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Medical Devices & Consumer Health Products 2021

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Law and Practice

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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 not contained in one comprehensive body of legislation, but is spread over various statutes, ordinances and guidelines, and also includes international regimes. These regulations contain different, and partially disparate, requirements in particular for design and manufacture, market access, sales and post-marketing surveillance, as well as advertising and product claims. The authorities responsible for enforcement are also different, as are the administrative measures and sanctions available to them.

A product may generally only be categorised in one product group. Both from a public health as well as from a practical industry and healthcare-provider perspective, it is important that individual products are categorised correctly. Perhaps most fundamentally, the mandatory authorisation by a public authority for the marketing of medicinal and biocidal products in Switzerland – which demands significant scrutiny, time and expense – is not required for medical devices, foodstuffs, nutrition supplements, and cosmetics. Also, an incorrect categorisation may have far-reaching consequences, including recalls and liability claims. Disclaimers generally do not have legal value if, at the same time, the product is marketed for another purpose.

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 Clinical Trials for Medical Devices (ClinO-MedD), 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.

Swiss medical devices law was recently completely revised with the entry in to force, on 26 May 2021, of the totally revised MedDO, the revised parts of the TPA, and the new ClinO-MedD. Thereby, Switzerland has improved the quality and safety of medical devices for patients in Switzerland, and it has adapted the main parts of its medical devices legislation to Regulation (EU) 2017/745 on medical devices (EU-MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (EU-IVDR); for legislative developments regarding in vitro diagnostics see **5.2 Legislative Reform**.

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 **1.4 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).

Pharmaceuticals (Medicinal Products) and Blood Products

According to Swiss nomenclature, medicinal products 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 diagnosis, 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). Complementary and herbal medicines are further regulated by the Ordinance on the Simplified Authorisation and the Notification Procedure for Complementary and Herbal Medicinal Products. Depending on the circumstances, sector-specific regulations may apply, in particular in the fields of research (Human Research Act and related ordinances), transplantation (Transplantation Act and related ordinances), reproductive medicine (Reproductive Medicines Act and related ordinances), and narcotics (Narcotics Act (NarcA) and related ordinances). Certain raw materials for medicinal products are also subject to Swiss chemicals law.

1.2 Healthcare Products

The increasing number of cosmetics, foodstuffs and nutrition supplements that have been put on the market in recent years and are advertised as having a positive effect on health because of their ingredients raises difficult questions of categorisation. Meanwhile, the regulatory approaches in Switzerland correspond, or are moving ever closer, to EU legislation.

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 the 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 mate-

rials 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, the Novel Foods Ordinance, the Ordinance on Food of Plant Origin, Mushrooms and Table Salt, 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 New Products/Technologies and Digital Health

Unlike therapeutic products and consumer healthcare products, the new products covered in this chapter are not governed by specific regulation in Switzerland. This makes their qualification, and regulatory governance, more complex and challenging.

Mobile Health (mHealth)

As defined by the WHO and the Swiss Competence and Co-ordination Centre of the Confederation and the Cantons (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 are generally qualified as 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 purpose, in particular for diagnosing, preventing, monitoring or treating diseases, injuries or disabilities (Article 3 paragraph 1, MedDO).

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. Other issues of relevance in connec-

tion with mHealth concern data protection, in particular sensitive personal health data, "big data" and EPRs that are governed by federal and cantonal legislation, including the Federal Act on Data Protection and the related Ordinance as well as the Federal Act on the Electronic Patient Record and related ordinances.

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.

The range of CBD-containing products is extensive and includes raw materials such as cannabis buds or powder with a high CBD content, extracts in the form of oils or pastes, ready-to-use products such as capsules, food supplements, liquids for e-cigarettes, tobacco substitutes, scented oils, and chewing gums or ointments, some of which are offered as care products.

Product safety-related aspects of CBD are governed by a number of different regulations, depending 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 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).

Drawing the line between medical devices and medicinal products can be difficult. The decisive factor is not their material composition, but whether the intended main effect of the product 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

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.

For example, face filtering pieces (FFP) respectively FFP2/FFP3-masks are qualified as PPE, while surgical masks that, when used correctly, primarily protect the patients from infection are considered medical devices subject to the MedDO. Meanwhile, textile and other DIY-masks that, at best, offer a certain degree of third-party protection, are considered utility articles and are subject to the FSA and PSA/PSO.

Cosmetics, Therapeutic Products and Biocides

Cosmetics, respectively utility articles, 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. The presence of a medicinal claim does not automatically make a product a medicinal product (BGer 2C_413/2015).

Products that have a primarily biocidal function are in principle subject to the OBP. This includes, for example, disinfectants. 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). Where a clear categorisation is difficult, the same distinction criteria as for cosmetics and medicinal products are deemed to apply.

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).

2. COMMERCIALISATION AND PRODUCT LIFE CYCLE

2.1 Design and Manufacture

Medical Devices and PPE

Any natural or legal 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).

Manufacturers of medical devices do not require a prior licence by 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 EU-MDR 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 by 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 (Articles 6, 46, 50, MedDO).

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 11, EU-MDR).

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 require-

ments in Annex II EU-PPE Regulation (Article 4 paragraph 1 lit a, OPPE).

Medicinal Products

Manufacturing means all stages in the manufacture of a therapeutic 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, in particular with respect to Good Manufacturing Practice (GMP) compliance, 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 package and label 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).

2.2 Corporate Social Responsibility, the Environment and Sustainability

Environment and Biosafety

The manufacture of medicinal products can affect the environment in a number of ways. 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 made by companies, 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. On 15 January 2020, the Federal Council adopted a revised CSR Action Plan 2020–23. As of today, obligations in respect of CSR and sustainability are primarily governed by soft law (eg, the UN Guiding Principles on Business and Human Rights). Apart from a company's own liability and its liability for unlawfully caused damage through auxiliaries (Article 55, Code of Obligations (CO)), no extended corporate liability exists for the conduct of third parties.

However, two amendments to the CO are at an advanced legislative stage: Similar to Directive 2014/95/EU regarding disclosure of non-financial and diversity information by certain large undertakings and groups, 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 laying down supply chain due diligence obligations for EU importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas, 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.

COVID-19

In light of the experiences during the COVID-19 pandemic, and in line with the respective OECD initiative, the State Secretariat for Economic Affairs (SECO) encourages active supply chain management to address vulnerabilities in the supply chain and to support contingency planning in order to manage disruptions.

Compulsory Licensing

Applicants may bring action before Swiss courts for a compulsory non-exclusive licence for the manufacture of patent-protected pharmaceutical products and for their export to a country that has insufficient or no production capacity of its own in the pharmaceutical sector and which requires these products to combat public health problems, in particular those related to epidemics (Article 40d paragraph 1, Patents Act). However, no such licence has been granted to date in the pharmaceutical products area.

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).

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 devices intended exclusively for use by professionals (Article 69 paragraph 3, MedDO).

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 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. In the broader context of advertising, it should also be recalled that, on 1 January 2020, revised rules on integrity and transparency, including the OIT, came into force that mainly focus on medicinal products.

Apart from information and instruction obligations according to the OPPE and the EU-PPE Regulation, advertising and product claims for PPE that are not qualified as medical devices 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).

Prohibited are, in particular, information on effects or properties of foodstuffs which, according to the current state of scientific knowledge, they do not posses 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 laying down common criteria for the justification of claims used in relation to cosmetic products, namely, legal compliance, truthfulness, evidential support, honesty, fairness, and informed decision-making (Article 10 and Annex 6, CosO). Finally, references to curative, soothing or preventive effects (eg, medicinal or therapeutic properties, disinfecting or anti-inflammatory effects) are prohibited, except for scientifically substantiated cavity-preventing and other preventive 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, Clinical Trials Ordinance).

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 of 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 52–54 and Annexes IX-XI of the EU-MDR (Articles 21 et seq, MedDO). 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; Annex IV, EU-MDR). 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; Annex V, EU-MDR). 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-MedD).

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)

In application of the principle of self-control, anyone who places foodstuffs and utility articles, including cosmetics, 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).

For certain foodstuffs, however, there are either positive lists (eg, the exhaustive list of permissible vitamins and minerals in Annex 1 of the Food Additives Ordinance), negative lists (eg, the list of impermissible plants or parts or preparations thereof in Annex 1 of the Ordinance on Food of Plant Origin, Mushrooms and Table Salt) or

prior authorisation requirements (eg, for novel foods; Article 15 et seq, FUAO; Novel Foods Ordinance).

2.5 Internationalisation

International Regulatory Harmonisation and Mutual Recognition

While most of the Swiss regulation on medical devices, consumer 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 of 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 Novel Foods Ordinance).

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**).

Generally, a claim can be brought before Swiss courts if the defendant resides in Switzerland, regardless of where the claimant resides. Irrespective of this, if a product liability claim is based on tort or the Product Liability Act (PLA), the claim may be brought in Switzerland if the defective or faulty product was manufactured, 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)). Claims based on contract can be brought 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).

In proceedings initiated by a foreign party, the defendant may request that plaintiff provides security for party costs (Article 11b, PILA; Article 99 paragraph 1 lit a, Civil Procedure Code (CPC)).

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).

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).

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). Serious adverse reactions should be reported within 15 days of diagnosis, and non-serious reactions within 60 days. 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). 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 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 intended 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).

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).

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).

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 recog-

nised 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 CHF 20,000 (Articles 49 et seq, ChemA).

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

4.2 Product Liability

Product liability suits in respect of therapeutic products, PPE, foodstuffs and utility articles, including cosmetics, as well as biocides may be based on (i) the PLA, (ii) contract law, (iii) tort law, or (iv) 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 (i) for damage on commercially used property, (ii) for damage on the faulty product itself, and (iii) 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).

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 damages 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 damages. In practice, how-

ever, 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. Hence, the breach of a statutory obligation can impose tort liability if such statutory obligation was introduced to prevent the damage 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; see **5.4 Impact of COVID-19** for further details).

Procedurally, a claimant wishing to initiate a product liability action must in general first start conciliation proceedings (Article 197, CPC). If no amicable settlement is reached, the conciliation authority grants a temporary authorisation to proceed with the claim, and the claimant then has to file the claim with the competent court within three months (Article 209, CPC). Product liability claims based on the EpA must be brought against the authority that officially ordered or recommended the vaccination – ie, either the FOPH or the respective cantonal authority.

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. 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.

In order to bring a claim before a Swiss court, such a claim needs to meet the following further requirements (Articles 59 and 209, CPC):

- the plaintiff must have an interest worthy of protection;
- the claimant and defendant must have the capacity to be parties and to litigate;
- the matter may not be pending elsewhere;
- the matter must not have been finally decided;
- the advance payment and the security for the costs of the proceedings, if any, must have been paid;
- a valid authorisation to proceed with the claim, if required, must have been submitted; and
- the claim must be brought with the authorisation of the conciliation authority within three months, if required.

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, 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

The mechanisms that are available in respect of product-related contentious matters depend on the acting authority that sets the cause of a complaint or appeal. In principle, a distinction must be made between federal and cantonal authorities.

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 Mass Tort Litigation

To date, no mass tort 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 as follows.

- Associations and other organisations that protect the interest of a certain group of individuals shall receive a reparatory group action right.
- Upon authorisation of the group members (opt-in), the organisation shall be entitled to initiate court proceedings for damages and forfeiture of profit in its own name for the benefit of the group members.

- The above-mentioned associations and other organisations shall have the opportunity to reach a collective settlement for their interest group; in this case, a court would have to approve the collective settlement agreement, upon which the settlement would become binding for all persons affected by the infringement, unless they opt out within three months from approval.

The introduction of such a collective redress system has been highly controversial, and, as of today, it is not known when the Swiss Parliament will resume discussions on the matter.

4.7 Class Actions, Representative Actions or Co-ordinated Proceedings?

As mentioned, there is to date no class action system in Switzerland. See **4.6 Mass Tort Litigation** for representative actions and co-ordinated proceedings.

4.8 ADR Mechanisms

In principle, a mandatory conciliation proceeding must be pursued before a claim can be filed with the court (Article 197, CPC, see **4.2 Product Liability**). 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 forego 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.

4.9 Interrelation between Liability Mechanisms

As mentioned in **4.2 Product Liability** and **4.8 ADR Mechanisms**, prior to bringing a claim, the claimant must normally initiate conciliation proceedings (Article 197, CPC). Alternatively, such conciliation proceedings can be replaced by a mediation. Hence, a conciliation proceeding or a mediation is a necessary prerequisite for a lawsuit and will be followed by such lawsuit if no amicable settlement is reached.

The public prosecutor's office is responsible for prosecuting product safety offences. Hence, it is not in the hands of civil litigants whether product safety issues are prosecuted. 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. The confederation and the cantons may introduce such a duty to report offences for members of other authorities (Article 302, Criminal Procedure Code).

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. POLICY AND LEGISLATIVE REFORM

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

In view of societal, technological, political and economic developments, as well as regulatory advances in the EU, Swiss therapeutic products regulation is continuously being updated.

Medical Devices

In the course of aligning Swiss medical devices regulation with the new EU-MDR and EU-IVDR, the MRA also needs to be updated in order to ensure mutual market access, co-ordinated market surveillance, information sharing between authorities, and the mutual recognition of certificates of conformity. The EU Commission is making the updating of the MRA subject to progress on the EU-CH Institutional Framework Agreement (InstA). However, on 26 May 2021, the Swiss Federal Council decided not to sign the Agreement, bringing the negotiations on the draft InstA to a close.

In order to mitigate the negative effects from this decision, the Federal Council, on 26 May 2021, approved amendments to the completely revised MedDO that was enacted on the same day. 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 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.

Despite the uncertainty around the MRA, the revisions of the national regulatory framework continue. On 14 April 2021, the Federal Council opened consultations on a new Ordinance on In Vitro Diagnostics, as well as on amendments to the ClinO-MedD.

Medicinal Products

In the course of the continued implementation of the Medicrime Convention, provisions are being drafted and discussed that should improve patient protection and fight forgery of medicinal products through a voluntary placing of safety features on product packaging. It is yet to be determined when these provisions will enter into force.

5.3 Impact of Brexit

As of 1 January 2021, the UK is no longer a member of the EU and, therefore, the MRA is no longer applicable to the UK as of said date. In connection therewith, Switzerland and the UK transferred and incorporated the MRA rules on medicinal products and GLP into their CH-UK Trade Agreement.

5.4 Impact of COVID-19

Medicinal products that are manufactured with a listed active substance for the treatment of COVID-19 patients may be placed on the market in Switzerland without marketing authorisation, pending Swissmedic's decision on authorisation. When examining applications for authorisation, Swissmedic may permit a relaxation of the relevant requirements for such medicinal products

on the basis of a risk-benefit analysis (Article 21 paragraph 1, Annex 5, COVID-19 Ordinance 3). For example, Gilead's remdesivir received such a temporary authorisation in 2020. Irrespective of this, Swissmedic will prioritise and appropriately accelerate applications for authorisation of medicinal products for the prevention and treatment of a pandemic disease.

In connection with COVID-19 vaccinations, as indicated in **4.2 Product Liability**, the EpA provides a special compensation scheme according to which anyone who is harmed by an officially ordered or officially recommended vaccination is entitled to damages, and also to moral compensation of maximum CHF70,000 if the severity of the impairment justifies it (Articles 64 et seq, EpA). However, the Swiss State only grants compensation if the damage cannot be covered otherwise with reasonable efforts – eg, by the vaccine manufacturer. While this compensation scheme existed already prior to the COVID-19 pandemic, it has attracted greater attention since.

Kellerhals Carrard has more than 200 legal professionals (consisting of partners, of counsel, associates, tax advisers and notaries) and more than 300 employees. The firm, established in 1885, is one of the largest and most traditional law firms in Switzerland, with offices in Basel, Berne, Geneva, Lausanne, Lugano and Zurich, and representative offices in Binningen, Sion, Shanghai and Tokyo. Kellerhals Carrard is active throughout Switzerland, maintaining very strong local roots, whilst advising clients nationally and abroad. The firm advises and represents companies and entrepreneurs from all industries and economic sectors, public authorities, national and international organisations and private individuals before all judicial and administrative bodies nationally and abroad in practically all areas of the law. Kellerhals Carrard focuses in particular on the areas of life sciences, financial services, IMT (information, media and technology), sport, energy, real estate/construction, as well as on trading and retail.

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