the right to review the authorisation, adapt it to changed circumstances or revoke it at any time (Article 16c TPA). Medical devices do not require an authorisation by a public authority but instead a certificate of conformity prior to being placed on the Swiss market. The conformity assessment procedure is based on Articles 52 and 54 and Annexes IX-XI of the EU-MDR (Articles 21 et seq. MedDO; Articles 17 et seq. IvDO). The certificate of conformity is valid for a maximum of five years and may be extended following a re-assessment (Article 26 MedDO). A designated body may suspend, revoke, or restrict the certificate, if there is a suspicion that the requirements are not fulfilled (Article 27 MedDO).

With regards to post-marketing vigilance see below in Question 4.

3. What is the regulatory process for food supplements, from first notification to the competent authorities until post-marketing vigilance in your country, and what regulations are applicable here? Please briefly describe.

Food supplements sold in Switzerland do not require an authorization from the cantonal or federal authorities. Nonetheless, in application of the principle of self-control, anyone who places food supplements on the market in Switzerland must ensure that the statutory requirements are complied with, in particular with respect to safety, hygiene and protection of consumers from deception (Articles 1, 7, 10, 15 and 26 FSA; Articles 8 et seq. and 45 et seq. FSO). Official inspection does not imply an exemption from the obligation to carry out self-supervision (Article 26 FSA).

For certain foodstuffs, however, there are either positive lists (e.g., the exhaustive list of permissible vitamins and minerals in Annex 1 of the Food Additives Ordinance (FAO)), negative lists (e.g., the list of impermissible plants or parts or preparations thereof in Annex 1 of the Ordinance on Food of Plant Origin, Mushrooms and Table Salt (FPO-O)) or prior authorization requirements (e.g., for novel foods; Article 15 et seq. FAO and the Novel Foods Ordinance (NovFO)).

4. What are the ongoing obligations in your country after a marketing authorization for medicinal products has been obtained or a conformity assessment been carried out for medical devices?

Marketing authorisation applicants for medicinal products as well as medical device manufacturers must have a post-market surveillance system (pharmacovigilance and materiovigilance plans, respectively) in place (Article 11 para. 2 lit a no 5 TPA; Article 56 MedDO; Article 49 IvDO).

Marketing authorisation holders for medicinal products with an API or a biosimilar must periodically and automatically file periodic safety update reports (PSURs) with Swissmedic on the safety and risk-benefit ratio for four years after authorisation (Article 60 OMP). Depending on the classification of a medical device, its manufacturer has similar trend report, periodic summary report and PSUR obligations to the designated body involved in the conformity assessment (Articles 59 et seq. MedDO; Articles 52 et seq. IvDO).

As for incident notification requirements, manufacturers of medicinal products, distributors of ready-to-use medicinal products and health care professionals (HCPs) must notify Swissmedic of adverse events, adverse drug reactions and quality defects. Such notifications are voluntary for consumers, patients, their organisations, and interested third parties (Article 59 TPA). Similarly, anyone placing medical devices on the Swiss market as a manufacturer must report to Swissmedic all serious incidents that occur, as well as field safety corrective actions that are undertaken in Switzerland (Article 66 MedDO; Article 59 IvDO). In response, Swissmedic may

take all administrative measures it considers necessary, including publishing recommendations and prohibiting the distribution and dispensing of therapeutic products, and ordering recalls (Article 66 TPA).

5. Which are the competent national authorities having the regulatory oversight over medicinal products, medical devices, food, and food supplements and what are their respective responsibilities?

In the sector of Swiss healthcare, the duties and responsibilities are divided among the federal, cantonal and municipal authorities. The Federal Office of Public Health (FOPH), as a part of the Federal Department of Home Affairs (FDHA), is responsible for public health in Switzerland. The cantonal authorities carry out enforcement tasks that are either assigned to them by the TPA or that are not expressly assigned to the federal government (Articles 69 et seq. and 82 et seq. TPA).

The authorization and supervision of therapeutic products lies within the responsibility of Swissmedic. Swissmedic, as a federal public law institution, is autonomous with respect to its organization and management.

The enforcement of food and food supplements regulation is decentralized and carried out by the cantons, unless the federal government, in particular the Federal Food Safety and Veterinary Office (FSVO), is responsible (Article 47 para. 1 and Articles 38 et seq. FSA).

6. Please briefly describe the procedure of challenging regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food supplements.

Administrative decisions of regulatory bodies are usually issued in the form of a ruling. These rulings can be challenged in administrative procedures or administrative court proceedings. Depending on whether a federal or a cantonal regulatory body has issued the decision, the appropriate legal action must be taken. Decisions issued by a federal authority can be appealed to the Federal Administrative Court (FAC). The FAC's decision may be subject to further appeal to the Federal Supreme Court (FSC). Regulatory bodies can also issue administrative and criminal sanctions in which criminal procedure rules may apply.

7. Please briefly describe the legal framework and the relevant regulatory procedure (e.g., application process, requirements, approval, denial) that applies in your jurisdiction to clinical trials for medicinal products and medical devices.

The key Acts regulating clinical trials in Switzerland are the TPA, the HRA, the Human Research Ordinance (HRO), the Clinical Trials Ordinance (ClinO) and the Ordinance on Clinical Trials with Medical Devices (ClinO-MD). To conduct clinical trials with therapeutic products a previous authorisation from Swissmedic (Article 54 para. 1 TPA) and the competent ethics committee (Articles 24 et seq. ClinO and Articles 9 et seq. ClinO-MD) is required. For clinical trials regarding medicinal products, Swissmedic examines whether the Good Manufacturing Practice (GMP) and safety requirements are met (Article 54 para. 4 lit a TPA). If a clinical trial with medical devices is to be conducted, the assessment includes the conformity of the products with the safety requirements (Article 54 para. 4 lit b, Article 45 paras 1 and 3 TPA).

The conduct of a clinical trial must be in line with the rules of good clinical practice. Regarding medicinal products, these rules are defined in the ICH Guideline on Good Clinical Practice of 9 November 2016 and the WMA Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects (Article 5 para. 1 ClinO; Article 3 ClinO-MD). In the context of medical devices, the applicable rules on good clinical practice were incorporated into Swiss legislation by way of reference to Article 72 and Annex XV Chapters I and III of the EU-MDR as well as in EN ISO 14155.

The application to the ethics committee in the canton, in whose territory the study is conducted, must be submitted by the investigator (Articles 24 et seq. ClinO; Articles 10 et seq. ClinO-MD). The responsible committee will then issue a decision and inform Swissmedic in case an authorisation by Swissmedic is necessary. The application to Swissmedic must be submitted by the sponsor and Swissmedic will issue a decision.

For appeals against Swissmedic rulings, see above 6.

8. Is there a public database for clinical trials in your country, and what are the rules for publication?

Authorized clinical trials must be recorded in a public registry (Article 56 para. 1 HRA).

Medicinal Products

Sponsors of clinical trials with medicinal products must register the data defined in Annex 5 number 1 ClinO in either a primary register recognized by the World Health Organization (WHO) or the registry of the US National Library of Medicine (Article 64 para. 1 ClinO). Furthermore, the data must be registered in the supplementary Swiss federal (from March 2025: cantonal) database (Article 64 para. 2 ClinO). This provision is implemented through the cross-cantonal application submission platform known as Business Administration System for Ethics Committees (BASEC). In principle, the relevant data must be registered before the clinical trial is conducted (Article 65 para. 1 ClinO; Article 64 para. 4 revClinO, applicable from 1 March 2025).

Clinical trials that are being conducted in Switzerland are published in the Swiss National Clinical Trials Portal (SNCTP, Article 67 ClinO). The data originates from (i) the cross-cantonal application submission platform BASEC and (ii) the international study database ICTRP (WHO database comprising 17 worldwide primary registers). The data listed in Annex 5 number 2.1 to 2.14 revClinO will be made automatically accessible to the public at the latest within six months from the grant date of the trial authorization (Article 64 para. 5 revClinO), including a brief description of the clinical trial, the site(s) where the clinical trial is conducted, the criteria for the participation in the clinical trial, the disease category and the health condition investigated, as well as an indication of whether the clinical trial includes rare diseases.

Clinical trials authorized by an ethics committee are also published on the Registry of All Projects in Switzerland (RAPS) of swissethics, the umbrella organization of the cantonal ethic committees.

Sponsors of clinical trials must in principle register a summary of the results of the clinical trial in the respective trial registry (Article 64 para. 1 ClinO, Article 65a para. 1 revClinO), as well as a lay summary in the cantonal database within a year from completion or discontinuation of the trial (Article 65a para. 2 revClinO). Further, the marketing authorization holder of a medicinal product for human use containing a new active substance must publish the results of clinical trials conducted for its development within three months of the marketing authorization being granted, in the form of a report. However, if the licensing authority of a country with comparable medicinal product supervision has already made this report on the results of clinical trials publicly accessible, the marketing authorization holder may also refer to it (Article 71 OMP).

Medical Devices

Sponsors of clinical trials with medical devices are subject to analogous registration obligations (Article 41 ClinO-MD).

Public access to the results of clinical trials with medical devices must be ensured by the sponsor by publication in one of the registries listed in Article 64 para. 1 ClinO (Article 42 ClinO-MD).

9. Please briefly summarize the rules that must be observed in your jurisdiction when using data from clinical trials?

Health data is classified as personal data which is subject to special protection. The HRA governs the further use and disclosure of health data falling within its scope (Article 32 et seq. and 41 et seq. HRA). Generally, the disclosure of health data is permissible both within an organization and to third parties, depending on the nature of the data (genetic or non-genetic health-related personal data), its intended use (research or other purposes), the level of individual identification (coded, uncoded, or anonymized), and the extent of informed consent.

Under the HRA and its implementing provisions (Article 43 HRA; Article 5 HRO), individuals storing biological material or health-related personal data for research purposes must implement appropriate technical and organizational measures to prevent unauthorized use and adhere to specified operational and professional requirements.

Since 2016, the Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks has complemented the Declaration of Helsinki.

10. Are there any trends and/or legislative proposals in your country on digitizing the process of conducting clinical trials (e.g., digitalization of the application process, decentralization of clinical trials)?

Swiss law already contains possibilities for integrating new technologies, which are especially relevant in the context of decentralized trials. However, determining the permissibility of decentralized clinical trials and hybrid decentralized clinical trials within the existing Swiss legal

framework necessitates an evaluation and case-by-case assessment of their feasibility.

For example, using electronic informed consent is currently allowed in principle, but a handwritten signature is still required, unless the trial participant can provide a qualified electronic signature that meets the legal requirements of the Federal law on electronic signatures.

11. What are your country's legal requirements for the authorization of manufacturing plants for medicinal products, medical devices, food, and food supplements? Please briefly describe.

Medicinal Products

According to Article 5 para. 1 lit a TPA, the manufacture of medicinal products in Switzerland is subject to a mandatory license by Swissmedic. The license is issued if the necessary technical and operational conditions have been fulfilled and an appropriate system of quality assurance exists (Article 6 TPA; Article 3 et seq. MPLO). The license is issued for an indefinite period, whereby Swissmedic performs periodic inspections and may revoke licenses if the requirements are no longer met.

Medicinal Devices

In Switzerland, manufacturers of medical devices are not obliged to meet licensing requirements. However, if a manufacturer is not domiciled in Switzerland, their devices may only be placed on the market if the manufacturer has appointed an authorized representative in Switzerland. The authorized representative is responsible for the formal and safety-related aspects and is registered with Swissmedic (Articles 51 and 55 MedDO; Articles 44 and 48 IvDO; Article 11 EU-MDR/ EU-IVDR).

Food Supplements

Manufacturers of food supplements generally do not require a license. However, anyone who handles foodstuffs (i.e. anyone who manufactures, imports, exports, processes, treats, stores, transports, labels, advertises, distributes or sells foodstuffs) must report their activities to the competent cantonal authority (Article 11 para. 2 FSA; Article 20 FSO). Important changes in the business that could have an impact on food safety and the closure of the business must also be reported.

12. Please briefly describe the typical process of distributing medicinal products, medical devices, and food supplements in your country, encompassing, if applicable, the wholesale distribution of products.

Medicinal Products

The distribution of medicinal products typically involves wholesalers who purchase the medicinal products directly from manufacturers or importers. These wholesalers then distribute the products to pharmacies, hospitals, and other healthcare facilities. Any person engaged in the wholesale trade of medicinal products must have a license (Article 28 para. 1 TPA). The license is issued following an inspection by Swissmedic, if the necessary technical and operational conditions are fulfilled and an appropriate system of quality assurance exists (Article 28 para. 2 and 4 TPA; Article 11 et seq. MPLO). Furthermore, a license by Swissmedic is mandatory for the professional import of ready-to-use medicinal products intended for distribution or dispensing (Article 18 para. 1 lit a TPA).

Swissmedic categorizes medicinal products into four dispensing categories. These categories determine who is authorized to dispense, prescribe and use the medicinal product (Articles 24 et seq. TPA):

- category A – medicinal products that may be dispensed on a one-time basis on a physician's prescription (Article 41 OMP);
- category B – medicinal products that require a prescription and can be obtained several times, whereby medicinal products on list B+ can also be dispensed without a prescription (Article 42 OMP);
- category D – medicinal products that may be dispensed without a prescription, but after specialist advice (Article 43 OMP); and
- category E – medicinal products that may be dispensed without a prescription and without specialist advice (Article 44 OMP).

Any person dispensing medicinal products must have a cantonal license (Article 30 para. 1 TPA). Mail-order trade in medicinal products is prohibited in principle (Article 27 para. 1 TPA). However, in the cases specified in Article 27 para. 2 TPA, a cantonal permit may be issued for this purpose.

Medicinal Devices

Medicinal devices are typically distributed by the Swiss manufacturer or their wholesalers, or from importers. Where the manufacturer of a device is not domiciled in Switzerland, the device may only be placed on the market

if the manufacturer designates an authorized representative domiciled in Switzerland by means of a written mandate (Article 51 para. 1 MedDO; Article 44 para. 1 IvDO). The manufacturers/wholesalers/importers supply the devices to healthcare facilities such as hospitals, clinics, and specialized medical equipment suppliers. Neither the wholesale nor the dispensing of medical devices require a license. However, manufacturers or their authorized representatives and importers must register with Swissmedic within three months of placing a device on the market for the first time (Article 55 MedDO; Article 48 IvDO). Medical Devices are supplied in accordance with their intended purpose and the information provided by the manufacturer (Article 68 MedDO; Article 61 para. 1 IvDO). Special provisions apply to the supply of certain in vitro diagnostic medical devices (Article 61 para. 2 and 3 IvDO).

Food Supplements

Food supplements are typically distributed through importers/wholesalers, who purchase them from manufacturers and supply them to retailers such as pharmacies, health food stores, supermarkets, and online platforms. The wholesale or distribution of food supplements is generally not subject to authorization. However, anyone who handles foodstuffs (i.e. anyone who manufactures, imports, exports, processes, treats, stores, transports, labels, advertises, distributes or sells foodstuffs) must report their activities to the competent cantonal enforcement authority (Article 11 para. 2 FSA; Article 20 FSO). Important changes in the business that could have an impact on food safety, as well as the closure of the business must also be reported.

13. Please briefly describe the pricing and reimbursement rules, if any, for medicinal products, medical devices, and food supplements in your jurisdiction?

Medicinal Products

According to Swiss law, the prices of medicinal products are regulated only with respect to reimbursement by the mandatory health insurance. For medicinal products not covered by said insurance, manufacturers, wholesalers, and retailers generally have pricing freedom. Regulations governing price determination are primarily outlined in the Health Insurance Act (HIA), the Health Insurance Ordinance (HIO), and the Ordinance on Benefits under Mandatory Health Insurance (OBHI).

Ready-to-use medicinal products qualify for reimbursement upon being listed on the Specialties List (SL). Medicinal products compounded in pharmacies are eligible for reimbursement if their active pharmaceutical ingredients (API) are listed in the List of Medicines with Tariff (LMT). The SL specifies both the ex-factory price and the public price, which represents the maximum amount (inclusive of VAT) insurers must reimburse in ambulatory settings. Health care service providers are prohibited from charging higher prices for medicinal products (so-called tariff protection, Article 44 HIA).

The FOPH determines the inclusion of a medicinal product on the Specialties List (SL) following consultation with the Federal Drugs Commission (EAK), except for certain cases such as generics, new galenic forms, or alternative package sizes of already listed medicinal products (Article 31 OBHI). An expedited procedure is available for products for which Swissmedic has approved an accelerated marketing authorization procedure (Article 31a OBHI). Inclusion on the SL is contingent upon meeting criteria of efficacy, suitability, and cost-effectiveness (Article 32 para. 1 HIA). Prices undergo review every three years (Article 65d HIO), with additional assessments occurring upon patent expiration and for newly authorized indications (Articles 65e et seq. HIO).

Price determination for medicinal products listed in the SL by the FOPH is based on two main criteria: (i) a therapeutic cross comparison, which evaluates the efficacy of the medicinal product compared to others used for the same indication (Article 65b^{bis} HIO); and (ii) an international price comparison with the prices of the same product in certain other European countries (cf. Article 65b^{quater} HIO; Articles 34a^{bis}-34c OBHI).

Generally, reimbursement is contingent upon the use of listed medicinal products for approved indications as authorized by Swissmedic and within approved quantities. Off-label uses can be reimbursed on a case-by-case basis according to the conditions outlined in Articles 71a-d HIO.

Medicinal Devices

The List of Items and Tools (LIT) defines the categories of devices eligible for reimbursement under the mandatory health insurance (Article 52 para. 1 lit a number 3 HIA). Unlike the SL, the LIT does not establish ex-factory and public prices but solely sets the maximum reimbursement amount. The tariff protection stipulated in Article 44 HIA does not apply to medicinal devices. Therefore, higher prices may be charged, with the patient (or a facultative private insurance) paying the difference. Specific regulations govern the process for seeking inclusion on the LIT (cf. Articles 21 et seq. OBHI). The

FDHA decides on the listing following consultation with the Federal Commission for Analyses, Instruments, and Tools (FCAIT). The criteria of efficacy, suitability, and cost-effectiveness equally apply to medical devices (Article 32 HIA).

Food Supplements

In Switzerland, the pricing for food supplements is not regulated (apart from general limitations based on competition law).

Reimbursement for food supplements under compulsory health insurance is not provided.

14. What legislative framework applies to the advertising for medicinal products, medical devices, and food supplements in your country?

Medicinal Products

Advertising of medicinal products is regulated by Articles 31 et seq. TPA and the OMPA.

- By way of an overview, advertising to the general public is prohibited for (i) prescription-only medicinal products, (ii) narcotic or psychotropic substances, (iii) products that are frequently the object of abuse or that lead to an addiction or dependence, and (iv) products that, due to their composition and intended use, should not be used without a physician's intervention for the necessary diagnosis, prescription or treatment.
- Any advertising of medicinal products must not:
  - be misleading or contrary to public order and morality,
  - encourage an excessive, abusive or inappropriate use of medicinal products,
  - promote medicinal products that may not be placed on the market.
- Restrictions set out in the TPA and OMPA apply only to product advertising. By contrast, mere information and company image advertising must only comply with general laws, such as the Federal Act Against Unfair Competition (UCA).

Medical Devices

Article 51 TPA and Article 69 of the MedDO regulate the advertising for medical devices. According to Article 69 MedDO, advertising of medical devices must:

- only contain statements that correspond to the product information,
- not include misleading statements, particularly concerning the intended purpose, safety and performance of a device,
- not target the general public if the respective devices are intended solely for use by healthcare professionals.

Food Supplements

Advertising of food supplements is governed by Article 18 of the FSA, Articles 12 and 36 et seq. of the FSO, the Swiss FDHA Ordinance on Food Supplements, (OFS), and the Swiss FDHA Ordinance on Food Information (FIO).

According to Article 18 FSA, advertising of foodstuffs must not be misleading to consumers. The law prohibits any presentation, labelling, packaging, and advertising that is capable of deceiving consumers as to the manufacture, composition, condition, method of production, storage life, country of production, origin of the raw materials or components, specific effects, or special value of the product.

Like EU law, Swiss law provides for a positive list of admitted health claims which must be observed in advertising of food supplements. To a large extent, permitted health claims correspond to those authorized in the EU.

15. What laws apply to patents and trademarks for medicinal products, medical devices, and food supplements in your country?

Patents

The majority of patents for medicinal products, medical devices, and food supplements for Switzerland are granted under the European Patent Convention (EPC) in a harmonized procedure before the European Patent Office.

Alternatively, Swiss law also allows for a patent grant procedure before the Swiss Federal Institute of Intellectual Property (IPI) governed by the Federal Act on Patents for Inventions (PatA) and the Ordinance on Patents for Inventions (PatO). Exclusions from subject-matter patentability under the PatA are largely congruent with the exclusions provided in the EPC, including the exclusion of therapeutic or diagnostic methods in human or veterinary medicine. However, unlike patents granted under the EPC, non-EPC patents are granted without a pre-screen for novelty and inventive step.

With respect to the pharmaceutical sector, the following aspects under Swiss law are noteworthy:

- Swiss patent laws include two exemptions for acts (i)

undertaken for research or experimental purposes to obtain knowledge about the subject-matter of the invention and its uses (so-called research exemption), as well as (ii) acts necessary for obtaining a marketing authorization for a medicinal product in Switzerland or in countries with equivalent medicinal product control (akin to the so-called "Bolar" exemption under US law).
- The maximum term of a patent in Switzerland is 20 years. Swiss patent laws do not allow for a patent term extension. However, holders of patents for active ingredients or a combination of active ingredients of medicinal products, or a manufacturing process or use of such ingredients or combinations, may apply for a supplementary protection certificate (SPC) if, at the time of application, a medicinal product containing the active ingredient or combination is authorized in Switzerland in accordance with Article 9 TPA, and further conditions for SPCs spelled out in patent laws are met.

Trademarks

In principle, trademarks for medicinal products, medical devices, and food supplements are regulated by the Swiss Federal Act on the Protection of Trade Marks and Indications of Source (TmPA) and the Swiss Ordinance on the Protection of Trade Marks and Indications of Source (TmPO).

Trademark registration in Switzerland is only granted if the requested trademark is not (i) part of the public domain, i.e. descriptive (e.g. "hydro cosmetique" für cosmetic products) (unless the respective sign has become established as a trademark through use), (ii), a shape constitutive of the nature of the protected goods themselves or that is technically necessary (iii) misleading (e.g., signs alluding to a health benefit not objectively present in a product, such as "med" or "pharm" for foods or food supplements), and (iv) contrary to public policy, morality, or applicable law (e.g., signs bearing prohibited health claims). By contrast, the IPI does not pre-screen for potential confusion with an existing trademark prior to registration.

Unlike names of medical devices and foods, the name of a medicinal product is an integral part of the medicinal product marketing authorization and must be approved by Swissmedic. Swissmedic can reject a medicinal product name that is contrary to public order or decency, could mislead or cause confusion (Article 9 para. 4 OMP). In its decision, Swissmedic is not bound by trademark law considerations.

16. Please briefly describe how patent infringements in relation to medicinal products and medical devices are addressed in your jurisdiction, including possible defense strategies and legal proceedings against patent infringements.

Patent infringement claims are generally addressed in civil proceedings. Although infringements can also be subject to criminal sanctions, criminal proceedings are of little relevance in practice.

Civil Proceedings

A patent holder, or an exclusive licensee (unless expressly excluded in the respective license agreement) can file civil law actions for patent infringement, including actions for injunction or remedy, damages, or declaratory judgements.

The validity or infringement of a patent is subject to the exclusive jurisdiction of the Federal Patent Court. Unlike courts in other jurisdictions, the Federal Patent Court is competent to rule on both the validity and infringement of a patent, and patentee and defendant need not bring claims and counterclaims before different courts. The Federal Patent Court's decisions in main proceedings on the merits are generally appealable to the Federal Court.

a) Actions for Injunction or Remedy

Persons threatened with or having their rights infringed can seek an injunction or remedy regarding the following acts:

- unlawful commercial use or imitation of a patented invention,
- refusal to disclose information about unlawfully manufactured or marketed products,
- unauthorized removal of patent marks,
- aiding or abetting any of such acts (Articles 66 and 72 PatA).

In addition to injunctions (which are a prime remedy under Swiss law), remedies can include product recalls, destruction of infringing products, publication of the court decision, or other appropriate measures.

b) Actions for Account Rendering and Damages

In addition to injunctions, plaintiffs may raise claims for damages (Article 73 PatA) and file actions for account and information rendering. Claims for damages can only be brought after the patent has been granted and in main proceedings, liability can however arise from the time the

infringing party first knew of the content of the patent application, or, if later, from the publication of the application.

c) Actions for Declaratory Judgement

Any person with a legitimate interest, including patent holders, can seek a declaratory judgment on the existence or non-existence of a circumstance, like the validity or infringement of a patent (Article 74 PatA).

Defense Strategies

Defendants can pursue several strategies, including initiating opposition proceedings before the IPI, challenging the patent's validity, claiming non-infringement, or filing counteractions for declaratory judgements, damages, and/or injunctions. In principle, infringers may also file counter claims for a compulsory license or invoke general civil law defenses, such as a lack of standing or forfeiture of rights.

a) Nullity Defense

In practice, the main avenue for defense is patent nullity, raised either as a formal (counter-)action or a defensive argument. Grounds for nullity include lack of patentability (lack of novelty, inventive step, or industrial application, exclusions or exceptions from subject-matter patentability), insufficient disclosure, the subject-matter of the patent going beyond the content of the patent application in the version that determined the filing date, or lack of entitlement (which can only be claimed by the person rightly entitled to the patent) (Articles 26 and 28 PatA).

b) Counteraction for Declaratory Judgements and Damages

Defendants can also seek declaratory judgments about the non-infringement or unenforceability, claim damages for unjustified infringement claims or request an injunction against the claimant.

c) General Civil Law Defenses

Defendants may also use general defenses like the lack of standing.

17. Does your jurisdiction provide for restrictions on the use of trademarks for medicinal products, medical devices, food, and food supplements?

In addition to general provisions under the UCA that safeguard fair competition and prohibit misleading or false claims, trademarks for medicinal products, medical devices, foods and food supplements must comply with the following requirements.

Medicinal Products

Medicinal product names require regulatory approval (Article 9 para. 4 MPO). Swissmedic provides guidance for naming medicinal products (*ZL000_00_043e_WL Guidance document Medicinal product name*). According to the guideline, a product name may be rejected for reasons such as potential confusion with other products, if it is considered misleading about the product's composition, quality, efficacy, risks, or safety, or promoting improper consumption.

For instance, the guideline states that medicinal products under the same core or "umbrella" brand must bear distinct name extensions (prefixes or suffixes) indicating differences (e.g., "expectorant" vs. "cough suppressant"). Name extensions must not be promotional (e.g., "super one daily", "boost", or "performance"), trivialize a therapeutic product by suggesting associations with food (e.g., "bio", "natura", "comfort", "instant", "express", or "active"), or misrepresent the product type (e.g., "med" should not be used to differentiate between prescription-only and non-prescription medicinal products, but it can be used to distinguish medicinal products from medical devices and cosmetics).

Medical Devices

Names for medical devices, while not requiring prior approval, must not be misleading and must comply with advertising restrictions and regulations regarding indications of origin (see Section 14 and Article 69 MedDO).

Foods and Food Supplements

For foods, including food supplements, any signs or elements suggesting properties for preventing, treating, or curing human diseases (such as "med" or "pharm") are prohibited. Likewise, signs that could mislead consumers about the food's origin, violate regulations on indications of origin and geographical indications, or contain prohibited health claims, are not allowed (Articles 12 and 38 FSO).

18. Please briefly describe the product liability regime for medicinal products, medical devices, and food supplements in your country.

Product liability for medicinal products, medical devices,

or food supplements can arise under contract, general torts, or the Federal Product Liability Act (PLA). Laws regarding product liability do not distinguish between, or provide product-specific regimes for, medicinal products, medical devices, foods, or food supplements.

Strict Product Liability

Strict product liability for defective medicinal products, medical devices, foods, or food supplements can be based on the PLA. Like the EU's Product Liability Directive 85/374/EEC, the PLA establishes strict liability for defective products that cannot be validly excluded in advance. The burden of proof for a product defect and its causality for damages generally lies with the claimant. The PLA only covers damage to life and limb (death and injury) and to property which is normally intended for private use and which is predominantly used privately by the injured party – damage to the product itself is not covered by the PLA. Importantly, unlike other European laws, the PLA does not provide for a cap on liability. Property damage of up to CHF 900 is the responsibility of the injured party.

Torts

Liability under general tort laws generally requires a negligent or intentional, unjustified breach of an absolute right (e.g., physical integrity or property) or a protective legal provision (e.g., product safety laws). In principle, and in contrast to damage claims under contract, the burden of proof for negligence or intentional misconduct generally lies with the claimant. Compared to contractual liability, general tort liability for agents is limited to subordinated auxiliaries who are subject to a principal's instructions. Where damages are caused by an auxiliary, the principal must exonerate itself by evidencing a lack of causality or the exercise of all due care required by the circumstances to prevent damage of this kind.

Neither under contract nor under torts can liability for gross negligence or intentional breaches be validly excluded in advance.

19. Please provide a short overview of risks of liability (criminal liability, serious administrative / civil liability) and enforcement practice with regards to medicinal products (including biologicals), medical devices, foods, and food supplements.

Criminal Liability

a) Medicinal Products and Medical Devices

The TPA provides for criminal liability relating to medicinal products and medical devices.

Inter alia, placing on the market, using, prescribing, importing, exporting, or engaging in foreign trade of medicinal products without the required marketing authorization or license is punishable with a custodial sentence of up to three years or a monetary penalty (if committed intentionally) or with a monetary penalty (if committed negligently) – unless the medicinal product is an over-the-counter product, in which case a violation is, in principle, subject to a fine of up to CHF 50'000 (Article 86 et seq. TPA). In severe cases, i.e., if the offender knows or must assume that the violation specifically endangers human health or achieves a high turnover or makes substantial profits through commercial activity violating criminal provisions, the prison sentence can be up to ten years.

The same criminal sanctions are faced by persons placing on the market, exporting, or using medical devices that do not satisfy the requirements of the TPA, or who use medical devices without fulfilling the necessary technical or operational requirements – unless the medical device belongs to class I according to the EU's Directive 93/42/EWG, in which case a violation is, in principle, subject to a fine of up to CHF 50'000 (Article 86 et seq. TPA).

Fines of up to CHF 50'000 can be imposed on persons willfully violating regulations regarding the advertising of medicinal products.

b) Foods and Food Supplements

Criminal liability related to foods and food supplements is regulated by the FSA. Inter alia, any person who intentionally manufactures, handles, stores, transports, or places on the market foods or food supplements in such a way that, when used normally or in a reasonably foreseeable manner, they present a risk to health, is liable to a custodial sentence of up to three years or a monetary penalty (Article 63 FSA). If the offender acts in a professional capacity or for personal gain, he or she is liable to a custodial sentence not exceeding five years or to a monetary penalty. Negligent offences are liable to a monetary penalty not exceeding 180 daily penalty units. Further criminal liability provisions regarding foods and food supplements inter alia apply to any person who willfully manufactures, handles, stores, transports, or places on the market foods (including food supplements) in breach of the requirements of the FSA or infringing the regulations regarding deceptive marketing of foods (Article 64 FSA).

Administrative Actions

Federal and cantonal authorities competent for enforcing product safety and marketing laws regarding medicinal products, medical devices, foods, and food supplements generally have the authority to take all appropriate measures necessary to remedy a breach of the relevant product safety and/or marketing laws.

Inter alia, enforcement authorities have the authority to inspect products and manufacturing sites. If necessary to protect the safety or health, competent public agencies may also prohibit the further placing on the market of a product, issue public warnings, order field corrective actions such as withdrawals or recalls, prohibit the importing or exporting of incompliant products, or confiscate and destroy or render unusable a product that poses an immediate and serious risk.

20. Does your jurisdiction provide for a specific legislative and regulatory framework for digital health applications (e.g., medical apps)? If yes, please briefly describe the relevant framework.

Digital health applications are not subject to specific regulation in Switzerland. They may classify as a medical device based on the TPA and the MedDO and if so, must comply with the legal requirements for medical devices, including regarding conformity assessments. The categorization of a health app as a medical device depends on its intended purpose to detect or treat diseases for individuals (Article 3 MedDO and Article 3 IvDO in conjunction with Article 2 no 1 EU-MDR and Article 2 no 1 EU-IVDR; Swissmedic Information Sheet on Medical Device Software (BW630_30_007e)). Hence, if an app is intended to fulfil a medical purpose that goes beyond mere data storage, archiving or communication, it is considered a medical device. For example, the Federal Administrative Court has qualified an app for monitoring the menstrual cycle as a medical device (BVGer C-669/2016, dated 17 September 2018). Conversely, applications designed for functions such as tracking fitness data or statistical analysis of clinical or epidemiological data do not fall under this classification.

In addition, the Federal Act on Data Protection (FADP), qualifies any personally identifiable data related to health as sensitive personal data (Article 5 lit c no 2 FADP). The standards for the processing of such data (including as to data security) are substantially higher. If processing of such data is envisaged to be established by means of consent, then, the consent must be given explicitly (Article 6 para. 7 lit a FADP).

In terms of strict product liability, it is controversial whether software-based medical devices should be considered products under Swiss law within the meaning of the PLA. Alternatively, liability may arise from general contract or tort law.

21. Does your jurisdiction provide for laws or certain legal measures to ensure the supply of medicinal products and medical devices, or are such rules envisaged in the future? If yes, please briefly describe those rules.

In Switzerland, the responsibility for ensuring the supply of medicines is shared between the private sector, the cantons, and the Swiss Confederation. Pursuant to the National Economic Supply Act (NESA), the private sector is primarily responsible for ensuring an adequate supply of medicines and other goods in Switzerland (Article 3 NESA). At the state level, medical care and the provision of medicines are the responsibility of the cantons. According to the Federal Constitution (Art. 102 Federal Constitution), the Swiss Confederation ensures the supply of essential goods and services only in the event of a threat of political-military conflict or war, or in the event of severe shortages that the economy cannot cope with on its own. It can do this either by supporting the supply (by drawing on compulsory reserves) or by managing the demand (prioritized distribution and allocation).

To ensure Switzerland's supply of essential human medicinal products, the Therapeutic Products Division of the National Economic Supply Organization operates a Notification Office. Human medicinal products authorized by the Swiss Agency for Therapeutic Products are deemed essential if they cannot be readily replaced or only replaced to a limited extent, and their absence would lead to severe health consequences over an extended period (Article 1 para. 1 and 2 Ordinance on the Notification Authority for Vital Medicinal Products for Human Use). A list of the current shortages of medicinal products and medicinal products subject to mandatory stockpiling can be found on the website of the Federal Office for National Economic Supply.

In respect of medical devices, in Switzerland, only blood bag systems for blood donations are subject to mandatory stockpiling (Federal Office for National Economic Supply, Report on stockpiling 2023, p. 47). The Swiss market often receives medical devices directly from foreign central warehouses. The introduction of compulsory stockpiling for all suppliers would have a significant impact on the market and logistics, potentially

jeopardising the security of supply of medical devices (Statement of the Federal Council on the interpellation 22.4379). In the event of supply disruptions, Swissmedic may grant temporary exemptions for the placing on the market of non-compliant medical devices if this serves public health or patient safety (Art. 22 MedDO).

22. Are there any specific compliance standards in your jurisdiction for the marketing of medicinal products and medical devices (e.g., codes of conducts of industry associations, etc.)? If yes, please give a brief overview of the relevant standards.

In Switzerland, the advertisement and promotion of medicinal products and medical devices are governed by a complex framework comprising statutes, ordinances, guidelines, and self-regulatory codes. This regulatory environment is characterized by stringent rules, including a prohibition on pre-approval promotion and direct-to-consumer (DTC) advertising of prescription medicines. The permissible scope of pharmaceutical advertising is tightly regulated, necessitating a deep understanding of both legal and regulatory intricacies, as well as substantial industry experience to navigate effectively. The key statutes regulating advertising and promotion of medicinal products are the TPA, the OMPA, the TPITO and the UCA. For medical devices, the key requirements can be found in the TPA, the MedDo and the UCA.

In addition, provisions in the Health Insurance Act HIA, the OHI and the Federal Act on the Medical Profession (MPA) may be of relevance. Swissmedic has issued several guidelines that further define the principles of pharmaceutical advertising.

The advertising of medicinal products in Switzerland is also subject to self-regulation through the Code of Conduct of the Pharmaceutical Industry in Switzerland (Pharma Code, PC) and the Code of Conduct of the Pharmaceutical Industry in Switzerland on Cooperation with Healthcare Professional Circles and Patient Organisations (Pharma Cooperation Code, PCC). These Codes are modeled after the practice codes established by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). They encompass both prescription and non-prescription medicines, including patented originals, generics, and biosimilars, though they do not extend to medical devices. These Codes have been embraced by various industry associations in Switzerland, such as scienceindustries, Interpharma, vips, ASSGP, and Intergenerika, thereby binding a significant portion of pharmaceutical companies in the country.

Moreover, healthcare professionals are guided by the Swiss Academy of Medical Sciences (SAMW) Guidelines on collaboration between the medical profession and industry. These guidelines, applicable to all members of the professional association of doctors and medical organizations, the Foederatio Medicorum Helveticorum (FMH), offer further insights into the advertising practices surrounding medicinal products.

For medical devices, the Swiss Medtech Code of Ethical Business Practice sets out the industry standards for member companies.

For both advertising of medicinal products and medical devices, advertising shall be deemed unlawful if it is misleading or contrary to public order and morality (Article 32 para. 1 lit a TPA). In addition, the UCA also provides relevant provisions on misleading advertising (see Section 14).

23. Please state 3-5 key decisions by courts or regulatory authorities that have been issued recently and that are relevant for the life sciences sector.

In its decision FSC 148 IV 39 of 28 October 2021, the FSC dealt with a case concerning a doctor's duty of care when prescribing pharmaceuticals. According to Article 26 para. 2 of the TPA, a pharmaceutical product may only be prescribed if the patient's state of health is known. The court found that the physician in this case had fulfilled his duty by first raising the issue of antibiotic allergy during the initial anamnesis and then requesting the patient's medical records, which showed that he had made sufficient efforts to inform the patient. The court ruled that the doctor was not obliged to personally obtain the records.

In the “Hip Prosthesis Case” (Bernese Superior Court, judgment ZK 20 399 of 26 November 2021), the court addressed the legitimacy of safety expectations and their fulfilment regarding a hip prosthesis implanted in 2007. The court considered events post-market placement and held that although there was a legitimate expectation of safety, it was not met. Regarding liability exclusion based on development risk, the court emphasized the need to distinguish this assessment from the defect evaluation. Due to the target group (individuals with health problems) and market circumstances (limited manufacturers), higher requirements were imposed, requiring the manufacturer to justify why in vivo testing was not

obligatory despite regulatory absence of clinical trial requirements.

In FAC (Federal Administrative Court) C-1256/2020 of 12 September 2022, Fondation Sympto-Therm appealed Swissmedic's ban on “sympto.org”, an online contraceptive application for natural contraception. The FAC stated, medical products must not endanger health and must fulfil intended benefits (Article 45 para. 1 TPA). As the distributor, the appellant must prove essential requirements compliance (Article 45 para. 2 TPA) and adherence to prescribed conformity assessments (Article 46 para. 1 TPA). The classification, based on risk assessment, categorizes “sympto.org” as a Class IIb device under EU Council Directive 93/42/EEC concerning medical devices (Medical Device Directive, MDD). Class IIb devices require certification from a conformity assessment body, unlike Class I devices with self-declaration by the manufacturer. The court rejected the appeal, ruling a conformity assessment body's certificate is necessary for placing “sympto.org” on the market.

In the FSC decision 2C_854/2021 of 29 November 2022, Swissmedic suspended the establishment license of two chemical-pharmaceutical manufacturers in the canton of Aargau. Chemicals were found in unlocked rooms due to damaged doors and windows during a search in March 2017. In addition, the search discovered Morphine bottles. The person responsible for substance handling faced convictions under the Chemicals Act (ChemA), the TPA, and the NarcA. The FSC upheld the lower courts' decision, maintaining the license suspension until a new responsible person is appointed (Article 39 para. 3 of MPLO). The judgment emphasizes the crucial role of the technically responsible person in Swiss pharmaceutical law, as their trustworthiness is a key requirement for most pharmaceutical licenses (particularly manufacturing, wholesale, import and export, foreign trade, brokerage, and agency licenses).

In its decision FSC 6B_1087/2021 of 22 May 2023, the Court ruled on the criminal liability of a doctor and a nurse who administered sodium pentobarbital to a person who was ready to die without first obtaining a psychiatric opinion. The Federal Supreme Court upheld the lower court's decision to acquit the doctor of wilful homicide. The lower court reasoned that the doctor had relied on the deceased's capacity to act rationally regarding her wish to die, even though no psychiatrist had been consulted to clarify the deceased's capacity. In particular, the doctor, who had many years of experience and routine as a doctor, particularly in the field of palliative medicine and assisted suicide, had consulted the deceased's medical records, which contained both somatic and psychiatric diagnoses. She had also held extensive discussions with the deceased and interviewed her carers. In addition, she had sought a second opinion and had credibly emphasised how important it had been to her that the deceased had known and weighed up her treatment options and had deliberately avoided further psychiatric treatment. The doctor could therefore not be accused of indifference to the integrity interests of third parties, which would lead to the conclusion that she had accepted the outcome of the death.

24. What, if any, are the key legal and regulatory trends in your jurisdiction with regards to the digitalization of the local healthcare system and with regards to the use of artificial intelligence in the life sciences sector? Please briefly describe.

The Swiss life sciences sector is experiencing a significant shift towards digitalization, particularly in healthcare. The Digital Transformation of the Healthcare System programme (DigiSanté), approved by the Federal Council in November 2023, aims to enhance efficiency, improve treatment quality, and prioritize patient safety (Press Release of the Federal Council of 23. November 2023). Additionally, the Federal Council is focusing on harnessing the potential of artificial intelligence (AI) while addressing associated risks. On 12 February 2025, it published its approach for regulating AI in Switzerland (Press Release of the Federal Council of 12 February 2024, including all reports). Unlike the EU, Switzerland has chosen not to adopt a comprehensive, horizontal AI Act but will instead implement sector-specific amendments. The FOPH is currently conducting a thorough assessment of AI's use and regulation in healthcare. Furthermore, the Federal Council has decided to ratify the Council of Europe's AI Convention and will propose the necessary amendments to Swiss law for parliamentary approval.

The ongoing revision of the Federal Law on Electronic Patient Records (EPDG) seeks to clarify responsibilities between the Confederation and cantons, centralize the technical infrastructure for the dossier on a federal level, and establish sustainable funding mechanisms to promote widespread adoption of electronic patient records (EPR) (Press Release of the Federal Council of 27 September 2024).

25. Please briefly highlight 3-5 key developments or trends in your jurisdiction with regards to the life sciences sector as you consider them relevant. This may include legislative proposals,

market activity, etc.

Switzerland and Canada signed a joint statement on science, technology, and innovation research. While research cooperation under the partnership is encouraged across disciplines, the themes of particular focus for 2023-2028 include: climate and sustainability; life sciences and health; quantum science and technology; and artificial intelligence. Canadian and Swiss universities have numerous partnerships, reinforcing the quality of education, research, and innovation in both countries (Press Release of the Federal Council of 14. April 2023).

Despite a challenging global environment, private funding in Switzerland held up well in 2023 (Swiss Biotech Report 2024). The Swiss Biotech Report 2024 also mentions that the life science sector had a record-breaking year in revenues in 2023, generating a revenue of CHF 7.3 billion.

Telemedicine is on the rise in the Swiss life sciences sector and is widely used by medical service providers (Cf. FMH, Fact Sheet: Telemedizin während der COVID-19-Pandemie, 12 July 2021).

Awareness of environmental, social and governance (ESG) issues is growing in the Swiss life sciences industry. Companies are increasingly considering sustainability, ethical practices and social responsibility in their operations, reflecting a wider trend towards corporate responsibility and accountability (Press Release of the Federal Council of 2 December 2022 and the Report of the Federal Council on Sustainable finance in Switzerland of 16 December 2022).

The HIA is currently being revised as part of the 'Cost Containment Package 2' (Dispatch on the amendment of the Federal Act on Health Insurance, Cost containment measures – package 2 of 7 September 2022, BBl 2022 2427). The focus is on establishing price models in the specialty list (proposed Article 52b HIA), their exemption from the Freedom of Information Act (proposed Article 52c HIA), and a proposal for the provisional reimbursement of medicinal products (proposed Article 52d HIA).

In early 2025, the FOPH launched a whistleblowing platform for reporting alleged violations of the provisions on integrity and transparency relating to (Articles 55 and 56 TPA and the TPITO), as well as the obligation to pass on benefits to payors (Article 56 para 3 HIA). This may indicate that the FOPH is aiming for a more active enforcement.

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