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1 Regulatory Framework

1.1 Please list and describe the principal legislative and regulatory bodies that apply to and/or regulate pharmaceuticals, medical devices, supplements, over-the-counter products, and cosmetics.

Swiss healthcare and life sciences legislation is regulated in various laws, Ordinances, guidelines and manuals. The key principles are outlined in the Federal Therapeutic Products Act (TPA), which contains the most basic regulations on the handling of medicinal products (i.e., pharmaceuticals) and medical devices. The TPA generically refers to medicinal products and medical devices as "Therapeutic Products". This also includes over-the-counter (OTC) medicinal products as well as supplements to medical devices. Due to the high export rate of such products to the European Union (EU), the Swiss legislator aims at a far-reaching conformity between Swiss and EU law.

Economic considerations as well as cost control and affordability of Therapeutic Products are not covered by the TPA but are dealt with by the Federal Health Insurance Act (HIA). The TPA is merely a framework law, containing only general provisions on medicinal products (Arts 5–44 TPA) and on medical devices (Arts 45–51 TPA), common provisions for both product categories (Arts 52–67b TPA), and provisions on enforcement, administrative and criminal procedures (Arts 82–90 TPA). Detailed provisions that are crucial in practice are regulated in several Ordinances. Among others, these include i) the Medicinal Products Ordinance (MPO), ii) the Medicinal Products Licensing Ordinance (MPLO), iii) the Medical Devices Ordinance (MedDO), iv) the *In vitro* Diagnostics Ordinance (IvDO), and v) the Veterinary Medicinal Products Ordinance (VMPO).

Special regulations apply to certain types of products. Blood and blood products are neither medicinal products nor medicinal devices but are treated as medicinal products (Art. 4(1)(a) TPA). Cosmetics belong to consumer goods and are considered articles of daily use, which are subject to the Federal Foodstuffs Act (FSA).

In Switzerland, the Federal Office of Public Health (FOPH) is by default the competent authority for all public health aspects, unless the cantonal authorities are responsible. In the area of Therapeutic Products, however, it is neither the FOPH nor the cantonal health authorities, but rather the Swiss Agency for Therapeutic Products (Swissmedic) that is the Swiss regulatory and supervisory authority for medicinal products, including OTC products as well as medical devices (Arts 68, 69 and 82 TPA). Swissmedic is a federal agency governed by public law with its own legal personality. Swissmedic is legally and economically independent from the rest of the administration and is mainly financed by fees. Swissmedic has the competence to issue further regulations that supplement the above-mentioned legal requirements, in particular by means of guidelines, instructions and manuals.

1.2 How do regulations/legislation impact liability for injuries suffered as a result of product use, or other liability arising out of the marketing and sale of the product? Does approval of a product by the regulators provide any protection from liability?

In general, i) the Swiss Product Liability Act (PLA), which is based on the EU product liability directive, ii) contract law, and iii) tort law may be used to establish product liability for Therapeutic Products. Thus, a manufacturer may be held jointly and severally liable with any authorised representative in Switzerland of a person injured by a defective medical device (Art. 47d(2) TPA).

A marketing authorisation by Swissmedic (for medicinal products) or a certificate of conformity (CoC) for medical devices may be an indicator that a Therapeutic Product is not defective. However, such CoC does not exempt the manufacturer of the respective product from potential product liability claims.

1.3 What other general impact does the regulation of life sciences products have on litigation involving such products?

Patients and consumers are expected to take their own responsibility and to handle Therapeutic Products with care. Careless personal use and any associated risk to oneself do not constitute grounds for liability.

Furthermore, a manufacturer is not liable under product liability law either i) if a life sciences product's fault is attributable to compliance with legally binding requirements (Art. 5(1)(d) PLA), or ii) if the manufacturer is successful in demonstrating that a fault could not have been detected given the state of science and technology at the time the product was placed on the market (Art. 5(1)(e) PLA).

1.4 Are there any self-regulatory bodies that govern drugs, medical devices, supplements, OTC products, or cosmetics in the jurisdiction? How do their codes of conduct or other guidelines affect litigation and liability?

Codes of conduct or other guidelines of self-regulatory bodies might have an impact on liability with respect to fault-based responsibility in the sense that a breach of such standards may indicate fault.

1.5 Are life sciences companies required to provide warnings of the risks of their products directly to the consumer, or to the prescribing physician (i.e., learned intermediary), and how do such requirements affect litigation concerning the product?

Manufacturers, authorised representatives, importers and/or distributors of Therapeutic Products are required to provide information for both the patient and the prescribing physician. This disclosure must provide the essential warnings regarding the Therapeutic Product's risks. According to the Federal Supreme Court (FSC), medicinal products that are not provided with appropriate information regarding the risks to the consumer may be considered defective within the meaning of the PLA (FSC 2C_60/2018 of 31 May 2018).

However, the FSC also ruled that if a medicinal product is exclusively accessible by prescription, it is acceptable that only the physician's information but not the patient information discloses specific risks of the product. The patient usually lacks the required knowledge to accurately judge risks (FSC 4A_365/2014 of 5 January 2015).

2 Manufacturing

2.1 What are the local licensing requirements for life sciences manufacturers?

The granting of manufacturing licences for pharmaceutical manufacturers is one of Swissmedic's core tasks. Anyone manu-facturing medicinal products therefore requires a licence from Swissmedic (Art. 5(1)(a) TPA). Such a licence is granted if the necessary technical and operational requirements are met and if a suitable quality assurance system is in place (Art. 6(1) TPA). The detailed provisions are specified in Art. 3 MPLO. Furthermore, the manufacture of medicinal products must be carried out in accordance with Good Manufacturing Practice (GMP) (Art. 4(2) MPLO).

Medical devices, however, do not need a manufacturing licence, but are instead required to go through a conformity assessment before being placed on the market (Art. 46(1) TPA). Accordingly, a medical device may only be placed on the market if it meets the requirements of the MedDO (Art. 6(1) MedDO) when properly supplied, correctly installed and maintained, and used in accordance with its intended purpose. In addition, medical devices must comply with the requirements of the EU Medical Devices Regulation (EU MDR) (Art. 6(2) MedDO) since Switzerland, although not being an EU Member State, harmonised its regulatory standards regarding medical devices with those of the EU.

2.2 What agreements do local regulators have with foreign regulators (e.g., with the U.S. Food and Drug Administration or the European Medicines Agency) that relate to the inspection and approval of manufacturing facilities?

National and international cooperation with foreign regulators is also one of Swissmedic's core tasks. As the EU is Switzerland's largest trading partner, Switzerland and the EU entered into a Mutual Recognition Agreement (MRA) in relation to conformity assessment. The MRA is designed to remove technical barriers to the trade of industrial goods between the parties, and applies, *inter alia*, to GMP inspections of medicinal products and certification of batches. Consequently, in the case of medicinal products, each party recognises the results of inspections conducted by the competent authorities of the other party at the premises of manufacturers, as well as the production authorisations provided by the competent authorities of the other party (Chap. 15 of Annex 1 MRA). In addition, foreign authorities are permitted, under certain conditions and after notifying Swissmedic, to audit Swiss companies active in the Therapeutic Products industry (Art. 64a TPA).

The MRA also applies, *inter alia*, to medical devices. Accordingly, conformity assessments of medical devices authorised in the territory of a party are, in principle, also acknowledged within the jurisdiction of the other party (Chap. 4 of Annex 1 MRA). In view of the recent changes to the EU regulatory framework on medical devices, it is necessary to revise the MRA's provisions on medical devices to guarantee mutual recognition of CoCs, facilitation of reciprocal market access, coordinated market surveillance, and information sharing between authorities. However, the EU Commission ties such an update to further progress in the stalled political negotiations between Switzerland and the EU on an Institutional Framework Agreement (InstA).

As a result of this impasse, the EU treats Switzerland as a third country in terms of medical devices, requiring Swiss companies to make higher administrative efforts to place medical products on the EU market. To counteract these negative impacts, the Swiss Federal Council amended on 26 May 2021 the MedDO to provide unrestricted access to EU-certified medical devices and to establish long transitional periods, therefore reducing supply issues in Switzerland.

Switzerland has also engaged into MRAs with relevance to life sciences with the EFTA Member States, Canada, South Korea and the United States (US). In addition, Swissmedic has entered into agreements with the medicines agencies of around 20 countries (*inter alia*, Australia, Brazil, China, Israel, Japan and the United Kingdom), which primarily include information sharing throughout the process of authorisation of medicinal products, market monitoring of Therapeutic Products, as well as the development of regulatory guidelines.

2.3 What is the impact of manufacturing requirements or violations thereof on liability and litigation?

The Swiss regulations outline in more detail the standard of care for the manufacture of a medicinal product by referring to the GMP (Arts 4(2) and 7(2) MPLO). The FSC has emphasised the importance of preventing low-quality Therapeutic Products from being placed on the market and being consumed or utilised by consumers (FSC 2A.156/2004 of 25 March 2004). If the GMP regulations are not observed, this may, *inter alia*, result in recalls (see question 7.1), revocation of the manufacturing licence (FSC 2C_659/2010 of 16 February 2011), imprisonment (Art. 86 TPA) or fines (Art. 87 TPA).

In addition to this, the risk of civil liability also exists. However, a manufacturer is not liable under the conditions set out above (see question 1.3).

3 Transactions

3.1 Please identify and describe any approvals required from local regulators for life sciences mergers/acquisitions.

Swiss law does not have specific laws addressing mergers/acquisitions in the life sciences sector. These transactions are subject to the generally applicable regulatory framework for transactions, such as Swiss merger control. However, certain exceptions may exist in the context of asset deal transactions if regulatory authorisations are part of the assets to be transferred.

3.2 What, if any, restrictions does the jurisdiction place on foreign ownership of life sciences companies or manufacturing facilities? How do such restrictions affect liability for injuries caused by use of a life sciences product?

There are no particular restrictions on the ownership of life sciences companies or manufacturing facilities by foreign investors. A life sciences company or production facility itself must comply with the applicable regulatory standards, not the shareholder(s) of a company or the owner(s) of a facility.

4 Advertising, Promotion and Sales

4.1 Please identify and describe the principal legislation and regulations, and any regulatory bodies, that govern the advertising, promotion and sale of drugs and medical devices, and other life sciences products.

In general, the TPA aims to protect consumers from sensational advertising and exaggerated healing expectations. To a large extent, advertising, promotion and sales of Therapeutic Products are governed by the TPA, the Medicinal Products Advertising Ordinance (MPAO) and the MedDO. Furthermore, the Federal Act on Unfair Competition (UCA) is applicable. In addition, the Pharma Code, the Pharma Cooperation Code and the Swiss Medtech Code of Ethical Business Practice are all examples of self-regulatory codes that include requirements related to the advertising, promotion and sale of Therapeutic Products.

Depending on whether the advertised product is a medicinal product or a medical device, different advertising regulations apply. Advertising directed at healthcare professionals prescribing or dispensing medicinal products is permitted in general for all medicinal products authorised in Switzerland (Art. 31(1) TPA). However, advertising that is misleading, contrary to public order or may lead to excessive, abusive or inappropriate use of medicinal products is not permitted (Art. 32(1) TPA). All information towards healthcare professionals must, *inter alia*, be in accordance with the medicinal product information approved by Swissmedic, accurate, balanced, factually correct and substantiated, recognisable as such and reflect the current status of scientific knowledge. Moreover, any publications must have a complete and verbatim citation, together with the source information (Art. 5 MPAO). Furthermore, advertising directed at healthcare professionals may not be made publicly available on the internet (Art. 5a MPAO).

On the other hand, advertising that is directed at the general public is only allowed if it does not make any reference to prescription-only medicinal products. Promotion to the general public of medicinal products that require a medical prescription is strictly prohibited (Art. 32(2)(a) TPA).

The advertising of medical devices, by contrast, is not subject to the same stringent regulations as advertising for medicinal products. The MedDO merely stipulates that advertising may only contain statements that correspond to the product information (Art. 69(1) MedDO) and that misleading statements are prohibited, especially regarding the intended purpose, safety and performance of a product (Art. 69(2) MedDO). Furthermore, advertising to the general public is prohibited for products intended exclusively for use by healthcare professionals (Art. 69(3) MedDO).

Violations of the rules on advertising for Therapeutic Products may result in administrative measures (Art. 66(2) TPA) as well as criminal sanctions (Art. 87(1)(b) TPA). Regarding the requirements of due care for the distribution of wholesale medicinal products, reference is made to the Good Distribution Practice (GDP) (Art. 29 TPA and Art. 15(2) MPLO).

4.2 What restrictions are there on the promotion of drugs and medical devices for indications or uses that have not been approved by the governing regulatory authority ("off-label promotion")?

The freedom of therapy gives a physician the possibility of prescribing a medicinal product for an indication, even if Swissmedic has not (yet) authorised this indication. However, off-label promotion is not allowed since medicinal products (Arts 5(1) and 16(1) MPAO) and medical devices (Art. 69(1) MedDO) may only be promoted for the respective indication authorised by Swissmedic, that also corresponds with the product information.

4.3 What is the impact of the regulation of the advertising, promotion and sale of drugs and medical devices on litigation concerning life sciences products?

Provisions regarding litigation for alleged violations of the rules on advertising are not included in the TPA or its Ordinances. However, the provisions on unfair competition of the UCA are applicable.

Accordingly, a company is deemed to be engaging in unfair business practices if, for instance, it disparages other companies, their goods, works, services and/or their prices by means of incorrect, misleading or unnecessarily offensive statements (Art. 3(1)(a) UCA), it makes incorrect or misleading statements about itself or its products (Art. 3(1)(b) UCA), or it takes measures likely to cause confusion (Art. 3(1)(d) UCA). In such cases, persons and organisations who have been harmed as well as consumer protection organisations and the federal administration have the right to pursue legal action against the company (Arts 9 and 10 UCA).

5 Data Privacy

5.1 How do life sciences companies that distribute their products globally comply with data privacy standards such as GDPR and other similar standards?

In Switzerland, privacy and data protection are governed by the Federal Data Protection Act (DPA) and the corresponding Ordinance (DPO). To align Swiss data protection law with the GDPR and similar standards, the DPA was revised in September 2020 as part of a comprehensive revision of Swiss data protection law. The revised DPA and DPO entered into force on 1 September 2023. For life sciences companies, it is particularly important to note that genetic and biometric data now explicitly qualify as sensitive personal data, necessitating increased data protection measures (Art. 5(c) DPA).

Since Switzerland is neither a member of the EU nor the European Economic Area (EEA), Swiss companies are not – by operation of their domicile – subject to GDPR. Nonetheless, Swiss companies operating in the EEA must abide by the GDPR and/or other similar standards, very much like companies domiciled in any other non-EU country. Therefore, due to the expansive scope of the GDPR, Swiss companies – regardless of whether they are in the life sciences sector or not – must comply with the GDPR when offering goods or services to EU data subjects or monitoring their behaviour (Art. 3(2) GDPR).

For Swiss-based life sciences companies, this means that they must review the types of data they process as part of clinical trials and other activities to determine whether the GDPR's health-specific requirements apply to the processed data. The same applies to other data privacy and protection standards, based on their respective scope(s).

5.2 What rules govern the confidentiality of documents produced in litigation? What, if any, restrictions are there on a company's ability to maintain the confidentiality of documents and information produced in litigation?

In principle, the DPA does not apply to pending civil proceedings, criminal proceedings, international mutual legal assistance proceedings or proceedings under administrative law. In such proceedings, the processing of personal data and the rights of data subjects are governed by the respective rules of procedure (Art. 2(3) DPA). Nevertheless, the Swiss Civil Procedure Code (CPC), Swiss Code of Penal Procedure (CPP) and Swiss Penal Code (SPC) allow for the confidentiality of documents and information under certain conditions.

In civil litigation, physicians, dentists, chiropractors, pharmacists, midwives and physiotherapists, as well as their assistants, must not disclose any secrets entrusted to them in the practice of their profession or gained during their profession (Arts 163(1)(b) and 166(1)(b) CPC and Art. 321(1) SPC). In addition, such qualified professionals may refuse to testify in a litigation matter if they can credibly demonstrate that the need for secrecy outweighs the interest in discovering the truth (Arts 163(2) and 166(2) CPC). In the event that evidence must nevertheless be gathered, and if this jeopardises the legitimate interests of the parties or third parties (such as trade secrets), the court must take the necessary steps to protect such legitimate interests (Art. 156 CPC).

In criminal proceedings, physicians, dentists, chiropractors, pharmacists, midwives and physiotherapists, as well as their assistants, must not disclose any secrets entrusted to them in the practice of their profession or gained during their profession (Art. 171(1) CPP). Despite the foregoing, such qualified professionals are required to testify if they are subject to a duty of disclosure or if they have been released from the obligation of secrecy by the owner of the secret or the competent authority (Art. 171(2) CPP). However, professional secrets that arose during research on humans under the HRA must not be disclosed (Art. 321bis(1) SPC). Exceptions apply in case i) the requirements of Art. 34 HRA are met, and ii) in the event the disclosure has been approved by the competent ethics committee (Art. 321bis(2) SPC; see question 6.1).

5.3 What are the key regulatory considerations and developments in Digital Health and their impact, if any, on litigation?

In Switzerland, there is no specialised or thorough regulation of digital health. Rather, analogous application of the general health law provisions and of the regulations governing Therapeutic Products is required. This leads to a steadily growing body of administrative and judicial precedents, which is used to evaluate regulatory considerations in digital health.

6 Clinical Trials and Compassionate Use Programmes

6.1 Please identify and describe the regulatory standards, guidelines, or rules that govern how clinical testing is conducted in the jurisdiction, and their impact on litigation involving injuries associated with the use of the product.

Regarding clinical trials, the TPA establishes certain fundamental principles; however, the regulatory requirements are primarily listed in the Human Research Act (HRA), the Human Research Ordinance (HRO), the Clinical Trials Ordinance (ClinO), the Ordinance on Clinical Trials with Medical Devices (ClinO-MedD), as well as the Stem-Cell Research Act (SRA) with its corresponding Ordinance (SRO). In addition, various provisions of other regulations must also be observed, namely the MedDO, the EU MDR and the Helsinki Declaration of the World Medical Association.

Before they can be conducted, clinical trials with Therapeutic Products, in principle, require prior authorisation from Swissmedic (Art. 54(1) TPA) and the competent cantonal ethics committee (Art. 45(1) HRA; Art. 24(1) ClinO; Art. 10(1) ClinO-MedD). Clinical trials with already authorised medicinal products that are used in accordance with the expert information are exempt from this (Art. 54(2) TPA). The ethics committee safeguards the trial subjects' safety. However, and in particular for medical devices, some exceptions from these rules are possible.

The HRA sets forth basic principles for clinical trials, which are specified in Ordinances, namely i) the primacy of human interests, ii) scientific necessity, iii) non-discrimination, iv) the prohibition of commercialisation, and v) scientific requirements (Art. 4 *et seq.* HRA). These are primarily intended to protect persons participating in clinical trials and set high standards for obtaining such persons' free informed consent for their participation in such trials (Arts 7 and 16 HRA).

Anyone arranging a research project involving human subjects is liable for any harm they incur because of the project (Art. 19(1) HRA), with certain exceptions (Art. 10 ClinO and Art. 3(1)(c) ClinO-MedD). This potential liability exposure must be appropriately covered by insurance or other means (Art. 20(1) HRA). The injured person or his/her legal successor may file a direct claim against the insurance company within the scope of coverage (Art. 14(2) HRA). In such a case, however, the insurance company has a right of recourse against the policyholder (Art. 14(3) HRA).

6.2 Does the jurisdiction recognise liability for failure to test in certain patient populations (e.g., can a company be found negligent for failure to test in a particular patient population)?

In general, there is no special liability for failure to test in certain patient populations in Switzerland. However, to fill gaps in the supply of medicinal products for children, a paediatric concept must be developed for medicinal products in an authorisation procedure. This concept must specify the requirements for the development of a medicinal product for paediatric use (Art. 54a(1) TPA and Art. 5 MPO). However, Swissmedic also

considers the paediatric concept assessed by a foreign authority with comparable medicinal product control (Art. 5(3) MPO).

6.3 Does the jurisdiction permit the compassionate use of unapproved drugs or medical devices, and what requirements or regulations govern compassionate use programmes?

Swissmedic may authorise the use of medicinal products that have not yet received a marketing authorisation for a limited period to certain persons or a certain group of persons outside clinical trials that have already been approved in advance (Art. 9b(1) TPA). Such temporary authorisation may be granted to a sponsor if, *inter alia*, i) the medicinal product has previously been used in a clinical trial authorised in Switzerland, ii) a major therapeutic benefit is to be expected, and iii) no alternatively applicable and equivalent medicinal product is authorised in Switzerland (Art. 52 MPLO).

6.4 Are waivers of liability typically utilised with physicians and/or patients and enforced?

Thus far, there is no evident stated special enforcement practice pertaining to waivers of liability for compassionate use. Thus, the general provisions of the Swiss Code of Obligations (CO) apply. The CO stipulates that an exclusion of liability for unlawful intent or gross negligence is null and void (Art. 100(1) CO).

6.5 Is there any regulatory or other guidance companies can follow to insulate or protect themselves from liability when proceeding with such programmes?

Swissmedic has published the "Guideline Temporary Authorisation to Use an Unauthorised Medicinal Product" on its website, which specifies and elaborates the legal provisions of the TPA and the MPLO. The guideline is periodically updated.

7 Product Recalls

7.1 Please identify and describe the regulatory framework for product recalls, the standards for recall, and the involvement of any regulatory body.

Whoever manufactures or distributes Therapeutic Products is required to install a reporting system and notify Swissmedic of adverse effects and incidents that i) are attributable to the Therapeutic Product itself, its use or improper instructions for use, or ii) may endanger the health of consumers, patients, third parties, or animals (Art. 59(1) TPA). Furthermore, quality issues must be reported to Swissmedic (Art. 59(2)(3) TPA). In addition to these notification obligations, there are notification rights – consumers, patients and their organisations, as well as third parties, may notify Swissmedic at will (Art. 59(4) TPA).

Based on such a notification or its official market surveillance, Swissmedic can take the necessary action in a particular instance (Art. 66(2)(e) TPA). As an administrative measure, Swissmedic can order the immediate recall of Therapeutic Products. Since the measures must adhere to the proportionality principle, Swissmedic may instead impose less severe measures, such as the dissemination of harm-preventive behavioural recommendations. Swissmedic and the affected company will typically consent on the measures.

7.2 What, if any, differences are there between drugs and medical devices or other life sciences products in the regulatory scheme for product recalls?

Swissmedic can recall both medicinal products and medical devices. Additionally, Swissmedic also has the competence to revoke the marketing authorisation for medicinal products (Art. 66(2)(b) TPA).

7.3 How do product recalls affect litigation and government action concerning the product?

Recalls of medicinal products or of medical devices, as well as a revocation of a marketing authorisation for medicinal products, can be challenged by ordinary administrative procedure, i.e., by appeal to the Federal Administrative Court (FAC). The decision of the latter can be appealed to the FSC.

Depending on when a recall occurred, it may potentially affect civil litigation. If a Therapeutic Product has already caused harm before it was recalled, such a recall may constitute circumstantial evidence that the Therapeutic Product was not sufficiently safe. Therefore, a recall may expose a manufacturer or distributor of Therapeutic Products to civil law claims.

7.4 To what extent do recalls in the United States or Europe have an impact on recall decisions and/or litigation in the jurisdiction?

A manufacturer or a marketing authorisation holder in Switzerland must report any adverse reactions suspected of being associated with a medicinal product that are detected in Switzerland or abroad to Swissmedic (Art. 61(4) MPO). Depending on the reason for the notification, different notification deadlines must be met (Art. 62 *et seq.* MPO). The response to such alerts is entirely up to Swissmedic's discretion. However, recalls in the US and/or the EU might encourage Swissmedic to take similar administrative measures in Switzerland, as well.

7.5 What protections does the jurisdiction have for internal investigations or risk assessments?

Internal investigations or risk assessments are in principle covered by the attorney-client privilege. Thus, communications between a life sciences company and its external attorney are privileged and do not have to be disclosed if they are part of a professional mandate. The attorney-client privilege therefore limits the duty to disclose documents on internal investigations or risk assessments. However, according to the FSC, this legal privilege (currently) does not extend to in-house legal counsel (see question 8.10).

7.6 Are there steps companies should take when conducting a product recall to protect themselves from litigation and liability?

Companies are well advised to work closely with the competent supervisory authorities to reduce or avoid any fines and to ensure a successful recall process. For the latter, it is essential to ensure the traceability of all medicinal products (Art. 16 MPLO) and medical devices (Art. 64(1) TPA).

8 Litigation and Dispute Resolution

8.1 Please describe any forms of aggregate litigation that are permitted (i.e., mass tort, class actions) and the standards for such aggregate litigation.

Aggregate litigation such as mass tort and class actions is generally not permissible under Swiss law. Since 2013, there have been discussions in Switzerland regarding the implementation of collective redress. Even though a concrete draft law has been available since 2021, it is currently unforeseeable whether or when the Swiss legislator may adopt the said revision to Swiss civil procedure law.

However, there are alternative, albeit less effective, ways for a group of claimants to cooperate to reduce or share litigation costs and strengthen their negotiating position. Thus, two or more individuals whose claims result from the same or similar factual basis and legal grounds may appear jointly as claimants (Art.71(1) CPC). In addition, associations and other organisations whose bylaws permit them to safeguard the interests of particular groups of persons (who need not be members of the association) may file an action in their own name for the alleged violation of core personality rights of the members of such groups (Art. 89(1) PC). Such proceedings are restricted to non-monetary claims, such as cease-and-desist orders and declarations of illegal activity. A revision of the CPC was enacted in March 2023 and will enter into force on 1 January 2025 (revCPC). However, the proposal to amend and expand actions of associations has not materialised in this revision for the time being.

8.2 Are personal injury/product liability claims brought as individual plaintiff lawsuits, as class actions or otherwise?

Personal injury and/or product liability claims are brought as individual plaintiff lawsuits.

8.3 What are the standards for claims seeking to recover for injuries as a result of use of a life sciences product? (a) Does the jurisdiction permit product liability claims? (b) Are strict liability claims recognised?

In general, i) the PLA, which is based on the EU product liability directive, ii) contract law, and iii) tort law may be used to recover for injuries as a result of using a defective life sciences product.

According to the PLA, a manufacturer is liable for damages if a defective product causes i) death or injury to a person, or ii) damage to or destruction of a commonly used consumer product (Art. 1(1) PLA). This liability cannot be contractually excluded (Art. 8 PLA). However, there are limitations on liability, such as when the product is used for commercial purposes (Art. 5(1)(c) PLA) or for damage of the defective product itself (Art. 1(2) PLA).

Since the PLA is neither a comprehensive nor an exclusive cause of action, an injured individual may claim damages based on other legal provisions, such as the CO (Art. 11(2) PLA). Hence, an injured person may assert further legal grounds to bring a claim against parties with whom he/she has a contractual relationship. Such additional legal grounds may include, for instance, the general contractual liability provisions (Art. 97 *et seq.* CO) and special contractual liability provisions, such as those of Swiss sales contract law (Art. 197 *et seq.* CO).

Furthermore, Swiss tort law permits for liability claims based on fault for unlawfully caused damages to third parties (Art. 41 *et seq.* CO). As the FSC has set an extremely high standard for such claims, the likelihood of success is uncertain.

8.4 Are there any restrictions on lawyer solicitation of plaintiffs for litigation?

The Federal Lawyers Act (FMLA) and the Rules of Professional Conduct govern the solicitation principles applicable to lawyers. Therefore, advertising is permitted "as long as it remains objective and meets the public's need for information" (Art. 12(d) FMLA). As a result, advertising by lawyers to launch litigation is very uncommon in Switzerland.

8.5 What forms of litigation funding are permitted/utilised? What, if any, regulation of litigation funding exists?

Litigation financing is permitted in Switzerland and widely used in practice (FSC 2C_814/2014 of 22 January 2015). At various times in the past, the FSC has been able to weigh in on this topic. Litigation financing must be provided by a third party who is not a party to the litigation and is typically used for amounts in dispute of approximately CHF 500,000 and above. Typically, the percentage of success ranges between 20–30%.

In Switzerland, there are currently no specific regulations regarding litigation funding. In the context of the latest revision of the CPC, the Federal Council (i.e., the Swiss government) is authorised to provide the public with information regarding litigation funding (Art. 400(2bis) revCPC). This is designed to offer individuals – who, on the one hand, lack the financial resources to fund civil procedures and, on the other, do not qualify for free legal aid – the option to eliminate the financial barriers to the procedural assertion of their rights.

8.6 What is the preclusive effect on subsequent cases of a finding of liability in one case? If a company is found liable in one case, is that finding considered *res judicata* in subsequent cases?

A preclusive effect only applies to the same claimant and defendant on the same dispute matter. If a company is the defendant in such litigation, there is no preclusive effect against a different claimant. Thus, if a company is found liable in one case, that finding is not considered *res judicata* in subsequent cases.

8.7 What are the evidentiary requirements for admissibility of steps a company takes to improve their product or correct product deficiency (subsequent remedial measures)? How is evidence of such measures utilised in litigation?

In civil proceedings, testimony, documents, visual inspection, expert opinions, written information, as well as party cross-examination and evidence statements are admissible as evidence (Art. 168(1) CPC). Which of these admissible evidence types is used in a particular proceeding depends on how the evidence can be introduced. However, first and foremost, documentary evidence is utilised. Therefore, it is suggested that subsequent remedial measures be documented and archived.

8.8 What are the evidentiary requirements for admissibility of adverse events allegedly experienced by product users other than the plaintiff? Are such events discoverable in civil litigation?

In general, civil litigation only involves the claimant and the

defendant. However, third parties may participate by intervening (Art. 73 *et seq.* CPC) or by appearing as witnesses (Art. 169 CPC). In the latter case, they are obliged to cooperate, namely by testifying truthfully, disclosing documents and by tolerating medical examinations by experts (Art. 160(1) CPC). To appear as a witness, the individual must be called as a witness by one of the parties to the proceedings.

8.9 Depositions: What are the rules for conducting depositions of company witnesses located in the jurisdiction for use in litigation pending outside the jurisdiction? For example, are there "blocking" statutes that would prevent the deposition from being conducted in or out of the jurisdiction? Can the company produce witnesses for deposition voluntarily, and what are the strategic considerations for asking an employee to appear for deposition? Are parties required to go through the Hague Convention to obtain testimony?

Conducting depositions is a particular method of collecting evidence suitable to common law systems and is mostly unknown in Swiss law. Switzerland, however, is a signatory to the Hague Evidence Convention. Thus, a procedural act that must be performed in Switzerland in support of judicial procedures in foreign countries may occur.

Examining a Swiss-based witness under oath, for example in the context of US discovery procedures, is therefore typically admissible from a Swiss perspective. However, Switzerland has a blocking statute that prohibits foreign states from engaging in unauthorised activity on Swiss soil. The examination of Swiss witnesses necessitates prior authorisation from i) the relevant cantonal authority, and ii) the Federal Department of Justice and Police, regardless of whether the deposition is performed in person or remotely through video conference. Swiss criminal law forbids acting on behalf of a foreign state without authorisation (Art. 271(1) SPC), as well as disclosing trade secrets to a foreign organisation or private company (Art. 273 SPC). Considering the potential consequences under Swiss criminal law, it is crucial to submit a deposition request addressing all pertinent facts.

The relevant witness must be summoned in the language of the place where he/she will testify. He/she is under no obligation to appear or assist in any way in the taking of evidence. Independently of this, Swiss criminal law also prohibits deposition witnesses from disclosing trade secrets gained during their profession (Art. 321(1) SPC; see question 5.2).

8.10 How does the jurisdiction recognise and apply the attorney-client privilege in the context of litigation, and with respect to in-house counsel?

Switzerland recognises the attorney-client privilege in the context of litigation. Attorneys are bound by professional secrecy for an indefinite period of time, and in relation to everyone (Art. 13(1) FMLA and Art. 321 SPC). This includes every piece of information that their clients entrust to them during their professional activity or that otherwise comes to their attention while acting for a client. Even a release by the client or the governing body does not compel an attorney to disclose information entrusted to him. Consequently, attorneys may also refuse to testify in court by invoking professional privilege (FSC 136 III 296, 299). Therefore, neither a party to the proceedings nor third parties are required to produce documents or communications from an attorney (Art. 160(1)(b) CPC).

According to the FSC, this legal privilege does not extend to in-house legal counsel. However, the recent reform of the CPC will introduce a limited in-house counsel privilege, which permits parties and third parties to refuse disclosure of documents under certain conditions as of 1 January 2025 (Art. 167a revCPC).

8.11 Are there steps companies can take to best protect the confidentiality of communications with counsel in the jurisdiction and communications with counsel outside the jurisdiction for purposes of litigation?

In Switzerland, all communications with and work products of an attorney enrolled at the Bar are automatically protected if they relate to the attorney's typical professional activity. The same applies to communications with and work products of EU/EFTA external legal counsel located outside of Switzerland. To avoid unintentional disclosure, however, it is best practice to designate privileged communication as "privileged and confidential", such as in the subject line of letters and emails.

8.12 What limitations does the jurisdiction recognise on suits against foreign defendants?

In international matters, Swiss courts will decide on their jurisdiction and applicable law based on the Private International Law Act (PILA). For cases concerning parties located in the EU, Norway and/or Iceland, the Convention on Jurisdiction and the Recognition and Enforcement of Judgements in Civil and Commercial Matters signed in Lugano (LugC) is applicable. In contrast to the PLA, it does not determine the applicable law but just the forum.

Regardless of where the claimant lives, a claim may be filed with Swiss courts if the defendant resides in Switzerland. If the defendant is located abroad, both the PILA and the LugC make numerous references to the legislation of the state in which the defendant is located. However, there are several conditions under which a foreign defendant may be sued in Switzerland.

8.13 What is the impact of U.S. litigation on "follow-on" litigation in your jurisdiction?

In Switzerland, "follow-on" litigation is not prevalent.

8.14 What is the likelihood of litigation evolving in your jurisdiction as a result of U.S. litigation?

Owing to substantial differences between the legal systems of the US and Switzerland, the emergence of civil litigation in the US is not necessarily predictive of litigation in Switzerland. However, it cannot be ruled out that Swiss authorities may initiate administrative and criminal proceedings in Switzerland in reaction to public cases in the US.

8.15 For EU jurisdictions, please describe the status and anticipated impact of the Collective Redress Directive and Product Liability Directive on drug and medical device litigation in your jurisdiction.

Since Switzerland is not an EU Member State, it is not required to implement EU directives into domestic law. In Switzerland, the Collective Redress Directive thus has no application. The installation of collective redress has been discussed for years but was (for the time being) not adopted in the last revision of the CPC (see question 8.1).

By contrast and as part of autonomous implementation, Switzerland has voluntarily transposed the Product Liability Directive and issued the PLA (see question 1.3 *et seq.*). It is therefore reasonable to assume that Switzerland might also implement the amended Products Liability Directive in the future. However, it could be quite some time before it becomes certain whether and when this will occur. Currently, a revision of the PLA is not apparent.

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