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Switzerland: Law & Practice

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SWITZERLAND

Law and Practice

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Bär & Karrer AG is a leading Swiss law firm with more than 200 lawyers in Zurich, Geneva, Lugano, Zug, Basel and St Moritz. The firm's core business is advising clients on innovative and complex transactions and representing them in litigation, arbitration and regulatory proceedings. Clients range from multinational corporations to private individuals in Switzerland and around the world.

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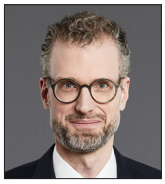

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Swiss healthcare regulation is spread over various statutes, ordinances and guidelines, including self-regulatory instruments such as best practice codes and references to international provisions. This makes navigating the life sciences landscape depend in large part on legal and regulatory expertise, as well as extensive practical industry experience.

The following key acts provide the principles of the national regulation of pharmaceuticals and medical devices, whereby the legal terminology in Switzerland refers to *"therapeutic products"* as the generic term encompassing both *"medicinal products"* (pharmaceuticals) and *"medical devices"*.

- Medicinal products – these are regulated by the Therapeutic Products Act (TPA), the Ordinance on Medicinal Products (OMP), the Medicinal Products Licensing Ordinance (MPLO), the Ordinance on the Requirements of Marketing Authorisation of Medicinal Products (OMAMP), the Ordinance on Medicinal Products Advertising (OMPA), and the Ordinance on Integrity and Transparency (OIT).
- Medical devices – these are regulated by the TPA, the Medical Devices Ordinance (*"MedDO"*) and the Ordinance on In Vitro Diagnostic Medical Devices (*"IvDO"*). Switzerland recently revised its medical devices law to align it with Regulation (EU) 2017/745 on medical devices (*"EU-MDR"*) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (*"EU-IVDR"*).

Duties and responsibilities for Swiss healthcare are divided among the federal, cantonal and municipal authorities, whereas this Global Practice Guide focuses on the federal level. As part of the Federal Department of Home Affairs (FDHA), the Federal Office of Public Health (FOPH) is responsible for public health in Switzerland. The Swiss Agency for Therapeutic Products (*"Swissmedic"*) is the Swiss authority responsible for the authorisation and supervision of therapeutic products. As a federal public law institution, Swissmedic is autonomous with regard to its organisation and management.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Administrative decisions of regulatory bodies are usually issued in the form of a ruling and can be challenged in administrative procedures or administrative court proceedings. The appropriate legal action depends on whether a federal or a cantonal regulatory body has issued the decision. If issued by a federal authority, decisions can be appealed to the Federal Administrative Court. Decisions of the Federal Administrative Court are subject to further appeal to the Federal Supreme Court.

These challenge procedures in general also apply to other regulated products. In certain areas, such as public procurement or social security, special provisions may apply. Besides, criminal procedure rules may apply to administrative and criminal sanctions issued by regulatory bodies.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Medicinal products are divided into four dispensing categories:

- category A – medicinal products that may be dispensed on a one-time basis on a physician's prescription (Article 41 of the 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 of the OMP);
- category D – medicinal products that may be dispensed without a prescription, but after specialist advice (Article 43 of the OMP); and
- category E – medicinal products that may be dispensed without a prescription and without specialist advice (Article 44 of the OMP).

The assignment to a particular category determines who is authorised to dispense, prescribe and use the medicinal product (Articles 24 et seq of the TPA). Non-prescription medicinal products, known as OTC medicinal products, are intended for self-medication. The classification into the different categories is made by Swissmedic (Article 23a of the TPA).

The TPA further contains special provisions for blood and blood products (Articles 34 et seq of the TPA) as well as for veterinary medicinal products (Articles 42 et seq of the TPA).

Medical devices are divided into different categories (classes I, IIa, IIb, III) – for which, different conformity assessment procedures apply. The classification follows the respective regulation in the EU-MDR (Article 16 paragraph 1 of the MedDO) and is based on the intended purpose and the associated risk. Certain medical devices may be classified as intended for use by healthcare professionals (HCPs) only.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials are mainly governed by the TPA, the Human Research Act (HRA), the Human Research Ordinance (HRO), the Clinical Trials Ordinance (*"ClinO"*) and the Ordinance on Clinical Trials with Medical Devices (*"ClinO-MD"*). In principle, clinical trials with therapeutic products require prior authorisation from Swissmedic (Article 54 paragraph 1 of the TPA) and the competent ethics committee (Articles 24 et seq of the ClinO and Articles 9 et seq of the ClinO-MD). Regarding medicinal products, Swissmedic examines whether the good manufacturing practice (GMP) and safety requirements are met (Article 54 paragraph 4 lit a of the TPA). Regarding medical devices, the assessment includes the conformity of the products with the safety requirements (Article 54 paragraph 4 lit b of the TPA and Article 45 paragraphs 1 and 3 of the TPA).

Clinical trials must be conducted in line with the rules of good clinical practice as set out, with regard to medicinal products, in the International Council for Harmonisation (ICH) Guideline on Good Clinical Practice of 9 November 2016 and the World Medical Association (WMA) Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects (Article 5 paragraph 1 of the ClinO and Article 3 of the ClinO-MD). With regard to 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.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

In order to secure authorisation for the conduct of a clinical trial, the investigator must submit an application to the ethics committee in the canton in whose territory the study is conducted (Articles 24 et seq of the ClinO and Articles 10 et seq of the ClinO-MD). This is followed by:

- acknowledgment of receipt/possible deficiencies' notification within seven days (medicinal products) or ten days (medical devices); and
- decision within 30 days (medicinal products) or 40 (medical devices) days and information of Swissmedic in the event that an authorisation by Swissmedic is necessary – in case of multi-centre clinical trials with medicinal products, the deadline is extended to 45 days.

The submission of the application to Swissmedic is made by the sponsor – following which:

- acknowledgement of receipt/possible deficiencies' notification within seven (medicinal products) or ten (medical devices) days respectively;
- as a general rule, decision within 30 days (medicinal products) or 45 days (medical devices); and
- in certain circumstances, Swissmedic must obtain the opinions from the Swiss Expert Committee for Biosafety (SECB), the Federal Office for the Environment (FOEN) or the FOPH before granting the authorisation.

2.3 Public Availability of the Conduct of a Clinical Trial

Sponsors of authorised clinical trials with medicinal products are subject to registration obligations (Articles 64–67 of the ClinO). Before conducting a clinical trial with medicinal products, the sponsor must enter the clinical trial either in a primary register recognised by the World Health Organization (WHO) or in the register of the National Library of Medicine of the United States of America as well as in the supplementary Swiss federal (from March 2025: cantonal) database using a Swiss national language.

The publicly accessible portal SNCTP (Swiss National Clinical Trials Portal) displays studies that are being conducted in Switzerland as soon as they have been approved by the cantonal ethics committee and released for publication by the researchers. The data originates from the cross-cantonal application submission platform BASEC (Business Administration System for Ethics Committees) and the international study database International Clinical Trials Registry Platform (ICTRP) (WHO database comprising 17 worldwide primary registers).

The data listed in Annex 5 number 2.1 to 2.14 of the revised ClinO (*"revClinO"*) will be made automatically accessible to the public at the latest within six months from the grant date of the trial authorisation (Article 64 paragraph 5 of the revClinO). This will include 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.

The Registry of All Projects in Switzerland (RAPS) of the Swiss Association of Research Ethics Committees (*"swissethics"*), the umbrella organisation of cantonal ethics committees, also publishes clinical trials that have been approved by an ethics committee.

Sponsors of clinical trials must, in principle, register a summary of the results of the clinical trial

in the respective trial registry (Article 64 paragraph 1 of the ClinO and Article 65a paragraph 1 of the revClinO), as well as a lay summary in the cantonal database within a year from completion or discontinuation of the trial (Article 65a paragraph 2 of the revClinO).

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

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

2.4 Restriction on Using Online Tools to Support Clinical Trials

Personal data held for research purposes must be protected by appropriate operational and organisational measures (cf Article 5 paragraph 1 of the HRO). The applicable ICH Guideline explicitly refers to the increasingly widespread use of electronic data handling and remote electronic trial data systems and outlines the additional requirements that must be met by the sponsor when using such tools (see Section 5.5.3 of the ICH Guideline for Good Clinical Practice E6(R2) of 9 November 2016). In addition, the use of online and electronic tools is subject to the limitations imposed by Swiss data protection law (in particular, the Federal Act on Data Protection (FADP) and the respective ordinance (Data Protection Ordinance, or DPO) – both of which have been completely revised as of 1 September 2023).

2.5 Use of Data Resulting From Clinical Trials

Health data is considered personal data requiring special protection. The HRA regulates in detail the further use and disclosure of health data that falls within its scope of application. In principle, the disclosure of health data is permissible both within an organisation and to third parties depending on the type of health data, the intended further use, and the assignability to a specific person. The data protection provisions do not apply to anonymised and pseudonymised data, insofar as the data subjects are no longer identifiable.

2.6 Databases Containing Personal or Sensitive Data

According to the HRA and its implementing provisions (Article 43 of the HRA and Article 5 of the HRO), anyone who stores biological material or health-related personal data for research purposes must take appropriate technical and organisational measures to prevent the unauthorised use thereof, and must fulfil certain operational and professional requirements.

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

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The decisive criterion for the classification of a product as a therapeutic product (ie, as a medicinal product or as a medical device) is the intended purpose of the product, which – considering all objective (nature of a product) and subjective (designation and promotion of a product) circumstances of the individual case –

must be the medical effect or application on the human organism.

As regards the distinction between medicinal products and medical devices, the decisive factor is not the material composition of the product, but whether its intended main effect in or on the human body is caused by pharmacological, immunological or metabolic means (medicinal products) or rather through mechanical, physical or physico-chemical effects (medical devices) (Article 4 paragraph 1 lit a and b of the TPA; BVGE C-2093/2006, E 3.5).

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

No specific requirements need to be met for the authorisation of biologic medicinal products (Article 2 paragraph 1 lit d of the Ordinance on the Simplified Marketing Authorisation Procedures (OSMA)). However, it is necessary that an equilateral black triangle standing on its apex is included in the package leaflet and information and is accompanied by the statement that this medicinal product is subject to additional monitoring (Article 14a paragraph 1 lit b of the OMAMP).

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The authorisation of medicinal products is initially valid for a period of five years and is subject to subsequent renewal upon application (Article 16 paragraph 2 of the TPA and Article 16b paragraph 1 of the TPA). If a medicinal product is not placed on the market within three years of the granting of the authorisation, or if it is no longer actually on the market during a period of three consecutive years after it has been placed on the market, Swissmedic may revoke the authorisation (Article 16a paragraph 1 lit a of the TPA). Medicinal products must fulfil their authorisation requirements for each production unit during the entire distribution period, whereby such requirements may only be modified, extended or restricted by a formal amendment procedure. Swissmedic may at any time review the authorisation, adapt it to changed circumstances, or revoke it (Article 16c of the TPA).

Regarding medical devices, the necessary certificates of conformity (see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices**) are valid for a maximum of five years and are extended following a re-assessment (Article 26 of the MedDO). If a designated body finds that a manufacturer no longer fulfils the requirements of the MedDO, it must set a deadline for correction and otherwise suspend, revoke or restrict the certificate (Article 27 of the MedDO).

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

An authorisation to place medicinal products on the Swiss market is granted based on a respective application (Article 11 of the TPA) and after a detailed examination by Swissmedic. Applicants must hold a manufacturing, import or wholesale licence issued by Swissmedic (see **4. Manufacturing of Pharmaceuticals and Medical Devices**), have a registered address, office or branch office in Switzerland, and must prove that the medicinal product is of high quality, safe and effective (Article 10 of the TPA).

Different authorisation procedures apply depending on the characteristics and the application of the medicinal product, as follows:

- ordinary procedures for first authorisations of new active pharmaceutical ingredients (APIs)

and major deviations (Article 9 paragraph 1 of the TPA and Articles 11 et seq of the TPA);
- compassionate use authorisations of medicinal products (in a simplified procedure, Articles 14 et seq of the TPA) for a limited period – ie, for life-threatening or debilitating diseases – if the medicinal products are compatible with the protection of health, their use is expected to have a major therapeutic benefit, and no authorised, alternative or equivalent medicinal product is available in Switzerland (Article 9a of the TPA and Articles 18 et seq of the OSMA);
- fast track procedures for first authorisations of new APIs and major deviations on request, available for promising therapies for the prevention or treatment of a severe, debilitating or life-threatening disease where there is a high therapeutic benefit and where the standard treatment is either unavailable or unsatisfactory (Article 7 of the OMP) (see **4.1 Fast Track Registration Routes**);
- simplified procedures for certain categories of medicinal products where this is compatible with the quality, safety and efficacy requirements and where there is no conflict with Swiss interests or international agreements – in particular, for generics (but not for biosimilars), orphan drugs, and certain categories of medicinal products authorised and/or used in foreign countries (Articles 14 et seq of the TPA and Articles 12 et seq of the OSMA); and
- the authorisation procedure on the basis of a notification – in particular, for certain complementary medicines without indications and other medicinal products with a low-risk potential (Article 15 of the TPA).

Changes to an authorisation that have no or only minimal consequences for the quality, safety or efficacy of a medicinal product must be communicated to Swissmedic within 12 months of their implementation (Article 21 of the OMP). Substantial variations require an additional marketing authorisation procedure. Marketing authorisations are in principle transferable upon approval of a respective application by Swissmedic.

Medical devices do not require an authorisation by a public authority prior to being placed on the Swiss market. Instead, they must bear a respective conformity (MD or CE) marking testifying the conformity of the device with the general safety and performance requirements.

The conformity assessment procedure is based on Articles 52 and 54 and Annexes IX-XI of the EU-MDR (Articles 21 et seq of the MedDO and Articles 17 et seq of the IvDO). Depending on the risk qualification of the medical device (see **1.3 Different Categories of Pharmaceuticals and Medical Devices**), the conformity is either to be declared by the manufacturer or by a private body certified to conduct conformity assessments.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

In principle, ready-to-use medicinal products may only be placed on the market after they have been authorised (Article 9 paragraph 1 of the TPA). However, there are a number of exceptions to this general rule.

- Medicinal products for which a review of the ordinary approval requirements (safe, effective, and of high quality) is not necessary or useful – eg, formula magistralis, officinalis and hospitalis products or products intended for clinical trials – may be placed on the market before they have been authorised (Article 9 paragraphs 2 et seq of the TPA).

- Orphan use – the use of medicinal products for the treatment of diseases that are so rare that there is hardly any incentive for a regular marketing authorisation that may be approved in Switzerland for a limited period in a simplified approval procedure is permissible (Article 9a of the TPA and Article 14 paragraph 1 lit f TPA).
- Temporary authorisation for use outside of clinical trials – Swissmedic may temporarily authorise the use of as yet unauthorised medicinal products intended for clinical trials outside the scope of a clinical trial (Article 9b paragraph 1 of the TPA and Articles 52 et seq of the MPLO).
- Temporary authorisation to bridge temporary unavailability – medicinal products may be temporarily or quantitatively authorised by Swissmedic to bridge the unavailability of an identical medicinal product in Switzerland, provided that they are authorised in another country with an equivalent medicinal product control and no essentially identical medicinal product is authorised and available in Switzerland (Article 9b paragraph 2 of the TPA).
- Off-label use (eg, the use of a (properly) authorised medicinal product for other indications) is generally permissible within the scope of Articles 3 and 26 of the TPA.
- Unlicensed use – an unlicensed medicinal product may be imported under the restrictive requirements of Article 20 paragraph 2 of the TPA and Articles 48 et seq of the MPLO.

Manufacturers of medical devices must generally carry out a conformity assessment before placing the device on the market (see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices**). However, in the interest of public health or patient safety or health, Swissmedic may – upon application – grant an authorisation even though the relevant conformity assessment procedure has not been carried out (Article 22 paragraph 1 of the MedDO and Article 18 paragraph 1 of the IvDO).

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Holders of marketing authorisations for medicinal products, as well as medical device manufacturers, must have a post-market surveillance system (ie, pharmacovigilance and materiovigilance plans) in place (Article 11 paragraph 2 lit a no 5 of the TPA, Article 56 of the MedDO, and Article 49 of the IvDO).

Holders of marketing authorisations for medicinal products with a new API or a biosimilar must automatically file periodic safety update reports (PSURs) with Swissmedic on the safety and risk-benefit ratio for four years after authorisation (Article 60 of the OMP). With its marketing authorisation, Swissmedic may impose additional conditions or obligations on the applicant, including further product evaluations (eg, in Phase IV clinical trials). 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 of the MedDO and Articles 52 et seq of the IvDO).

As for incident notification requirements, manufacturers of medicinal products, distributors of ready-to-use medicinal products, and HCPs must notify Swissmedic of adverse events, adverse drug reactions, and quality defects within 15 days in the event of serious adverse reactions and within 60 days in the event of non-serious reactions. Similarly, anyone placing medical devices on the Swiss market must

report to Swissmedic all serious incidents as well as all field safety corrective actions that are undertaken in Switzerland (Article 66 of the MedDO and Article 59 of the IvDO).

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

Authorities must, in principle, treat all data collected within the framework of the TPA and its implementing regulations as confidential, including all data communicated to the authorities in the context of a marketing authorisation application (Article 62 of the TPA). Granted marketing authorisations for medicinal products are published in the monthly *Swissmedic Journal*, together with essential information about the medicinal product. Swissmedic publishes an assessment report (SwissPAR) for all medicinal products with a new API – as well as for transplant products – for which a decision to approve or reject authorisation has been issued. The SwissPAR includes the evaluation results of the application for new authorisation or additional indication of a medicinal product, but not the applicant's commercial or manufacturing secrets or personal data.

Regarding medical devices, the conformity assessment procedures by Swiss or European assessment bodies are not accessible to third parties. The successful completion of a conformity assessment is made public together with the issuance of the declaration of conformity for the respective product (Article 90 lit f of the MedDO).

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

Medicinal Products

For the approval of a human medicinal product, a fast track procedure may be conducted. Unlike the standard procedure, the fast track procedure requires a previously approved request for the implementation of this procedure. Once such a request is received, Swissmedic will determine within 30 days whether the criteria for the fast track procedure are met (Article 7 of the OMP) (see Section 5.3 of Swissmedic guidance document *"Fast-Track Authorisation Procedure"*).

To qualify for a fast track authorisation procedure for a human medicinal product, the following criteria must be met.

- The medicinal product must provide promising prevention or treatment for a severe, disabling, or life-threatening disease (Article 7 lit a of the OMP).
- No currently authorised medicinal product exists for the condition, or existing treatments are unsatisfactory (Article 7 lit b of the OMP). Authorised medicinal products may be deemed unsatisfactory owing to various factors, including limited effectiveness, safety concerns, or the absence of an established standard treatment (see Section 5.1 of Swissmedic guidance document *"Fast-Track Authorisation Procedure"*).
- The new medicinal product must offer a significant improvement based on new clinical evidence. To provide a comparative basis, applicants must evaluate efficacy and safety data against existing authorised medicinal products available in Switzerland (see Section 5.1.c of Swissmedic guidance document *"Fast-Track Authorisation Procedure"*).

Medical Devices

For medical devices, Switzerland currently does not explicitly provide a fast track registration route, meaning there is no expedited conformity assessment procedure. However, in exceptional cases, Swissmedic may – upon a duly justified request – authorise the placing on the market and use of a specific medical device in the interest of public health or patient safety, even if the full conformity assessment has not been completed (eg, because the device has not undergone a complete conformity assessment procedure or the certificate for a device for the device has been declared invalid) or the language requirements are not met (Article 22 paragraph 1 of the MedDO and Article 18 paragraph 1 of the IvDO).

Article 22 paragraph 2 of the MedDO and Article 18 paragraph 2 of the IvDO permit the placing on the market and use of individual devices without valid certificates in an individual case if the following conditions are fulfilled:

- the device serves to avert life-threatening conditions or to prevent the permanent impairment of a bodily function or, in the case of in vitro diagnostic medical devices, is used to test samples with the aim of averting or treating life-threatening conditions or permanent impairments of a body function;
- no conforming device is available for this specific intended purpose;
- the device is used exclusively by HCPs either directly on an individual patient or in a laboratory setting for patient-specific sample testing;
- the HCP using the device or providing treatment has informed the patient about the non-conformity of the device and the associated risks; and
- the patient concerned has provided consent for the use of the device.

The decision to use a non-conforming device must be based on a thorough risk–benefit assessment for the specific case. A Swissmedic authorisation is not required for these cases (see Swissmedic information sheet *"Derogation MEP"*). However, the exemption is limited to the manufacturer or importer making the device available to the user for the first time. Devices authorised under these exceptional provisions must not be traded or made widely available on the market. To ensure compliance with Article 22 paragraph 2 of the MedDO and Article 18 paragraph of the IvDO, the responsible HCP must document compliance with the specified conditions and retain all relevant records for regulatory verification.

4.2 Regulatory Reliance

Medicinal Products

Swissmedic may expedite the approval process for certain medicinal products if they have already been authorised by internationally recognised regulatory bodies, such as the European Medicines Agency (EMA), the US Food and Drug Administration (FDA), or others.

Applicants seeking authorisation, an extension, or a variation for a medicinal product or procedure that has already been approved in a country with a comparable regulatory system may benefit from Swissmedic's reliance on foreign assessment results (Article 13 of the TPA) – provided the following conditions are met.

- The submitted foreign authorisation documents, including all variations, must be no older than five years and reflect the product's current approval status abroad (Article 16 lit a of the OMP). Minor deviations from the

foreign submission are permissible if they are justified (Article 16 paragraph 2 of the OMP). Such differences may, in particular, concern a different name for the medicinal product, a different pack size, or a different secondary packaging.
- The full and final assessment reports from the foreign regulatory agency must be available (Article 16 lit b of the OMP).
- The documentation must include all necessary information for Switzerland, particularly medicinal product information and labeling texts (Article 16 lit c of the OMP).
- The documentation must be provided in an official Swiss language or in English. If a translation is submitted, the applicant must confirm that it is correct (Article 16 lit d of the OMP).

Articles 16–20 of the OMP provide detailed provisions on the application of Article 13 of the TPA and Swissmedic has issued a respective guidance document on the procedure (*"Authorisation Human Medicial Product Under Art. 13 TPA"*). The current list of countries recognised by Swissmedic as having comparable regulatory oversight for human medicinal products (Article 16 paragraph 4 of the OMP) is available on the Swissmedic website. In practice, the Article 13 TPA procedure can significantly reduce approval timelines – saving several months compared to the standard process.

In addition, Article 14 of the TPA provides for certain simplified authorisation procedures, which may apply when a medicinal product has already been approved by international regulatory authorities (see Swissmedic guidance *"Authorisation in Accordance with Art. 14 paragraph 1 abis-quarter TPA"*), as follows.

- A medicinal product may qualify for simplified authorisation if its active substances have been used in an approved medicinal product for at least ten years in an EU or European Free Trade Agreement (EFTA) country and if it is comparable to a foreign-authorised product in terms of indication, dosage (strength and recommendation), and route of administration (Article 14 paragraph 1 lit abis and Article 14a paragraph 1 lit a in conjunction with Article 17a and 17b of the OSMA).
- Furthermore, a non-prescription medicinal product with a stated indication may qualify for simplified authorisation if it has been medically used for at least 30 years, including at least 15 years in EU or EFTA countries (Article 14 paragraph 1 lit ater of the TPA and Article 14a paragraph 1 lit b of the TPA, in conjunction with Article 17c of the OSMA).

Finally, Switzerland has entered into multiple mutual recognition agreements (MRAs) that allow for respective products to be placed on the Swiss market and within the territory of the contracting party with as few obstacles as possible. For medicinal products, Switzerland has signed MRAs under which each contracting party recognises the results of GMP inspections conducted by the competent inspectorates of the other party. Additionally, these agreements provide for the mutual acceptance of manufacturing authorisations issued by the respective regulatory authorities, thereby reducing the need for duplicate inspections and authorisations. A comprehensive list of all MRAs is available on the Swissmedic website.

Medical Devices

Regarding medical devices, Swiss law currently allows only a limited regulatory reliance. Following the expiration of the MRA between Switzerland and the EU, Switzerland unilaterally

recognises conformity certificates (CE markings) issued by recognised bodies in EU/European Economic Area (EEA) countries (Article 25 paragraph 4 of the MedDO and Article 21 paragraph 4 of the IvDO), provided additional requirements are met. These additional requirements include the appointment of an authorised representative in Switzerland, who is responsible for ensuring compliance with both formal and safety-related requirements and who must be registered with Swissmedic (Articles 51 and 55 of the MedDO and Articles 44 and 48 of the IvDO).

In terms of recent developments, in 2022, the two Swiss parliamentary chambers adopted a motion mandating the Swiss Federal Council to amend the current legislation so that medical devices conforming to non-European regulatory systems (including FDA-approved devices) can be placed on the market in Switzerland by way of unilateral recognition. The FOPH is currently examining how this motion can be implemented.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

The manufacture of medicinal products in Switzerland is subject to a mandatory licence (Article 5 paragraph 1 lit a of the TPA). The same applies to anyone withdrawing blood from humans for the purpose of transfusion or the manufacture of therapeutic products or for supply to a third party (Article 34 of thr TPA). The licence is issued if Swissmedic has successfully verified during an inspection that the necessary technical and operational conditions have been fulfilled and an appropriate system of quality assurance exists (Article 6 of the TPA and Articles 3 et seq of the MPLO). The licence is issued for an unlimited period of time, whereby Swissmedic performs periodic inspections and may revoke licences if the requirements are no longer fulfilled.

Manufacturers of medical devices are not subject to licensing requirements in Switzerland. However, if a manufacturer is not established within Switzerland, its devices may only be placed on the market if it has appointed an authorised representative in Switzerland who is responsible for the related formal and safety-related aspects and is registered with Swissmedic (Articles 51 and 55 of the MedDO, Articles 44 and 48 of the IvDO, Article 11of the EU-MDR/EU-IVDR).

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

Any person engaged in the wholesale trade of medicinal products must possess a licence (Article 28 paragraph 1 of the TPA). The licence is issued following an inspection by Swissmedic (Article 28 paragraph 2 of the TPA and Articles 11 et seq of the MPLO).

No licences are required for the wholesale (Article 4 paragraph 1 lit i of the MedDO and Article 4 paragraph 1 lit h of the IvDO) of medical devices. Foreign manufacturers, however, need to appoint an authorised representative domiciled in Switzerland (see **5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices**).

6.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

Importation and exportation of medicinal products and medical devices are mainly governed by the TPA, the MPLO, the MedDO and the Swiss customs legislation. At the point of entry, the responsibility for the application and enforcement of the respective regulations lies with the Federal Office for Customs and Border Security (FOCBS). The competent governmental authority for any subsequent market surveillance is Swissmedic. The FOCBS and Swissmedic co-operate closely in their joint areas of competence (cf Article 65 of the MPLO).

7.2 Importer of Record of Pharmaceuticals and Medical Devices

Any person that professionally imports medicinal products intended for distribution or dispensing must possess a licence issued by Swissmedic (Article 18 paragraph 1 lit a of the TPA) following an inspection confirming that the necessary technical and operational conditions have been fulfilled and that an appropriate system of quality assurance exists (Article 19 paragraph 1 of the TPA and Articles 11 et seq of the MPLO).

Importers of medical devices (Article 4 paragraph 1 lit h of the MedDO and Article 4 paragraph 1 lit g of the IvDO) are not subject to licensing requirements in Switzerland. However, if a manufacturer is not established within Switzerland, its devices may only be placed on the market if it has appointed an authorised representative in Switzerland that is responsible for the related formal and safety-related aspects and if the importer is registered with Swissmedic and is assigned a CHRN (Swiss Single Registration Number) (Article 55 of the MedDO and Article 48 of the IvDO) (see **5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices**).

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

In principle, only medicinal products that have been granted a marketing authorisation by Swissmedic can be imported into Switzerland (Article 9 of the TPA) and importation is subject to a specific licence (Article 18 paragraph 1 lit a of the TPA). Subject to certain exceptions – in particular, in connection with an official batch release from a foreign control authority belonging to the Official Control Authority Batch Release Network (OCABR) – anyone wishing to import immunological medicinal products or blood and blood products generally requires a special licence for each individual shipment (Article 44 of the MPLO). Under certain circumstances, ready-to-use medicinal products without a marketing authorisation in Switzerland may be imported in small amounts by persons for private use or by HCPs (cf Articles 48 and 49 of the MPLO).

While no licence for the import of medical devices is required (see **7.2 Importer of Record of Pharmaceuticals and Medical Devices**), medical devices must – prior to their placing on the Swiss market – undergo a conformity assessment to ensure that general safety and performance requirements are met (Articles 6 and 21 et seq of the MedDO and Articles 6 and 21 et

seq of the IvDO). Certifications of conformity (CE markings) issued by bodies from EU/EEA countries are unilaterally recognised in Switzerland (Article 25 paragraph 4 of the MedDO and Article 21 paragraph 4 of the IvDO).

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

Non-tariff restrictions are set forth in the Swiss customs tariff. The entries in the relevant Harmonised Tariff Schedule (HTS) line will determine which market surveillance authority is competent to examine and approve import. The product-related laws and implementing ordinances set out the restrictions in detail.

7.5 Trade Blocs and Free Trade Agreements

Switzerland is a member of the EFTA and is, among others, signatory to the free trade agreement with the EU of 1972 as well as to a network of currently 33 free trade agreements with 43 partners. The EU has unilaterally ceased the application of the MRA as regards medical devices. As a result, exportation of medical devices from Switzerland into the EU has become more burdensome. Negotiations are currently taking place between Switzerland and the USA on a free trade agreement concerning the pharmaceuticals sector, which is intended to facilitate market access for Swiss pharma companies.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Under Swiss law, prices of therapeutic products are controlled to the extent that they are reimbursed by the compulsory health insurance. With regard to therapeutic products not reimbursed by compulsory health insurance, manufacturers, wholesalers and retailers are, in principle, not restricted in their pricing.

Pharmaceuticals are reimbursed subject to a listing on the Specialties List (SL) where ready-to-use medicinal products are included. Medicinal products that are manufactured in a pharmacy are reimbursed if their APIs are included in the List of Medicines with Tariff (LMT). The requirements for price fixing are mainly contained in the HIA, the Health Insurance Ordinance (HIO), and the Ordinance on the Benefits under the Mandatory Health Insurance (OBHI). The SL determines the ex-factory price as well as the public price, which is the maximum amount (including VAT) that must be reimbursed by health insurers.

The FOPH decides on the inclusion of a medicinal product on the SL after consultation with the Federal Drugs Commission (*Eidgenössische Arzneimittelkommission*, or EAK), except in the case of certain medicinal products, such as generics and new galenic forms or package sizes of already-listed medicinal products (Article 31 paragraph 2 lit a of the OBHI). An accelerated procedure applies in the case of an accelerated market authorisation (Article 31a of the OBHI). The procedure is initiated by the market authorisation holder (Article 31 paragraph 1 lit a of the OBHI). Medicinal products can only be included in the SL if the criteria of efficacy, appropriateness and cost-effectiveness are met (Article 32 paragraph 1 of the HIA). The prices are reviewed every three years (Article 65d of the HIO) and additional reviews take place upon patent expiry and in the event of the authorisation of further indications.

The List of Items and Tools (LIT) determines which devices are covered by the compulsory health insurance. Unlike the SL, the LIT does not

fix the ex-factory and public price, but only sets the maximum reimbursement amount. In principle, higher prices may be charged and the difference is borne by the patient. There are specific provisions governing the application for inclusion on the LIT. The FDHA decides upon consultation of the Federal Commission for Analyses, Instruments and Tools (FCAIT) on the addition, change, or delisting (cf Articles 21 et seq of the OBHI). The criteria of efficacy, appropriateness and cost-effectiveness also apply to medical devices.

8.2 Price Levels of Pharmaceuticals or Medical Devices

When setting and reviewing the prices of the medicinal products included in the SL, the FOPH relies on the following comparisons:

a therapeutic comparison in which the effectiveness of the medicinal products is assessed in relation to other medicinal products used for the same indication (Article 65b paragraph 1 lit a of the HIO); and

a price comparison with the same medicinal product abroad (cf Article 34a of the OBHI and Article 34b of the OBHI). The two comparisons are given the same weight. The latter comparison is carried out according to the guidance of the EAK, taking into account foreign countries whose pharmaceuticals sector is economically comparable with that of Switzerland.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Under the compulsory health insurance, insurers must reimburse costs for prescribed medicinal products listed in the SL and the LMT at the maximum amount set out therein. The reimbursement may be restricted to specific indications, quantities or durations. Reimbursement is, in general, only granted for listed medicinal products under the condition that they are used in connection with indications approved by Swissmedic and within approved quantities. Exceptions from this general rule apply on a case-by-case basis subject to the conditions set out in Article 71a of the HIO. In addition, there is also room for reimbursement in individual cases of medicinal products not yet authorised, not yet included in the SL, or used outside their marketing authorisation (Articles 71b-d of the HIO).

Medical devices applied by the patient are reimbursed under the condition that they belong to a specific group of medical devices in the LIT, are prescribed by a physician or chiropractor, and are dispensed by an authorised provider. The reimbursement of listed medical devices may be restricted to specific medical indications, quantities or durations. Case law has not yet addressed the question of whether the provisions of Article 71a-d of the HIO are also applicable to medical devices by analogy.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Among the conditions for the inclusion of medicinal products on the SL are their efficacy, appropriateness and cost-effectiveness, and the existence of these conditions must be periodically reviewed (Article 32 of the HIA). Medicinal products that no longer meet these criteria are removed from the SL by the FOPH. The same applies to medical devices (to be) included in the LIT.

It is usually undisputed that an authorised medicinal product is effective and appropriate. In practice, the main focus is therefore on the criterion of cost-effectiveness, including the respective comparisons with other medicinal

products and markets (see **8.2 Price Levels of Pharmaceuticals or Medical Devices**).

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Although the main purpose of the prescribing and dispensing regulations is to safeguard patient welfare and safety in the dispensing and use of medicinal products by requiring that only HCPs with sufficient education, training and continuing education are involved (Articles 24–26 of the TPA), HCPs are required by their professional duties and corresponding provisions in their self-regulations to also observe the aspect of economic efficiency. Furthermore, the legal provisions on the advertising of medicinal products explicitly provide for the inadmissibility of advertising (including to HCPs) that may encourage the excessive use of medicinal products (cf Article 32 paragraph 1 lit b of the TPA). Lastly, the integrity provisions (cf the OIT and Article 55 of the TPA) prohibit the excessive prescribing of medicines.

In general, physicians may prescribe any authorised medicinal product for a given indication without regard to its price and they are not obliged to propose a more affordable (generic) alternative. That said, if the SL contains different medicinal products containing the same API, the cost share that must be borne by the patient may vary. Physicians must inform their patients accordingly. Equally, for medicinal products that are not included in the SL or that are used off-label or off-limitation, HCPs must inform the patients that the costs might not be reimbursed under the compulsory health insurance. According to Article 52a of the HIA, pharmacists are allowed – but not obliged – to substitute a prescribed original medicinal product listed on the SL with a generic unless there is an explicit request by the prescribing physician or chiropractor to dispense the original.

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