Chambers
AND PARTNERS

CHAMBERS GLOBAL PRACTICE GUIDES

Healthcare: Medical Devices 2023

Definitive global law guides offering
comparative analysis from top-ranked lawyers

Switzerland: Law and Practice
Oliver M. Brupbacher, Claudia Götz Staehelin
and Djamila Batache
Bär & Karrer AG

SWITZERLAND

Law and Practice

Contributed by:
Oliver M. Brupbacher, Claudia Götz Staehelin and Djamila Batache
Bär & Karrer AG

Contents

Bär & Karrer AG is a leading Swiss law firm with more than 200 lawyers in Zurich, Geneva, Lugano, Zug and Basel. Its core business is advising clients on innovative and complex transactions, and representing them in litigation, arbitration and regulatory proceedings. The firm's clients range from multinational corporations to private individuals in Switzerland and around the world. Bär & Karrer has been repeatedly recognised by the most important international legal ranking agencies.

Authors

Oliver M. Brupbacher is a partner at Bär & Karrer AG. He advises and represents national and multinational clients, particularly from the life sciences and healthcare sectors, in the areas of dispute resolution, regulatory and compliance, and data and digital. Oliver specialises in internal investigations, crisis management, large-scale and cross-border litigation and mutual legal assistance, as well as high-profile regulatory matters, data protection, information governance and cybersecurity. As a former senior litigation counsel, global product lawyer and head of global discovery at Novartis, Oliver combines deep expertise in his areas of practice with an intimate understanding of the industry and of clients' needs at all organisational levels.

Claudia Götz Staehelin is a partner at Bär & Karrer AG. Her practice focuses on complex investigation and litigation matters at the intersection of civil, criminal and regulatory proceedings. Claudia leads large-scale internal investigations, supports her clients in crisis management and advises them on all aspects of their compliance framework. She represents and advises her clients in domestic and cross-border litigation, in international judicial and administrative assistance matters and in internal and regulatory investigations led by Swiss and foreign authorities. One of her industry focuses is the healthcare & life sciences industry, where she advises clients on pharma regulatory and all compliance matters.

Djamila Batache is an attorney at law, and an associate in the life sciences and litigation team at Bär & Karrer. Prior to joining the team she wrote her PhD thesis on the liability implications of using AI medical devices, gaining extensive knowledge in the area of health and liability law, along with a strong technical understanding.

Bär & Karrer AG

Lange Gasse 47
4052 Basel
Switzerland

Tel: +41 58 261 50 50
Email: basel@baerkarrer.ch
Web: www.baerkarrer.ch

1. Applicable Product Safety Regulatory Regimes

1.1 Medical Devices

In Switzerland, the product safety regulation of therapeutic products (medicinal products and medical devices), consumer healthcare products and new products/technologies is spread over various statutes, ordinances and guidelines, and also includes international regimes.

Navigating the various product categories, their complex regulation and, on occasion, the subtle delimitation issues demands extensive practical industry experience as well as legal and regulatory expertise (see the rest of **1. Applicable Product Safety Regulatory Regimes** and **2. Commercialisation and Product Life Cycle** for further detail).

Medical Devices and Medical Instruments

According to Swiss nomenclature, 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 (Article 4 paragraph 1 lit b, Therapeutic Products Act (TPA)).

Product safety-related aspects of medical devices are mainly governed by the TPA, the Medical Devices Ordinance (MedDO), the Ordinance on In Vitro Diagnostic Medical Devices (IvDO), the Ordinance on Clinical Trials for Medical Devices (ClinO-MD), and (in parts) the Ordinance on Integrity and Transparency in the Therapeutic Products Sector (OIT). Depending on the circumstances, sector-specific regulations may apply, in particular in the fields of research, transplantation and reproductive medicine.

Personal Protective Equipment (PPE)

In line with EU law, PPE is defined as equipment, as well as interchangeable components and connection systems for such equipment, designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety (Article 1 paragraph 3, Ordinance on the Safety of Personal Protective Equipment (OPPE); Article 3(1), Regulation (EU) 2016/425 on personal protective equipment (EU-PPE Regulation)).

Depending on whether it is intended for medical use (see **1.5 Borderline Products** for further detail), PPE may qualify as a medical device and be subject to the respective regulation. To the extent it does not so qualify, its product safety-related aspects are governed by the OPPE,

which implements pertinent parts from the EU-PPE legislation, or by the utility articles regulation (see **1.2 Healthcare Products**) as well as the Product Safety Act and the related Ordinance (PSA, PSO; Article 1 paragraph 5, OPPE).

1.2 Healthcare Products

Cosmetics

Cosmetic products generally qualify as utility articles (Article 5 lit b, Federal Act on Foodstuffs and Utility Articles (FSA)) and are defined, as under Regulation (EU) 1223/2009 on cosmetic products, as substances or mixtures intended to be placed in contact with external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours (Article 53 paragraph 1, Ordinance on Foodstuffs and Utility Articles (FUAO)).

Product safety-related aspects of cosmetics are mainly governed by the FSA, the FUAO and the Cosmetics Ordinance (CosO) which, in its Appendix 1, contains an exemplary list of products qualifying as cosmetics. Certain raw materials for cosmetics may also be subject to the Swiss chemicals and biocides regulation.

Food and Nutrition Supplements

Foodstuffs are 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 (Article 4 paragraph 1, FSA).

Product safety-related aspects of foodstuffs and nutrition supplements are mainly governed by the FSA; the FUAO; 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 Contaminants (ContO); and the Ordinance on Information about Foods (FoodIO). Certain raw materials for foodstuffs and nutrition supplements may also be subject to the Swiss chemicals and biocides regulation.

Biocides

Biocidal products are active substances and preparations that are not plant protection products and are designed to deter, render harmless, destroy or otherwise control harmful organisms, or prevent damage from being caused by harmful organisms (Article 4 paragraph 1 lit d, Chemicals Act (ChemA); Article 2 paragraph 1 lit a, Ordinance on Biocidal Products (OBP)). Biocides can be roughly divided into four main groups: disinfectants, protectants, pesticides and other biocidal products (antifouling products, embalming and taxidermy fluids, etc).

The Swiss regulation of product safety-related aspects of biocides is technically equivalent to Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products, and is mainly contained in the ChemA, the Chemicals Ordinance (ChemO) and the OBP.

1.3 Medicines

Pharmaceuticals and Blood Products

According to Swiss nomenclature, medicinal products (pharmaceuticals) are products of chemical or biological origin which are intended or claim to have a medicinal effect on the human or animal organism, in particular in the diagno-

sis, prevention or treatment of diseases, injuries and disabilities. They include prescription as well as over-the-counter products. Blood and blood products are also considered medicinal products (Article 4 paragraph 1 lit a, TPA).

Product safety-related aspects of medicinal and blood products are mainly governed by the TPA, the Medicinal Products Licensing Ordinance (MPLO), the Ordinance on Medicinal Products (OMP), the Ordinance on the Requirements of Marketing Authorisation of Medicinal Products, the Ordinance on the Simplified Marketing Authorisation Procedures, the OIT, and the Ordinance on Advertising of Medicinal Products (OMPA).

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. Clinical trials with medicinal products are mainly governed by the TPA, the Human Research Act, the Human Research Ordinance and the Clinical Trials Ordinance (ClinO).

Psychedelics

The Swiss Narcotics Act (NarcA) distinguishes between narcotics and psychotropic substances. The former are defined as substances and preparations that cause dependence containing an effective concentration of morphine, cocaine or cannabis, and substances and preparations produced on their basis of or that have a similar effect; the latter are substances and preparations that cause dependence and that contain amphetamines, barbiturates, benzodiazepines or hallucinogens such as lysergide or mescaline or that have a similar effect to the same (Article 2 lit a and b, NarcA). Further provisions can be found in the Narcotics Control Ordinance (NCO), the Narcotics Addiction Ordinance, and the Narcotics Control Ordinance of the Federal Department of Home Affairs (FDHA).

Products Containing Cannabidiol (CBD)

CBD is an important cannabinoid that occurs in large quantities in the cannabis plant but that, unlike THC (tetrahydrocannabinol), does not produce a comparable psychoactive effect and, hence, is not subject to the NarcA.

Product safety-related aspects of CBD are governed by a number of different regulations, depending on the respective categorisation, which has to be undertaken on a case-by-case basis taking into account all relevant factors, including composition, intended use, dosage, etc. Whoever places the product on the market is required to provide information on the intended use – eg, as a medicinal product or medical device (see in particular TPA, MedDO), as a foodstuff, a cosmetic or utility article (see in particular FSA, FUAO, ContO, FoodIO), as a tobacco substitute (see Tobacco Ordinance), or as a chemical (see in particular ChemO).

1.4 Technologies and Digital Health

Mobile Health (mHealth), including Medical Apps, Wearables and Telemedicine

As defined by the WHO and eHealth Suisse, mHealth describes the technical requirements for the use of health data from portable medical devices and other wearables for the electronic patient record (EPR). mHealth is a component of eHealth, which covers all electronic means that are used in the health sector to improve processes and network those involved, including telemedicine.

mHealth devices that act directly in or on the human body, or that are used in vitro for the examination of specimens derived from the human body, are generally qualified as (in vitro diagnostic) medical devices. The same applies to software that is part of such an mHealth device. Standalone software (eg, medical apps) installed on devices that are not themselves medical devices, such as mobile phones, tablets and PCs, may – in line with European legal practice – qualify as a medical device if the manufacturer specifically intends the software to be used for a medical or diagnostic purpose, in particular for diagnosing, preventing, monitoring, treating or providing information on conditions, diseases, injuries or disabilities (Article 3 paragraph 1, MedDO; Article 3 paragraph 1, IvDO).

mHealth is not a defined legal category. To the extent an mHealth item is qualified as a medical device, the respective regulations apply (see **1.1 Medical Devices**). Otherwise, the PSA and PSO may apply.

Stem Cells

Research involving embryonal stem cells is regulated by the Stem Cell Research Act which, subject to strict conditions, allows for research purposes to obtain stem cells from surplus human embryos and to import embryonic stem cell lines from abroad. The use of stem cells, such as the injection of products based on stem cells, is subject to the TransPA and, under certain conditions, to the TPA, eg, if the stem cells are subject to substantial manipulation.

1.5 Borderline Products

Medical Devices and Medicinal Products

The intended use of a therapeutic product, taking into account the entire circumstances of the individual case, must be the medical effect or use on the human organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and disabilities (BGer 6B_979/2009). Such intended use can be objective (where, by its very nature, the product can be used exclusively for medicinal purposes) or subjective (due to the purpose a manufacturer or distributor gives to the product in connection with its designation and promotion, whereby the focus should not be on the promotion alone; BGer 2A.565/2000, E. 4b/cc; BGer 6B_600/2020 E. 5.2 et seq).

Drawing the line between medical devices and medicinal products can be difficult. The decisive factor is not a product's material composition but whether its intended main effect in or on the human body is caused by pharmacological, immunological or metabolic means, in which case the product qualifies as a medicinal product. By contrast, the typical main effects of a medical device are mechanical, physical or physico-chemical (BVGE C-2093/2006, E. 3.5).

PPE and Medical Devices

Equipment intended primarily for self-protection, and not for a medical effect or use on the human organism, is generally considered to constitute PPE that is governed by the OPPE, and not a medical device. Depending on its use, however, it is possible that the same PPE in parallel qualifies as a medical device and is in so far governed by the medical devices regulation.

Cosmetics, Therapeutic Products and Biocides

Utility articles, including cosmetics, and therapeutic products are mutually exclusive categories (Article 2 paragraph 4 lit d and Article 4 paragraph 3, FSA). There is no unregulated space between these two categories (BGer 6B_979/2009).

Substances or preparations that are intended to be ingested, inhaled, injected or implanted in the human body cannot be considered cosmetic products from the outset (Article 53 paragraph 2, FUAO). Where the distinction is less obvious, a product has to be categorised on the basis of an overall and objectified evaluation, considering its predominant purpose according to the perception of the market.

Products that have a primarily biocidal function are in principle subject to the OBP. Where biocidal materials or active substances are added to cosmetic products, such products are generally subject to cosmetics regulation as long as the biocidal function is only secondary to a primary cosmetic function (eg, added biocidal preservatives) or the biocidal function is inherent in the cosmetic function (Article 1a paragraph 3 lit a, OBP; Article 46, FUAO). When distinguishing therapeutic products from biocidal products, both the manufacturer's intended purpose as well as the impressions of consumers are to be taken into account (BVGer C-900/2007, E. 6.3.3).

Medicinal Products and Food

Medicinal products and foodstuffs are mutually exclusive categories. There is no unregulated space between these two categories (BGer 6B_979/2009).

The key circumstances for the purpose of distinction include product composition, pharmacological effects including adverse reactions (Article 7 paragraph 1, FSA) and the intended use as perceived by the average consumer. The impression that the average consumer has in terms of intended use depends on a variety of circumstances, including the presentation of the product, form of administration and distribution channels. From the perspective of intended use, the question to be asked with reference to the nature of the foodstuff is to what extent a product contributes to the development or maintenance of the human body. If a product also has curative properties, these need to be qualified; the more the primary purpose is nutrition, the more the product is a foodstuff (BGer 2A.565/2000 E. 4 b) cc)).

2. Commercialisation and Product Life Cycle

2.1 Design and Manufacture

Medical Devices and PPE

Any natural or juridical person who manufactures or fully refurbishes a medical device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trade mark in Switzerland is considered a manufacturer (Article 4 paragraph 1 lit f, MedDO; Article 4 paragraph 1 lit e, IvDO).

Manufacturers of medical devices do not require a prior licence from a public authority. Instead, they must guarantee that their devices, including as regards mHealth, meet the general safety and performance requirements set out in Annex I of the Regulation (EU) 2017/745 on medical devices (EU-MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (EU-IVDR) when they are placed on the market or are put into service in Switzerland, taking into account their intended purpose. If such requirements are specified by designated technical standards, common specifications or prescriptions of the pharmacopoeia, compliance with these requirements is presumed as long as the product conforms to those standards, specifications or regulations. Obligations regarding the quality and risk management systems are governed by Article 10 EU-MDR/EU-IVDR (Articles 6, 46, 50, MedDO; Articles 6, 39, 43, IvDO).

If the 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 formal and safety-related aspects (Article 51, MedDO; Article 44, IvDO; Article 11, EU-MDR/EU-IVDR).

If PPE qualifies as a medical device, its manufacture is governed by the respective regulation. Otherwise, when placing PPE on the market in Switzerland, manufacturers have to ensure that it has been designed and manufactured in accordance with the essential health and safety requirements in Annex II EU-PPE Regulation (Article 4 paragraph 1 lit a, OPPE).

Medicinal Products

Manufacturing means all stages in the manufacture of a medicinal product, from the acquisition of the precursors and the processing to the packaging, storage and delivery of the end products, including quality controls and batch releases (Article 4 paragraph 1 lit c, TPA).

The manufacture of medicinal products in Switzerland requires a prior licence issued by the Swiss Agency for Therapeutic Products (Swissmedic). Such a licence is generally granted if the applicant proves that the necessary technical and operational conditions are fulfilled, and that an appropriate system of quality assurance exists (Articles 5 et seq, TPA; Articles 3 et seq and Annex 1, MPLO).

Foodstuffs and Utility Articles (Including Cosmetics)

In application of the principle of self-control, Swiss manufacturers of foodstuffs and utility articles, including cosmetics, 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, 26, FSA; Articles 8 et seq and 45 et seq, FUAO; Article 3 paragraph 1, CosO).

Biocides

Manufacturers that place biocidal products on the market in Switzerland are responsible for ensuring that they do not endanger life or health. In particular, they shall assess and classify biocides according to their properties as well as packaging and labelling them in accordance with the type of hazard concerned, whereby they must obey certain specifications on test methods, Good Laboratory Practice (GLP), assessment and classification criteria, as well as packaging and labelling requirements (Article 5, ChemA).

Psychedelics and Products Containing CBD

The FOPH may issue exceptional licences for cultivating or manufacturing psychedelics, unless prohibited under an international agreement, and only for the purpose of scientific research, the development of medicinal products or restricted medical use (Article 8 paragraph 5, NarcA). If psychedelics serve as an active ingredient of an approved medical device, their cultivation is subject to an exceptional licence from the FOPH and their manufacturing is subject to a licence from Swissmedic (Article 8 paragraphs 6 and 7, NarcA).

The requirements for the manufacturing of CBD products depend on their respective categorisation and the applicable regulations (see **1.3 Medicines** for further details).

2.2 Corporate Social Responsibility, the Environment and Sustainability

Environment and Biosafety

In response to increasing concerns about environmental risks caused by pharmaceuticals, a

risk assessment is carried out before a marketing authorisation is granted for a new active pharmaceutical ingredient (API) (Article 81 paragraphs 2 and 3, OMP).

A number of regulations protect employees, the public and the environment against serious harm or damage resulting from major accidents in connection with the handling of genetically modified, pathogenic or alien organisms in contained systems, such as laboratories and production units (Ordinance on Handling Organisms in Contained Systems; Ordinance on Protection against Major Accidents; Ordinance on Protection of Employees from Dangerous Micro-organisms).

Corporate Social Responsibility (CSR)

The Swiss Confederation understands CSR to be a contribution to sustainable development, and it expects companies based or operating in Switzerland to take responsibility for all activities they perform here or abroad in accordance with internationally recognised CSR standards and guidelines.

Two amendments to the Code of Obligations (CO, Articles 964bis et seq) entered into force on 1 January 2022. Similar to Directive 2014/95/EU, they introduce transparency obligations on large Swiss companies to report on the risks of their business activities, and respective measures relating to the environment, social and employee matters, human rights and the fight against corruption. Furthermore, similar to Regulation (EU) 2017/821, they require companies with risks in the areas of child labour and so-called conflict minerals to comply with special and far-reaching due diligence obligations. The new requirements apply for the first time in the fiscal year 2023.

2.3 Advertising and Product Claims

Therapeutic Products and PPE

Generally, advertising aimed at healthcare professionals (HCPs) is allowed for medicinal products authorised for marketing in Switzerland and for medical devices. Such advertisements are limited, respectively, to the authorised indications and use of the medicinal product and the product information of the medical device (Article 5 paragraph 1, OMPA; Article 69 paragraph 1, MedDO; Article 62 paragraph 1, IvDO).

In contrast, advertising of therapeutic products aimed at the general public is restricted. Such advertising is prohibited for prescription medicinal products, for medicinal products that are often misused, that can lead to habituation or addiction, that contain narcotic or psychotropic substances, or that may not, on account of their composition and their intended use, be used without the intervention of a doctor for the necessary diagnosis, prescription or treatment, as well as for medicinal products that are reimbursed by health insurance companies (Article 32 paragraph 2, TPA; Article 65 paragraph 2 and Article 68 paragraph 1 lit d, Health Insurance Ordinance), whereas advertising for over-the-counter medicinal products is allowed with certain limitations (Article 31 paragraph 1 lit b, TPA; Articles 14 et seq, OMPA). Advertising for medical devices aimed at the general public is prohibited only for medical devices intended exclusively for use by professionals (Article 69 paragraph 3, MedDO; Article 62 paragraph 3, IvDO).

To prevent false expectations about the quality, efficacy, composition or safety of a therapeutic product, consumers are to be protected against misleading information (Article 1 paragraph 2 lit a, TPA). Swissmedic rejects an application for marketing authorisation of a medicinal product,

inter alia, if the product name or the design of the container or packaging material is contrary to public policy or morals, is misleading or is likely to cause confusion (Article 9 paragraph 4, OMP). Provisions to protect HCPs and consumers from misleading advertising of therapeutic products are contained in the OMPA (eg, Articles 5 and 22) and in Article 69 paragraph 2 of the MedDO and Article 62 paragraph 2 of the IvDO.

Apart from information and instruction obligations according to the OPPE and the EU-PPE Regulation, advertising and product claims for PPE that is not qualified as a medical device are governed by the Federal Act on Unfair Competition, which is generally applicable to advertising in Switzerland.

Foodstuffs and Utility Articles (Including Cosmetics)

Foodstuffs, consumer articles and cosmetics must ensure the protection of consumers against deception, imitation and confusion. The presentation, labelling and packaging of such products must correspond to the facts and may not mislead consumers (Articles 18 et seq, FSA; BGE 144 II 386 E. 4.2.2).

Prohibited are, in particular, information on effects or properties of foodstuffs which, according to the current state of scientific knowledge, they do not possess or which are not sufficiently scientifically proven; claims that foodstuffs contain properties of preventing, treating or curing a human disease or suggesting that such properties exist; as well as claims of any kind that give foodstuffs the appearance of medicinal products (Article 12, FUAO). Health claims relating to foodstuffs are permitted if they are explicitly provided for in Annexes 13 and 14 of the FoodIO or are approved by the Federal Food Safety and Veterinary Office (FSVO).

With respect to cosmetics in particular, advertising claims are only permitted if they fulfil six common criteria, which are also contained in Regulation (EU) 655/2013, namely, legal compliance, truthfulness, evidential support, honesty, fairness and informed decision-making (Article 10 and Annex 6, CosO). Finally, references to curative, soothing or preventative effects are prohibited, except for scientifically substantiated cavity-preventing and other preventative properties of dental and oral care products (Article 47 paragraphs 3 and 4, FUAO).

Biocides

Only authorised biocides may be advertised, and no misleading information shall be given in respect of the risks to human or animal health, the environment or their efficacy. In any case, claims such as “low-risk biocidal product”, “non-toxic”, “harmless”, “natural”, “environmentally friendly” or “animal friendly” must not be made (Article 38 paragraph 1 and Article 50, OBP).

2.4 Marketing and Sales

Medicinal Products and Biocides

Medicinal and biocidal products may in principle only be placed on the market in Switzerland if they are authorised. Unless an exemption (Article 9 paragraph 2, TPA) or a case of early and managed access applies, such as in connection with compassionate use (Article 9b paragraph 1, TPA) or off-label and unlicensed use (Article 20, TPA), medicinal products can obtain a marketing authorisation from Swissmedic for Switzerland if the applicants prove that the product is of high quality, safe and effective, if they hold a licence to manufacture (see **2.1 Design and Manufacture**), import or conduct wholesale trade, and have a registered address or office in Switzerland (Article 10, TPA). Pre-marketing, (serious) adverse events and suspected unexpected serious adverse reactions in clinical trials

of medicinal products have to be documented and reported to Swissmedic and the responsible ethics committee, depending on their severity (Articles 39 et seq, ClinO).

Unless an exemption applies (Article 3 paragraph 3 lit b and c, OBP), biocides may only be placed on the market, or be used professionally or commercially, in Switzerland if they are authorised by the Notification Authority for Chemicals of the Federal Office for the Environment (FOEN), the Federal Office of Public Health (FOPH) and the State Secretariat for Economic Affairs (SECO), and are appropriately labelled (Article 3 paragraph 1, OBP). Biocides authorised in the EU may be authorised in Switzerland by means of recognition procedures (Article 3 paragraph 3 lit a, OBP). Certain biocides may not be authorised for use by the general public (Article 11d, OBP).

Medical Devices and PPE

In contrast to medicinal products and biocides, and unless an exemption applies, there is no prior authorisation by a public authority for medical devices (including mHealth) and PPE in Switzerland. Instead, anyone who is domiciled in Switzerland and places a device on the market here, or puts a device into service without placing it on the market, must undertake a prior assessment of the conformity of that device with the general safety and performance requirements. The conformity assessment procedure is based on Articles 52 and 54/48 and Annexes IX–XI of the EU-MDR/EU-IVDR (Articles 21 et seq, MedDO; Articles 17 et seq, IvDO). If successful, the manufacturer issues, and continuously updates, a declaration of conformity and thereby assumes responsibility for ensuring the compliance of the device (Article 29, MedDO; Article 25, IvDO; Annex IV, EU-MDR/EU-IVDR). Devices placed on the Swiss market, or made available in Switzerland, must bear a respective conformity (MD or CE) marking (Article 13 and Annex 5, MedDO; Article 12 and Annex 4, IvDO; Annex V, EU-MDR/EU-IVDR). Pre-marketing, (serious) adverse events in clinical trials of medical devices have to be documented and reported to Swissmedic and the responsible ethics committee, depending on their severity (Articles 32 et seq, ClinO-MD).

The regulation of PPE that is not qualified as a medical device equally follows the principle of self-control by the persons placing the product on the market. They must be able to prove, if necessary with the assistance of a conformity assessment body, that their products comply with the essential health and safety requirements (declaration of conformity; Article 3 paragraph 2, OPPE; Articles 14, 15 and 19 and Annexes I–IX, EU-PPE Regulation) or, where no such requirements have been specified, that they have been manufactured according to the current state of knowledge and technology (Article 3 paragraph 2, PSA). There is no requirement in Switzerland to attach a CE marking (Article 3 paragraph 3, OPPE).

Foodstuffs and Utility Products (Including Cosmetics)

Foodstuffs and utility articles, including cosmetic products, sold in Switzerland do not require an authorisation from the cantonal or federal authorities. Nonetheless, in application of the principle of self-control, anyone who places such products 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, FUAO; Article 3 paragraph 1, CosO). 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 (eg, the exhaustive list of permissible vitamins and minerals in Annex 1 of the FAO), negative lists (eg, the list of impermissible plants or parts or preparations thereof in Annex 1 of the FPO-O) or prior authorisation requirements (eg, for novel foods; Article 15 et seq, FUAO; NovFO).

Psychedelics and Products Containing CBD

The FOPH may issue exceptional licences for the marketing of psychedelics, unless prohibited under an international agreement, and only for the purpose of scientific research, the development of medicinal products or restricted medical use (Article 8 paragraph 5, NarcA). If psychedelics serve as an active ingredient of an approved medical device, their marketing is subject to a licence from Swissmedic (Article 8 paragraph 7, NarcA). Currently no psychedelics are contained in an approved medicinal product. They may, however, be dispensed to patients following a patient-specific production (so-called extemporaneous preparations) based on a prescription (Article 9 paragraph 2, TPA).

The requirements for the marketing of CBD products depend on their respective categorisation and the applicable regulations (see **1.3 Medicines** for further details).

2.5 Internationalisation

International Regulatory Harmonisation and Mutual Recognition

While most of the Swiss regulation on medical devices, healthcare products and mHealth has been, and is continuously being, harmonised with EU, and (in parts) international, regulatory standards, Switzerland is not part of the EU and, hence, international commerce to and from the country is subject to the Swiss customs regime and certain barriers to trade.

To address the latter, Switzerland and the EU entered into an Agreement on Mutual Recognition in Relation to Conformity Assessments (MRA). The MRA ensures that, for the products and areas covered by the agreement (including PPE, GMP inspections, manufacturing licences and batch releases for medicinal products, biocides and GLP), Swiss manufacturers and conformity assessment bodies have, to the greatest extent possible, the same access to the EU market as their EU or EEA competitors.

With respect to medical devices, however, the EU and Switzerland have to date found no agreement to update Chapter 4 of the MRA on medical devices, as would be necessary to ensure the continued compatibility of the Swiss medical devices regulation in light of the recent amendments to the EU regulatory framework. As of 26 May 2021, therefore, the EU has been treating Switzerland as a third country as regards medical devices. The effect is that Swiss companies now face more demanding requirements when seeking to export medical devices to the EU, including the requirements to appoint an authorised representative, depending on the risk class of the device to present a certificate issued by an EU conformity assessment body, and to comply with the EU requirements on registration and labelling of products (see **5.2 Legislative Reform** for further detail).

In the novel foods sector, applicants regularly submit a novel foods application in the EU and not in Switzerland, given the superior geographic range of the European novel foods authorisation and its automatic dynamic recognition in Switzerland (Annex to NovFO).

International Product Liability

Upon entry into an international market, Swiss manufacturers of medical devices, consumer

healthcare and mHealth products become exposed to international product liability litigation (see also **4.2 Product Liability** and **4.3 Judicial Requirements**).

2.6 Post-marketing Obligations, Including Corrective Actions and Recalls

Therapeutic Products and PPE

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

Marketing authorisation holders for medicinal products with a new 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 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).

To the extent that PPE is not qualified as a medical device, manufacturers or distributors must monitor such PPE and notify the competent control body (the Swiss National Accident Insurance Fund (SUVA), the Swiss Council for Accident Prevention (BFU) or the organisations designated by the Federal Department of Economic Affairs, Education and Research (EAER)) if it poses a risk to the safety or health of users (Article 6, OPPE; Article 8 paragraph 5, PSA; Article 19 et seq, PSO). If it is necessary to protect the safety or health, warnings may be issued, further marketing or export may be prohibited, or the PPE may be recalled (Article 10, PSA).

Foodstuffs and Utility Articles (Including Cosmetics)

Where the responsible person identifies, or has reason to believe, that foodstuffs, utility articles or cosmetics that are imported, produced, processed, handled, dispensed or distributed by the respective company have endangered or may endanger health, they shall immediately inform the competent cantonal enforcement authority where the foodstuffs or utility articles are no longer under the direct control of the company. The authority may take the necessary measures, including withdrawal from the market and recall (Article 84 paragraph 1, FUAO).

Biocides

The competent authority (see **2.4 Marketing and Sales**) must be informed without delay if new findings emerge relating to a biocidal product or if significant changes occur with regard to essential points such as properties or intend-

ed use (Article 17, ChemA). The authority may take the necessary measures, including recall, seizure and destruction (Article 42 paragraph 3, ChemA).

3. Regulator Engagement and Enforcement

3.1 Regulatory Authorities

On the federal level in Switzerland, the main relevant authorities for therapeutic products are Swissmedic and the FOPH. 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). To the extent that PPE is not qualified as a medical device, the competent control authorities are SUVA, BFU and the organisations designated by EAER (Articles 20 et seq, PSO).

The enforcement of the foodstuffs and utility articles (including cosmetics) regulation in Switzerland is decentralised and carried out by the cantons, unless the federal government, in particular the FSVO, is responsible (Article 47 paragraph 1 and Articles 38 et seq, FSA).

The biocides regulation is enforced by a series of federal and cantonal authorities including, depending on the respective field of application, FOPH, FOEN, SECO and FSVO (Articles 50a et seq, OBP).

For narcotics, including psychedelics, the main relevant authorities are the FOPH, Swissmedic and the FDHA (Articles 1 et seq, NCO).

3.2 Regulatory Enforcement Mechanisms

The regulatory authorities referenced in **3.1 Regulatory Authorities** generally have the power to conduct inspections and take all administrative measures necessary to enforce the respective regulation (eg, Article 58 paragraph 1 and Articles 66 et seq, TPA; Article 10, PSA; Articles 19 et seq, PSO; Articles 30 et seq and 34 et seq, FSA, Articles 1 et seq, NCO).

Where applicable, the prosecution of criminal offences is a matter for the cantons, except where the respective regulation provides otherwise (eg, Articles 86 et seq, TPA; Articles 49 et seq, ChemA).

4. Liability

4.1 Product Safety Offences

Therapeutic Products and PPE

For therapeutic products and PPE qualified as a medical device, the penalties for product safety offences under the TPA range from felonies to misdemeanours and contraventions. For felonies, the penalty is a sentence with custody of up to ten years, potentially combined with a monetary penalty, or (merely) a monetary penalty (Article 86 paragraph 2, TPA), while for misdemeanours the penalty is a custodial sentence of up to three years or a monetary penalty (Article 86 paragraph 1, TPA). For contraventions, the penalty is a fine (Article 87 paragraph 1, TPA). For PPE that does not qualify as a medical device, the maximum penalty for product safety offences under the PSA is custody of up to three years or a monetary penalty. Unlawful pecuniary advantages may be confiscated (Articles 16 et seq, PSA). Product safety offences regarding stem cells may range from felonies to misdemeanours and contraventions (Articles 69 et seq, TransPA and/or Articles 86 et seq, TPA).

The Federal Supreme Court (FSC) has discussed the application of the aforementioned penalties, inter alia, in the following cases.

- In BGE 135 IV 37, a person was accused of having distributed Viagra to third parties without a doctor's prescription. The lower court sentenced the accused to 16 months' imprisonment and a monetary penalty of CHF600. The FSC reversed this ruling and referred the case back to the lower court for a new decision.
- In BGE 138 IV 57, a person was accused of having specifically endangered the health of people by recommending the use of a food supplement (which did not have a medical effect on the organism) instead of a recognised medicinal product therapy. The lower court sentenced the accused to a monetary penalty of CHF18,000. The FSC reversed this ruling as this recommendation constituted neither a prescription nor a placing on the market of medicinal products in the sense of the TPA.

Foodstuffs and Utility Articles (Including Cosmetics)

For foodstuffs and utility articles, including cosmetics, the penalties for product safety offences under the FSA range from felonies to misdemeanours and contraventions. For felonies, the penalty is custody of up to five years or a monetary penalty (Article 63 paragraph 2, FSA), while for misdemeanours the penalty is a custodial sentence of up to three years or a monetary penalty (Article 63 paragraph 1, FSA). For contraventions, the penalty is a fine not exceeding CHF40,000 (Article 64 paragraph 1, FSA).

In BGE 127 IV 178, the FSC applied the penalty provisions of the FSA to a person who was accused of having sold mushrooms that contain active substances which are harmful to health.

Biocides

For biocides, the ChemA provides for penalties for product safety offences that amount, at most, to custody of up to five years, with a monetary penalty of up to CHF500,000 or with a fine up to CHF20,000 (Articles 49 et seq, ChemA).

The FSC has not yet had the opportunity to rule on these product safety offences in connection with biocides.

Psychedelics

For narcotics, including psychedelics, the penalties for product safety offences under the FSA range from felonies to misdemeanours and contraventions (Articles 19 et seq, NarcA).

4.2 Product Liability

Product liability suits in respect of therapeutic products, PPE, foodstuffs and utility articles, including cosmetics, as well as biocides and narcotics, including psychedelics, may be based on the following:

- the Product Liability Act (PLA);
- contract law;
- tort law; or
- statutory provisions applicable to specific industries.

First, if a product causes damage because it did not provide the safety which could reasonably be expected, a claim can generally be brought against the product's manufacturer, importer or supplier as, based on the PLA, they are strictly liable for personal injuries. Compensation of damage to property is limited pursuant to the PLA. The injured person cannot claim compensation:

- for damage on commercially used property;
- for damage on the faulty product itself; or
- for property damage below CHF900.

Since the PLA is neither a complete nor an exclusive cause of action, an injured person may raise additional claims based on alternative legal grounds (Article 11 paragraph 2, PLA).

Second, if a contractual relation exists between the injured person and the supplier, a defective product can also give rise to a claim for breach of contract. The CO contains general contractual liability provisions (Articles 97 et seq, CO) and special contractual liability provisions, such as in the case of sales contracts (Articles 197 et seq, CO). While contractual liability is generally fault-based, in sales contracts the seller is strictly liable for direct losses caused to the buyer (Article 208 paragraph 2, CO). If auxiliary persons, usually employees, are used for the fulfilment of the contractual obligations, suppliers of a defective product are strictly liable for their conduct in the same way as for their own conduct (Article 101 paragraph 1, CO).

Third, tort law provides for fault-based liability claims. Hence, if a person unlawfully caused damage to another person, the person causing the damage is liable pursuant to Article 41 of the CO. In practice, tort liability is often derived from the principal's liability (Article 55, CO). According to this specific provision, the principal – usually an employer – is liable for the unlawfully caused damage by its employees or ancillary staff in the performance of their work. An exemption from liability for the principal is only possible if they can prove that they took the necessary due care to avoid any damage. In practice, however, the FSC set the bar extremely high for the acceptance of such a defence. As a result, the principal's liability amounts to that of strict liability. In order to be held liable under tort law, damage must, inter alia, be caused unlawfully – ie, in violation of absolutely protected legal interests (life, physical integrity, property) or of a statutory obligation, the purpose of which is to prevent damage of the very kind suffered.

In addition to these general product liability claims, the Epidemics Act (EpA) provides a special ground for liability claims for vaccines, which has been of particular relevance since the beginning of the COVID-19 vaccination campaign in 2021. Anyone who is harmed by an officially ordered or officially recommended vaccination is entitled to compensation (Article 64, EpA).

Technical advancements to therapeutic products, PPE, psychedelics, foodstuffs and utility articles, including cosmetics, as well as biocides in medical devices and consumer health products have so far not had a recognisable impact in case law on the application of product liability laws to these products. However, if such products are faulty, a lower standard applies to the burden of proof: generally, the standard for proving the existence of an alleged fact that needs to be met by the person who derives rights from such facts, ie, the plaintiff, is "full evidence". However, with regard to the burden of proving causation, the FSC has lowered the claimant's burden of proof and held that the involvement of a faulty product in an accident is already a significant indicator of the causal link. Moreover, where the causation can only be proven indirectly and by circumstantial evidence, the applicable standard of proof is not "full evidence" but the lower standard of "preponderant probability" (BGE 133 III 81). Nevertheless, the burden of proving causation still poses a high bar for product liability claims, as a recent judgment of the FSC indicates (BGer 4A_635/2020).

4.3 Judicial Requirements

In principle, a Swiss jurisdiction is required for a lawsuit in Switzerland. Generally, a claim can be brought before Swiss courts if the defendant resides in Switzerland, regardless of where the claimant resides. There are a number of different provisions based on which foreign defendants may be sued in Switzerland.

If a product liability case is based on tort or the PLA, the claim can be brought in Switzerland if the defective or faulty product was manufactured there or if the damage occurred in Switzerland (Articles 129 et seq, Private International Law Act (PILA); Article 5(3), Convention on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters between Switzerland and the Member States of the EU (LugC)). If the claim is based on contract law, the foreign defendant can be sued in Switzerland if the product causing the loss was delivered to Switzerland, if the defendant is a consumer and resides in Switzerland, or if the parties contractually agreed on Swiss jurisdiction (Articles 5, 113 et seq, PILA; Articles 5(1), 15 et seq and 23, LugC).

4.4 Costs

In general, Swiss law follows the "loser pays" rule – ie, the prevailing party may recover its legal costs (attorneys' fees and expenses) from the unsuccessful party (Article 106 paragraph 1, Civil Procedure Code (CPC)). However, party costs are awarded on the basis of statutory tariffs that mainly depend on the amount in dispute. In most cases, the compensation awarded covers only part of the actual costs incurred. The unsuccessful party has to bear the court fees and other incidental expenses as well as its own legal costs.

Throughout the proceedings, the parties are free to settle at any time. If an agreement can be reached, the legal costs incurred up to that point are distributed at the discretion of the court. Generally, each party has to bear its own costs, and the court costs are split equally.

Before the court takes on a case, it may demand an advance payment from the claimant up to the amount of the presumed court costs (Article 98, CPC). The defendant may request that the plaintiff shall provide security for the defendant's attorneys' fees if the plaintiff is not domiciled in Switzerland.

4.5 Product-Related Contentious Matters

Decisions by federal regulatory bodies, such as Swissmedic, can be appealed to the Federal Administrative Court (Article 31, Federal Administrative Court Act; Article 5, Administrative Procedure Act). The Federal Administrative Court's decision can be further appealed to the FSC (Article 75 paragraph 1, Federal Supreme Court Act (FSCA)).

Decisions by cantonal regulatory bodies, such as cantonal ethics committees, can be appealed to a cantonal administrative court. The cantonal administrative court's decision can be further appealed to the cantonal court of appeal or, depending on the canton, directly to the FSC (eg, in Basel according to Section 29 of the Constitutional and Administrative Jurisdiction Act of the Canton of Basel-Stadt; Article 75 paragraph 1, FSCA).

If a regulatory body conducts an inquiry, replies to a request or issues a preliminary assessment, but does so without issuing an official decision, such act cannot by itself be appealed. However, each concerned party may request an official decision in order to receive a valid object of

appeal (for federal regulatory bodies, see Article 25a of the Administrative Procedure Act).

4.6 Class Actions, Representative Actions or Co-ordinated Proceedings

To date, no class action system exists in Switzerland. A group action right is available to certain associations to protect the interest of a specific group of individuals. However, this group action right is limited to non-monetary claims, such as cease-and-desist orders and declarations of unlawful conduct (Article 89, CPC). Because monetary group action claims are, to date, not allowed, group actions are practically irrelevant for liability claims.

There are, however, alternative instruments for collective redress, such as the simple rejoinder pursuant to Article 71 of the CPC. According to this provision, two or more claimants whose rights or duties result from similar circumstances or legal grounds may jointly appear as plaintiffs, or be sued as joint defendants, provided that the same type of procedure is applicable.

In 2018, against the background of respective EU developments, Swiss lawmakers suggested the introduction of a collective redress system. After controversial discussions on the introduction of such a collective redress system, the Parliament decided in June 2022 not to respond to a new proposal from 2021, but instead to ask for further clarifications. The Swiss Parliament is expected to resume discussions on the matter in the second quarter of 2023 at the earliest.

4.7 ADR Mechanisms

In principle, a mandatory conciliation proceeding must be pursued before a claim can be filed with the court (Article 197, CPC). If the amount in dispute is higher than CHF100,000, the parties can agree to waive the conciliation proceedings (Article 199 paragraph 1, CPC). Moreover, the claimant can unilaterally forgo conciliation if the defendant's registered office or domicile is abroad or if the defendant's residence is unknown (Article 199 paragraph 2, CPC). No conciliation proceeding takes place if the case must be filed with a special commercial court (Article 6, CPC).

Pursuant to Article 213 of the CPC, the parties can also jointly decide to replace the conciliation proceeding by a mediation. In practice, the parties rarely make use of this possibility.

4.8 Interrelation Between Liability Mechanisms

As mentioned in **4.7 ADR Mechanisms**, prior to bringing a claim, a conciliation proceeding or a mediation is a necessary prerequisite for a lawsuit.

The public prosecutor's office is responsible for prosecuting product safety offences. If, in order to settle a case, litigants apply pressure by threatening to report product safety offences to the prosecutor, such conduct might qualify as coercion (Article 181, Criminal Code) and result in a separate criminal proceeding.

The criminal justice authorities are obliged to report to the competent authority all offences that they have ascertained in the course of their official activities or that have been reported to them, unless they are themselves responsible for prosecution.

If a criminal proceeding is initiated first, such proceeding can be combined with a product liability claim, as harmed persons may assert their civil claims as private plaintiffs by way of adhesion to criminal proceedings.

5. Applicable Product Safety Regulatory Regimes

5.1 Policy Development

For the policy developments relating to CSR, the environment and sustainability, see **2.2 Corporate Social Responsibility, the Environment and Sustainability**.

For details on the current legislative reform projects, see **5.2 Legislative Reform**.

5.2 Legislative Reform

Medical Devices

As explained above, the update of the MRA is still pending (see **2.5 Internationalisation**).

To mitigate the negative effects, the Federal Council, on 26 May 2021, approved amendments to the completely revised MedDO that was enacted on the same day. These amendments are also reflected in the new IvDO of 26 May 2022. Inter alia, the amendments allow unilateral access to medical devices certified in the EU and set lengthy transitional periods of – in many cases – over one year for the appointment of an authorised representative, thereby alleviating supply problems in Switzerland. Manufacturers, importers and authorised representatives must register with Swissmedic and, once available, obtain a unique identification number (Swiss Single Registration Number, CHRN), which is to enable continued market surveillance and compensate for Swissmedic being denied access to the central European database for medical devices (EUDAMED 3) and to the EU working groups on the joint surveillance of new medical devices.

These mitigating measures were found to achieve their objective and the Federal Council concluded, in June 2022, that no further measures to safeguard the supply of safe and correctly performing medical devices were required.

Following the urgent adoption by the European Commission of Regulation (EU) 2023/607, which aims to alleviate the risk of shortages of safe medical devices, and, on the other hand, the adoption of Regulations (EU) 2022/2346 and (EU) 2022/2347, establishing new requirements for groups of products without an intended medical purpose, the Federal Council expects to take over the necessary modifications to the MedDO and IvDO in autumn 2023.

Lastly, the Swiss Federal Council has been mandated to revise the legislation to enable the authorisation of medical devices from regulatory systems outside Europe. The FOPH is currently examining implementation options.

Biocides

In the area of biocidal products, a new reporting obligation on the quantities of biocidal products placed on the market and quantifiable targets for the reduction of risks from biocidal products (Articles 10a and 25a, revised OBP) will enter into force in January 2024. The proposed obligation to report on the use of certain biocidal products (Article 10b, revised OBP) can only be implemented later, via a further revision of the OBP.

5.3 Impact of Artificial Intelligence

Artificial intelligence (AI) is also making its way into the healthcare sector. In the area of pharmaceuticals, AI is primarily used in research and development, among other things for better processing of large amounts of data and quicker evaluation of different combinations of active ingredients. In medical treatment, AI increasingly comes into use in medical devices, either as

stand-alone software or integrated into hardware components.

From a legal perspective, there are currently no specific AI regulations; rather, the regulations outlined above apply, namely the general regulations on clinical trials, approvals, product monitoring and liability law. In contrast to the EU, no legislative projects are yet underway. The Federal Council has announced that it will continue its analysis of developments in the field. In order to drive forward the digital transformation in healthcare, the roll-out of a national programme ("DigiSanté") to address Switzerland's backlog in the digitalisation of healthcare is being discussed.

CHAMBERS GLOBAL PRACTICE GUIDES

Chambers Global Practice Guides bring you up-to-date, expert legal commentary on the main practice areas from around the globe. Focusing on the practical legal issues affecting businesses, the guides enable readers to compare legislation and procedure and read trend forecasts from legal experts from across key jurisdictions.

To find out more information about how we select contributors, email Katie.Burrington@chambers.com