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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.

The Medical Products Agency (*sw. Läkemedelsverket*) (MPA) is the regulatory authority for pharmaceuticals, medical devices and cosmetics.

The principal legislation for pharmaceuticals, implementing the key parts of Directive 2001/83/EC, is the Medicinal Products Act (2015:315), supplemented by the Regulation (2015:458) on medicinal products. Regulation (EU) 536/2014 on clinical trials on medicinal products (CTR) is directly applicable in Sweden. The rules for the trade with pharmaceutical products are found in the Medicinal Products Trading Act (2009:366) and the supplementary Regulation (2009:659). Entities other than pharmacies may trade certain over-the-counter (OTC) products, which is regulated in a separate law, the Act on trade with certain over-the-counter medicinal products (2009:730). The legislation described above is supplemented by a great number of ordinances issued by the MPA.

Both Regulations (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) are directly applicable in Sweden. However, the Regulations are complemented by the Act (2021:600) with supplementary rules to the EU Regulations on medical devices, the Ordinance (2021:631) with supplementary rules to the EU Regulations on medical devices, as well as a number of ordinances issued by the MPA.

The principal pieces of legislation for cosmetic products are Regulation (EC) 1223/2009 on Cosmetic Products (CPR), Regulation (EU) 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products, Regulation (2013:413) on Cosmetic Products, and the Ordinance (LVFS 2013:10) on Cosmetic Products.

Supplements are considered foodstuff, which is regulated under Swedish food law, including the Food Act (2006:84) and the supplementary ordinances issued by the Swedish Food Agency.

The Dental and Pharmaceutical Benefits Agency (*sw. Tandvårds- och läkemedelsförmånsverket*) decides the pricing and reimbursement of pharmaceuticals and medical devices.

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?

A liability claim can be based on, for example, the Product Liability Act (1992:18) (*sw. Produktansvarslagen*) (PAL), or the Tort Liability Act (1972:207) (*sw. Skadeståndslagen*). PAL provides for a strict liability for the manufacturer and importer, if there are any safety deficiencies to the product in question. A safety deficiency is when a product is not as safe as could reasonably be expected, determined on the basis of how the product is to be used and how it has been marketed, also taking into account the instructions provided with the product. If there are no safety deficiencies, a claim could be brought under the Tort Liability Act. Such a claim requires that the liable party has been negligent.

Injuries incurred on patients by caregivers entitle the patient to compensation according to the Patient Injury Act (1996:799) (*sw. Patientskadelagen*). Caregivers are required to have insurance covering such claims.

For pharmaceuticals, product liability cases are scarce in the general courts, as most claims are made under the Swedish Pharmaceutical Insurance (*sw. Läkemedelsförsäkringen*) (LFF). For a claim to be covered under the insurance, the Marketing Authorisation (MA) holder must be part of the LFF, which is voluntary for the pharmaceutical company in question. Currently, about 99 per cent of all sales of pharmaceuticals in Sweden are covered by the LFF. A decision by the LFF can be appealed to the Pharmaceutical Injury Panel (*sw. Läkemedelsskadenämnden*).

For a clinical trial drug, the sponsor must, in accordance with the CTR, have insurance or similar covering personal injuries for the subjects of the clinical trial.

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

For product liability claims, the fact that the product does not comply with applicable Regulations could indicate that the product does not fulfil the safety demands that could reasonably be expected. Similarly, non-compliance with applicable Regulations could indicate that the manufacturer or importer has been negligent, and is thus liable to pay damages under the Tort Liability Act. However, a case-by-case assessment must be made.

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?

The Ethical Rules adopted by the trade association for the research-based pharmaceutical industry in Sweden (*sw. Läkemedelsindustriföreningen*) regulate the promotion of pharmaceuticals, as well as interactions with, for example, healthcare

professionals (HCPs), healthcare organisations and patient organisations. The rules on collaboration with healthcare also apply to members of Swedish Medtech.

The Ethical Rules are not mandatory, and only members have committed to apply the rules. However, the Ethical Rules serve as a guideline for the courts, for example, when determining "good practice" under the Marketing Act (2008:486).

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?

The product leaflet and the summary of the product characteristics (SmPC) need to provide warnings regarding the pharmaceutical product. Hence, warnings to the public and prescribers are normally provided through these documents. Warnings must also be included in the marketing of a pharmaceutical product. Companies also have an obligation to continuously collect and report side effects in periodic safety reports to the MPA.

For medical devices, the rules on product safety in the MDR and IVDR are supplemented by the general rules in the Product Safety Act (2004:451). Similarly, the rules on product safety in the CPR are supplemented by the general rules in the Product Safety Act, as well. Accordingly, information should be provided so the product can be used in a safe manner, which would include warnings of the risks of a medical device or cosmetic product.

2 Manufacturing

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

In order to manufacture, package or repackage a pharmaceutical product, or import such products from a third country, a manufacturing permit from the MPA is required. For example, a manufacturer must have at least one responsible person, either employed or contracted as an agent. The responsible person must have adequate education and experience, and certify that the quality is according to the Good Manufacturing Practices (GMPs) as well as the demands of the MA.

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?

Within the EU, it is the Member State where the manufacturing site is located that is responsible for the inspection and approval of the facility. If a product has been manufactured in a third country, the importer is the one subject to inspection, unless a Mutual Recognition Agreement is in place. The EU has such agreements regarding certain conformity assessment procedures relating to, e.g., GMPs for pharmaceuticals and medical devices with Australia, Canada, Israel, Japan, New Zealand, Switzerland and the U.S.

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

The fact that the manufacture of a product does not comply with applicable Regulations could affect the liability of the manufacturer; see question 1.3 above.

3 Transactions

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

As for all other mergers and acquisitions, such transactions are regulated under the Swedish Competition Act (2008:579), with the Swedish Competition Authority (SCA) as the competent authority. As such, any merger or acquisition should be reported to the SCA if the concerned companies together have an annual turnover in Sweden that exceeds SEK 1 billion and at least two of the companies concerned each have annual sales in Sweden that exceed SEK 200 million.

In addition, life sciences businesses may fall under the scope of the Swedish Foreign Direct Investment Act (2023:560) (FDI Act) as "essential services" which are worthy of protection in Sweden. Essential services are defined in the Swedish Civil Contingencies Agency (MSB)'s implementing Regulations MSBFS (2023:4).

Direct and indirect investments into businesses covered by the FDI Act must be notified to the Inspectorate of Strategic Products (ISP) ahead of their implementation, but not before they are imminent. Such notification is mandatory and suspensory if, *inter alia*:

i. After the investment, the investor, someone in its ownership structure, or someone on whose behalf the investor is acting, would, directly or indirectly, come to hold votes equal to or exceeding any of the thresholds of 10, 20, 30, 50, 65 or 90 per cent of the votes in such a limited liability company or European company, or such an economic association engaged in activities worthy of protection.
ii. The investor, someone in the investor's ownership structure or someone on whose behalf the investor is acting, in any other way through the investment would acquire a direct or indirect influence in the management of such a limited liability company, European company, trading partnership or simple partnership, or in the management of such an economic association or foundation that carries out or will carry out activities worthy of protection.

There are additional rules for less common business forms, as well as exceptions for newly established businesses and certain industries within the category of essential services. Due to word-count limitations, a full recount of the Act cannot be made here. A case-by-case assessment is necessary.

The ISP is mandated to prohibit foreign investments that could have a detrimental effect on Sweden's security and public order or public safety in Sweden. If an investor fails to notify a notifiable investment, the ISP may prepare a basis for such notification. The ISP can also initiate reviews on its own initiative in situations where a filing has not been triggered, if it has reason to assume that the investment may have a detrimental effect on Sweden's security or on public order or public safety in Sweden.

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 specific restrictions placed on foreign ownership of life sciences companies or manufacturing facilities. However, as for other companies, life sciences companies that have a change in ownership need to report the ultimate beneficial owner to the Swedish Companies Registration Office.

Currently, as at the time of writing, Swedish law presents no immediate restrictions on existing foreign ownership in life sciences businesses. Foreign investors looking to invest (or increase existing ownership) in businesses covered by the FDI Act should, however, be aware of the specific obligations for investment into such businesses (see further at question 3.1 above).

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.

The Marketing Act governs the advertising and promotion of all products in Sweden, including pharmaceuticals, medical devices and other life sciences products.

The principal pieces of legislation that govern the advertising, promotion and sale of pharmaceuticals are the Medicinal Products Act and the Medicinal Products Trading Act. Additionally, the MPA has issued a number of ordinances; for example, the Ordinance (LVFS 2009:6) on Marketing of Medical Products for Humans, the Ordinance (LVFS 2009:20) on Trade with Non-prescription Pharmaceuticals, and the Ordinance (LVFS 2009:9) relating to pharmacies' trade with pharmaceuticals.

Moreover, if the pharmaceutical company has committed to adhere to the Ethical Rules, these will include detailed rules regarding advertising, promotion and sale of pharmaceuticals. The Swedish pharmaceutical industry's Information Examiner Committee (IGN) and the Information Practices Committee (NBL) have the task of auditing and assessing any pharmaceutical company's violation of these rules.

As briefly described above, the MPA is also the responsible authority for the marketing and sale of medical devices and cosmetic products. A notification of a medtech company's breach of the Ethical Rules is prepared by Swedish Medtech's office. Decisions are made by Swedish Medtech's board.

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")?

Unauthorised pharmaceuticals may not be marketed. Further, all marketing of pharmaceuticals must be in accordance with the SmPC.

To market a medical device for off-label use would normally be considered misleading in accordance with the Marketing Act. Further, in accordance with the MDR and IVDR, it is prohibited to use text that may mislead the user with regard to the device's intended purpose, safety and performance by suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

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?

In case a company breaks the rules in the Medicinal Products Act, the MPA may issue a prohibition or injunction, which in turn could be accompanied by a penalty such as a fine.

Under the Marketing Act, an actor may be prohibited from continuing the marketing under penalty of a fine. Although rarely utilised, an actor may additionally be ordered to pay a special punitive fee (*sw. marknadsstörningsavgift*).

If the company has committed to adhere to the Ethical Rules and these rules are breached, the company may receive a fine. The IGN and NBL are entitled to determine the fee.

For medical device companies that are members of Swedish Medtech, three different measures may be considered in the event of an infringement of the Ethical Rules: reminder; warning; or exclusion from the organisation.

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?

The General Data Protection Regulation (EU) 2016/679 (GDPR) applies directly in Sweden, and is supplemented by the Act (2018:218) with Supplementary Rules to the GDPR. The GDPR has a broad territorial reach and applies to any life sciences company established in the EU, as well as any company established outside the EU that carries out processing activities related to the offering of goods or services in the EU. Thus, the GDPR applies to any life sciences company distributing products to (or from) Sweden.

The processing of personal data concerning a person's health is prohibited unless there is an applicable express exception for the processing in the GDPR. Moreover, the ruling from the Court of Justice of the European Union in Case C-311/18 (*Schrems II*) poses further challenges for companies transferring personal data to countries outside the EU/EEA. Such companies need to carry out a case-by-case assessment before transferring personal data to entities established in a third country. On 10 July 2023, the European Commission decided that the U.S. has an adequate level of protection and thus, provided that the recipient is a part of the EU-U.S. Privacy Data Framework, transfers to the U.S. are possible. For other third countries without an adequacy decision and any further third-country transfers conducted by U.S. companies, the controller must still carry out the transfer impact assessment and adopt relevant safeguards.

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?

The principle of public access to official records is one that is fundamental in Swedish law. As a main rule, any document submitted to the courts or any other public authorities is available to the general public.

However, under the Public Access to Information and Secrecy Act (2009:400), potential trade secrets may be classified as confidential. An assessment is made on a case-by-case basis, and a decision that a document or part of a document should be kept secret can be appealed to court.

The confidentiality of documents, produced or submitted by a party under arbitration proceedings, is agreed upon by the parties.

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

Digital care activities must be conducted so that all requirements for healthcare are met, including the patient's need for continuity and security. Any caregiver providing healthcare and

prescribing pharmaceuticals to patients, via video, for example, is obligated to have an electronic system giving the company access and allowing the company to submit information to the national list of prescription of pharmaceuticals. In addition, safety requirements of the GDPR must be considered.

Digital health products may, depending on the intended purpose and use, be considered medical devices. In such case, they must comply with the legal requirements for medical devices.

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.

Rules on clinical trials on pharmaceuticals can be found in the CTR and in the Act (2018:1091) with supplementary rules on ethical review to the CTR. In addition, the Medicinal Products Act also includes rules that are supplementary to the CTR, in relation to, for example, permits and the responsible examiner. It is supplemented by the Regulation (HSLF-FS 2021:109) on complementing rules to the CTR, which includes rules on when authorisation of manufacturing is not needed.

The CTR entered into force on 31 January 2022. From 31 January 2022, there are three yearly transitional rules to transfer all active clinical trials to be conducted under the CTR. However, since 31 January 2023, all applications for new clinical trials must be submitted in the EU Clinical Trial Information System (CTIS) and performed in accordance with the CTR.

Prior to the CTR, the Medical Products Act governed clinical trials for pharmaceuticals. It was supplemented by the Regulation (LVFS 2011:19) on Clinical Trials on Humans. The Regulation has been replaced by the Regulation (HSLF-FS 2021:109) on complementing rules to the CTR for human use.

Prior to clinical trials on humans, approval is needed. In Sweden, the applications for approval are handled in parallel by the MPA, the Swedish Ethical Review Board (*sw. Etikprövningsmyndigheten*) and the Regional Biobank Center (*sw. Regionalt Biobankscentrum*), which contributes with a national decision to be provided in the CTIS.

The principal legislation that governs clinical testing on medical devices is the MDR and IVDR.

Clinical trials must be conducted in line with the rules of good clinical practice, the international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. The World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects is not legally binding, but has had great influence on the rules in Sweden. These rules do not impact litigation involving injuries associated with the use of the product *per se*, as this will be assessed based on all facts of the case at hand.

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)?

The rules regarding approval of new pharmaceuticals in Sweden are based on Directive 2001/83/EC. For a pharmaceutical product to be approved, the company must show a positive risk-benefit relationship for the patient group that is defined by the indication. No special liability for failure to test in certain patient populations exists.

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

Compassionate use of unapproved pharmaceuticals is permitted in Sweden under a certain programme. The programme targets patients with chronic or severe weakening illnesses or patients with a life-threatening disease that cannot be treated satisfactorily with an approved pharmaceutical product.

The pharmaceutical product must be subject to the categories in articles 3.1 and 3.2 of Regulation (EC) 726/2004, and must either be subject to an application for sale through the central procedure or through clinical trials.

Further, there must be sufficient documentation as to the effect and safety of the product, where the benefit in relation to the risks must be assessed as mainly positive for the patient group. The pharmaceutical product must be available until it has obtained approval and is available on the market, i.e., available in pharmacies, or alternatively until the programme is stopped by the MPA or the holder of the programme.

HCPs can also meet the need for a drug that is not approved in Sweden via a licensing procedure with the MPA.

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

No, not typically. The sponsor must ensure insurance coverage for injuries in connection with the clinical trial. For a clinical trial drug, the sponsor must, in accordance with the CTR, have insurance covering personal injuries to the subjects of the clinical trial. Further, in the application for ethical approval, the sponsor must state if the Patient Injury Act is applicable, or if a special insurance can be obtained for the study.

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

No such regulatory or other guidance is available at the moment.

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.

The regulatory framework for product recalls differs depending on the type of product.

In general, the Product Safety Act is applicable to the extent there is no *lex specialis*. A product is safe if it, with normal or reasonable foreseeable use and life expectancy, does not convey any risk for people's health and safety. The risk must be acceptable, taking into consideration how the product is used, and shall be compatible with the high safety level with regard to people's health and safety.

However, most recall situations are regulated for pharmaceuticals, medical devices and cosmetics.

The MPA may decide that a company shall recall a pharmaceutical product if, e.g., it is needed to prevent injury, the pharmaceutical product is not effective for its purpose, the

pharmaceutical product is not functional, the pharmaceutical product is not of good quality, or the pharmaceutical product's qualitative or quantitative composition does not correspond with the stated or essential requirements in connection with production or import.

Further, the MPA may decide that an MA shall be temporarily revoked, amended or withdrawn if a company that has received an injunction cannot show that the pharmaceutical product still meets the requirements for the authorisation, the conditions specified in the approval were not complied with, a decision to recall a drug has not been complied with, or the basic conditions for approval in other cases are no longer being met.

Under the MDR and IVDR, medical devices need to fulfil the general safety and performance requirements listed in Annex 1 to the relevant Regulation. The regulatory framework for product recall differs depending on the type of product.

The safety requirements for cosmetic products are regulated in the CPR. A cosmetic product must be safe for human health when used under normal or reasonably foreseeable conditions of use, taking into account, in particular, the requirements specified in article 3 of the CPR. If a company's responsible person considers or has reason to believe that a cosmetic product that they have placed on the market is not in conformity with the CPR, it shall immediately take the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate. Furthermore, where the cosmetic product presents a risk to human health, responsible persons shall immediately inform the competent national authority.

Where a cosmetic product is deemed to pose a serious health risk to consumers, the MPA may decide to withdraw or recall the product.

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?

Pharmaceuticals, medical devices and cosmetic products can be recalled and withdrawn. The regulatory agency is, in all cases, the MPA. For pharmaceutical products, the MPA also has the possibility to withdraw the MA.

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

A decision by the MPA to recall a product is a decision that may be appealed to the Administrative Court. A leave to appeal is necessary to have a case tried in the Administrative Court of Appeal and the Supreme Administrative Court.

With respect to potential civil litigation, companies may recall their products to prevent damages and in order not to expose themselves to potential liability 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 referral is a European procedure used to resolve issues such as concerns over the safety of a pharmaceutical product or a class of pharmaceuticals within the EU. In a referral, the European Medicines Agency is requested to conduct a scientific assessment. Situations that fall under this procedure include, e.g., consideration for suspension or revocation of an MA. For most referrals, the European Commission issues a decision to all Member States, reflecting the measures to take to implement the Agency's recommendation.

Articles 93–100 of the MDR and 88–95 of the IVDR contain provisions on market control. Through market control, the competent authority ensures that the products placed on the market comply with the applicable legislation. The Member State concerned must take appropriate measures to restrict or prohibit the supply of the product on the market.

Under article 23 of the CPR, there is an obligation for the competent authority to inform authorities in other EU Member States. The authorities may then use the information for market surveillance, etc.

Recalls in the U.S. do not have a direct impact on recall decisions in Sweden. However, under the Sectoral Annex for Pharmaceutical Good Manufacturing Practices of the Mutual Recognition Agreement between the U.S. and EU, the MPA shares and takes part in information concerning recalls.

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

Internal investigations or risk assessments carried out by a company are normally considered trade secrets. If such documents are supplied to an authority or court, they are subject to the rules in the Public Access to Information and Secrecy Act; see question 5.2 above.

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

It is important for companies to comply with traceability demands in order to be able to recall products. The MDR and IVDR impose new demands on companies dealing with medical devices.

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.

Group actions are possible in Sweden but are extremely rare. Under the Swedish Group Proceedings Act (2002:599), a group action may be brought by a representative for a group of claimants, but with legal effects for all group members.

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

A great majority of product liability cases are brought as individual plaintiff lawsuits. Product liability claims due to the use of pharmaceutical products are normally made under the insurance provided by the LFF. Other product liability claims, for instance due to injuries incurred from medical devices, are made to a general court.

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?

Product liability claims are recognised in Sweden. There is a strict liability for the manufacturer/importer according to PAL, provided that the product has a safety deficiency as defined in the Act.

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

According to the Ethical Rules of the Swedish Bar Association, it is forbidden for members of the Swedish Bar Association to use or exploit someone's vulnerable situation (i.e., ambulance chasing).

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

Sweden does not have a tradition of litigation funding. However, the interest in litigation funding has increased in the last couple of years, including the life sciences sector. There are several different actors on the Swedish market, and they apply flexible funding setups.

Due to litigation funding being a relatively novel phenomena in Sweden, third-party funding of litigation is unregulated as such. However, the SCC Arbitration Institute has adopted a policy encouraging the parties to disclose any third party with a significant interest in the outcome of the dispute, including funders, parent companies and ultimate beneficial owners. In order to facilitate a court's or expert's conflict-of-interest check, it may be necessary to disclose such information during litigation in general courts as well.

A member of the Swedish Bar Association may not have a financial interest in their cases, as it would be contrary to the Ethical Rules of the Swedish Bar Association. Contingency fees are therefore normally not allowed.

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?

If a company is found liable in one case, that finding is not considered *res judicata* in subsequent separate cases. Accordingly, a different claimant is entitled to relitigate the issues. A court of law is not formally bound by the findings of another court in another case. However, in practice, prior judgments on the same matter may have a substantial influence on the later proceedings.

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?

Subsequent remedial measures would normally not affect the outcome in a pending case. However, there is a general principle that a claimant must limit the negative effects of a tortious act. A lack thereof could justify an alteration of the damages awarded by the court, with reference to contributory negligence by the claimant.

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, a principle of free evaluation of evidence applies in Swedish courts. In relation to a claim brought under PAL, there must be a safety deficiency. The claimant bears the burden of proof that there has been a safety deficiency, but in the preparatory works it is stated that the evidence required to show that there is a proximate cause should not be put too high.

When a claim is made under the LFF insurance, the claimant must make it probable that the personal injuries sustained have been caused by the pharmaceutical product, and that the injury could not be foreseen.

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?

Depositions are not utilised in Swedish courts, as a principle of immediateness applies. Subject to the national legislation of another country, a foreign court can turn to a Swedish court and ask for assistance in accordance with the international conventions governing such agreements.

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?

An attorney's duty of confidentiality is regulated in the Code of Judicial Procedure. In short, an attorney is obliged to ensure the confidentiality of what he or she has become aware of in his or her professional practice. The attorney-client privilege also applies in relation to a court of law. An attorney may only be heard as a witness of what they have become aware of in their professional practice, if this is permitted by law or if the person to whose advantage the duty of confidentiality applies allows it. Further, attorneys may not be subject to an order for production of documents. Attorney-client privilege does not apply between in-house counsel and a company.

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?

Attorney-client privilege applies between Swedish counsel and the client or foreign counsel in the case. However, the Regulations of the country of the foreign counsel should also be subject to careful review.

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

There are no limitations as such to claim damages from foreign companies. Rather, the general rules on choice of law and competent courts will be applicable, taking into account, e.g., where a claimant is domiciled, where the tortious act has been committed, etc.

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

As a main rule, foreign proceedings have no legal effect in

Sweden. The court will likely consider and review the facts of the U.S. case, but they will not have any direct legal effect for the Swedish proceedings.

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

It depends on the circumstances of the case. For civil litigation, due to the fact that the U.S. and Swedish law systems differ, both with respect to procedural and material law, litigation evolving in the U.S. does not necessarily mean that litigation will develop in Sweden. With respect to administrative and criminal proceedings, it is possible that regulatory authorities in Sweden will open investigations as a result of litigation in the U.S.

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.

The Swedish Regulation implementing the Collective Redress Directive entered into force on 1 January 2024. As already mentioned above, Sweden does not have a great tradition of group actions. However, with reference to the new law, a slight increase in collective redress could be anticipated, which in turn also could affect drug and medical device litigation.

As the proposal for the Product Liability Directive has not yet been adopted in the EU, no proposal for a Swedish Act implementing the Directive has been set forth yet. Swedish law already complies with the Directive to some extent. For example, Swedish law already contains provisions enabling a court to order a party to disclose evidence. However, some changes in the current legislation are expected. For instance, the proposed presumption of defectiveness in the Directive will likely ease the claimant's burden of proof as compared to the current legislation.

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Setterwalls is one of Sweden's leading full-service business law firms and one of Sweden's largest law firms, assisting clients from its three offices in Sweden's largest cities – Stockholm, Gothenburg (Göteborg) and Malmoe (Malmö). Setterwalls is an independent law firm with an extensive, well-established international network, and is also a member of the global business law firm network the World Law Group (WLG). Established in 1878, Setterwalls is also Sweden's oldest law firm.

Our intellectual property team includes specialists on all aspects of intellectual property law. We maintain a strong position in the patent litigation and regulatory arenas in Sweden, both in the life sciences field and in other fields of technology.

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