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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.

For medicinal products, finished medicinal products and over-the-counter (OTC) medicinal products, as well as medical devices, the Federal Ministry of Health (*Bundesministerium für Gesundheit* – BMG) is the principal legislative body. Within the remit and scope of the BMG the areas of responsibility are divided between the Paul-Ehrlich-Institute (PEI), which is the competent higher federal authority responsible for vaccines and biomedicines, and the higher federal authority responsible for medicinal products and medical devices (*Bundesinstitut für Arzneimittel und Medizinprodukte* – BfArM) situated in Bonn.

The local state supervisory authorities of the Federal States (*Bundesländer*) are responsible for monitoring the products in the market. Supplements and cosmetics, however, are under the supervision of the Federal Office of Consumer Protection and Food Safety (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* – BVL), which is responsible for the coordination and registration of the products. For these products, the local authorities of the Federal States are also responsible for market surveillance – according to Article 34 of Regulation (EC) 1223/2009. After supplements have been registered with the BVL, it will inform the local authorities of the Federal States, which must then carry out market surveillance of the registered products. The Federal Ministry for Nutrition and Agriculture (*Bundesministerium für Ernährung und Landwirtschaft* – BMEL) is the principal legislative body for foodstuffs.

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?

According to Section 84 of the German Medicinal Products Act (*Arzneimittelgesetz* – AMG), last amended on 27 July 2023, the pharmaceutical entrepreneur who placed a medicinal product which is subject to compulsory marketing authorisation or is exempted by ordinance from the need for a marketing authorisation on the market is liable without fault being required if a person is killed or the body or the health of a person is substantially damaged as a result of the use of the medicinal product. In this case, the pharmaceutical entrepreneur is obliged to compensate the injured person for the damage caused, provided that the medicinal product has been used in accordance with its intended purpose and the harmful effects do not exceed the limits considered tolerable in light of the current medical knowledge, or the damage has occurred as a result of labelling, expert information or instructions for use that do not comply with current medical knowledge. This means that side effects listed in the package insert leaflet (PIL) and Summary of Product Characteristics (SmPC) do not trigger any obligation to pay damages. In this respect, the approval of the medicinal product and the contents of the PIL and the SmPC approved by the competent licensing authority provide a protection from liability for the pharmaceutical entrepreneur. Section 88 AMG provides the maximum amounts to be paid by a party liable pursuant to Section 84 AMG.

In addition to liability pursuant to Section 84 AMG, the obligation to pay damages may also arise from the general provisions – according to Sections 823 *et al.* of the German Civil Code (*Bürgerliches Gesetzbuch* – BGB), last amended on 22 December 2023. The fault-based liability pursuant to Sections 823 *et seq.* BGB is unlimited, and may also encompass compensation for immaterial damage, and the approval of a medicinal product does not provide any protection from this liability.

With respect to medical devices, the liability and extent of the obligation to pay damages in the event of death or personal injury is also governed by the Product Liability Act (*Produkthaftungsgesetz* – ProdHaftG), last amended on 17 July 2017. The CE certification by a notified body does not provide the manufacturer of a medical device any protection from liability.

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

The regulation of life sciences products may have an impact on litigation concerning the promotion of pharmaceuticals and medical devices. The provisions of the Law on Advertising in the Field of Health Care (*Heilmittelwerbegesetz* – HWG), last

amended on 19 July 2023, and some provisions of the AMG are intended to regulate market conduct in the interest of market participants. Infringements of the HWG and some stipulations of the AMG are considered unfair within the meaning of the Law against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb – UWG*), last amended on 8 October 2023.

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?

With regard to advertising to healthcare professionals (HCPs) and the collaboration between the pharmaceutical industry and partners in the healthcare system, there are a number of codes of conduct, for example: the Association for Voluntary Self-Regulation of the Pharmaceutical Industry (*Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.* – FSA) Code of Conduct; and the Association for Pharmaceuticals and Cooperation in the Healthcare Sector (*Arzneimittel und Kooperation im Gesundheitswesen e.V.* – AKG) Code of Conduct. The FSA Code of Conduct reflects the requirements of the Code of Conduct of the European Federation of Pharmaceutical Industries and Associations (EFPIA). These codes do not have the force of law and are only binding for member companies. The codes of conduct can be interpreted as an indication of what the relevant sections of the public consider unfair.

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?

For medicinal products the instructions for use address the patients and the SmPC addresses the HCPs, with in each case the relevant information regulated by the legislator. Warnings are generally a mandatory part of the PIL as well as the SmPC. However, if at a later point in time, due to the market observation obligation, additional information/new findings require further warnings, the responsible marketing authorisation holder must inform the specialist circles by so-called "*Rote-Hand-Briefe*", which is an information letter on newly recognised drug risks or a recall of faulty drug batches. Warnings that are incorporated in the PIL and the SmPC are considered known risks, which have to be accepted as possible when taking the drug. However, in an ongoing lawsuit, if the facts of the case that are subject of a warning in a *Rote-Hand-Briefe* are of relevance in the lawsuit, this can influence the outcome of the proceedings depending on the time that the marketing authorisation holder became aware of those facts. With regard to medical devices, important information must be present on the labelling of the product or alternatively in the user information. Regarding other life sciences products, there is no obligation to provide warnings – as these products cannot, in the first place, be put on the market as they are not safe for the consumer.

2 Manufacturing

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

According to Section 13 AMG, a manufacturing authorisation is required to manufacture pharmaceuticals and active ingredients. Which competent authority of the Federal State is responsible for the granting of the manufacturing authorisation depends on location of the manufacturing site. The manufacturer is entitled to receive a manufacturing authorisation if all of the requirements of Section 14 AMG are fulfilled, which stipulate the prerequisites for the granting of the manufacturing authorisation – including, in particular, that a Qualified Person with the required knowledge is available, and the manufacturing is carried out in accordance with the Good Manufacturing Practice (GMP) requirements and the Ordinance on the Manufacturer of Medicinal Products and Active Ingredients (AMWHV).

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?

The national competent authorities are responsible for inspecting and approving manufacturing sites located within their own territories. Manufacturing sites located outside of the EU are inspected by the national competent authority of the Member State where the EU importer is located, unless a mutual recognition agreement (MRA) is in place between the EU and the country concerned. If an MRA applies, the authorities mutually rely on each other's inspections. This also applies fully with respect to Germany.

The EU has concluded such MRAs with Australia, Canada, Israel, Japan, New Zealand, Switzerland and the United States (U.S.). With respect to the U.S., the EU and the U.S. have fully implemented an MRA with respect to inspections of manufacturing sites. This means that inspectors from the U.S. Food and Drug Administration and EU Member States can rely on each other's inspection results for human medicines and hence avoid duplication of work.

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

If with respect to medicinal products there is a deviation from the approved manufacturing specifications or if GMP rules are violated, and the medicinal product is nevertheless placed on the market, the medicinal product may be considered unsafe within the meaning of Section 5 (2) AMG. According to Section 5 AMG, the marketing of unsafe drugs is prohibited. In case of a violation of the manufacturing rules and regulations, pursuant to the strict liability rules provided by Section 84 AMG, it is assumed that the medicinal product is capable of causing the damage claimed in a liability litigation. Therefore, it is assumed that the damage was caused by the specific medicinal product. The burden of proof concerning the opposite then lies with the pharmaceutical company and not with the injured party.

With regard to medical devices, the CE certification does not provide any protection from liability for damages caused by the medical device in question.

3 Transactions

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

Life sciences mergers as well as acquisitions are subject to merger control by the Federal Cartel Office (*Bundeskartellamt* – FCO) like

any other merger or acquisition. The German merger control rules are laid down in Sections 35–43 of the Act against Restraints of Competition (*Gesetz gegen Wettbewerbsbeschränkungen* – GWB), last amended on 22 December 2023. Mergers and acquisitions may only be implemented after clearance by the FCO.

In addition, Sections 55–59 of the Foreign Trade and Payments Regulation (*Außenwirtschaftsverordnung* – AWV) set out special rules concerning the acquisition of a German company by a non-EU resident, which apply irrespective of the applicability of German merger control rules. If an investor from outside the EU intends to acquire 20% or more of the voting rights of a German medical device or medicinal products company, the transaction may be subject to a separate examination by the Federal Ministry for Economic Affairs and Energy into whether it is likely to pose a threat to the public order or security of the Federal Republic of Germany.

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?

The German jurisdiction does not place any specific restrictions on foreign ownership of life sciences companies or manufacturing facilities.

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.

Advertising, promotion and sales of medicinal products and medical devices are mainly governed in Germany by the HWG. In addition, the general provisions of the UWG apply with respect to medicinal products and medical devices as well as any other life sciences products.

In Germany, there is, contrary to a lot of other countries, no general requirement stipulating that advertising, promotion and sales of medicinal products, medical devices and other life sciences products must receive prior approval from a public authority in general or in specific circumstances. However, in accordance with Section 8 para. 1 no. 2 AMG, BfArM will examine whether the medicinal product name used or the presentation of the medicinal product is misleading, i.e. in particular whether medicinal products are attributed a therapeutic effect that they do not have, or whether the impression is falsely created that a success can be expected with certainty or that no harmful effects will occur after intended or prolonged use. In addition, so-called "green claims", i.e. environmentally related advertising claims, will require authorisation once the Green Claims Directive comes into force.

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")?

Off-label promotion of medicinal products is strictly prohibited. The promotion of any indication or use of a medicinal product that is not covered by a marketing authorisation is inadmissible according to Section 3a HWG. This also applies to so-called "pre-marketing measures" for pharmaceuticals. In addition, off-label promotion with respect to both medicinal products and medical devices is considered to be misleading according to Section 3 HWG and Sections 3a and 5 UWG and by that inadmissible, too. Pre-marketing advertising for medical devices, on the other hand, is generally permitted.

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?

As no approval requirement for advertising, promotion and sales by a supervisory authority exists, competitors usually take action themselves to prohibit alleged inadmissible advertising. Competitors may seek to obtain a cease-and-desist declaration by sending a warning letter to the advertising company and – if not successful – file a lawsuit with the civil court or seek to obtain injunctive relief against unlawful advertisements.

In addition, the intentional breach of the HWG provisions on misleading advertising can be considered a criminal offence punishable by a fine or imprisonment for up to one year. All other intentional or negligent breaches of the stipulations of the HWG may result in administrative fines of up to EUR 50,000. In practice, however, such a public prosecution of infringements of the HWG is very rare.

Apart from those judicial sanctions, a breach of the HWG provisions on misleading advertising may constitute a violation of the FSA Code of Conduct, provided that the company subject to the breach is a member of the FSA, and result in a fine of at least EUR 5,000 to EUR 400,000.

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?

Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation – GDPR) applies directly in each EU Member State. Furthermore, in addition to the GDPR, the requirements of the German Federal Data Protection Act (*Bundesdatenschutzgesetz* – BDSG) must be observed. These requirements apply to any life sciences company operating in Germany. As a result, those life sciences companies must comply with the GDPR requirements in the form as they were implemented by the BDSG.

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?

As a rule, documents submitted in German litigation are in general not confidential. According to Article 103 of the Basic Law for the Federal Republic of Germany, each party has the right to access all of the submissions of the opposing party and comment on them. Pursuant to Section 299 (1) and (2) of the Code of Civil Procedure (*Zivilprozessordnung* – ZPO), the content of the procedural files is open to all parties and, in general, even partially publicly accessible to a limited extent. The protection of trade or business secrets and confidential data must be taken into account when granting access to files to third parties in accordance with Section 299 (2) ZPO.

With respect to trade secrets, the requirements of Article 9 of Directive (EU) 2016/943 concerning the preservation of confidentiality of trade secrets in the course of legal proceedings have been implemented in German law by Sections 16–20 of the Trade Secret Act (*Geschäftsgeheimnisgesetz* – GeschGehG), effective as of 26 April 2019. These provisions provide for the possibility of obtaining the confidential classification for specific documents, which essentially means that only a limited number of specific persons can access the documents, and the scope of the oral hearing and the right to inspect the court files is limited. However, this only applies to trade secret disputes, i.e. proceedings in which the infringement of trade secrets is the subject matter of the dispute.

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

The relevant laws in the area of Digital Health in Germany are as follows: Regulation (EU) 2017/745 (MDR); Regulation (EU) 2017/746 (IVDR); the Medical Device Law Implementation Act (*Medizinprodukterecht- und Durchführungsgesetz* – MPDG); and MDCG 2019-11 on qualification and classification of software under MDR and IVDR. Software and apps are considered medical devices if they are intended for a medical purpose. The competent authority BfArM provides information on the demarcation of apps considered medical devices and those only for informational or wellness purposes. In 2019, the *Digitale-Versorgungs-Gesetz* (DVG) came into force to provide better care through digitalisation and innovation in the health sector by encouraging the use of medical apps by patients and for prescriptions by treating physicians, as well as video consultations and access to secure data networks in the healthcare treatment of patients. Currently, the draft of the *Digitale-Versorgung- und Pflege-Modernisierungs-Gesetz* (DVPMG) is being discussed in the German Federal Parliament to strengthen Digital Health literacy further, expand telemedicine and make it more attractive, further develop the provision of Digital Health Applications (DiGAs) and provide DiGAs in the home care sector. So far, there are no observations on how these developments in Digital Health would have an impact on litigation.

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.

In Germany, clinical trials for medicinal products are governed by Regulation (EU) 536/2014 and Sections 40–42c AMG. The design, conduct and documentation of human clinical trials and reporting on such trials must comply with the Guidelines on Good Clinical Practice (GCP). They must also be approved by the competent higher federal authority – either BfArM or PEI, depending on the type of product. In addition, a favourable opinion from a competent Ethics Committee (Section 41 AMG) is required. A general condition for the conduct of a clinical trial in Germany is that there is an insurance policy in place that provides benefits, even when no one else is liable for the damage, in the event that the person participating in the trial is killed or its body or health is injured during the course of the clinical trial (Section 40 no. 3 AMG). The scope of the insurance must be proportionate to the risks associated with the clinical trial and determined on the basis of a risk assessment, in such a way as to ensure that for every case of death or permanent occupational disability of a person affected by the clinical trial at least EUR 500,000 will be available.

Clinical testing for medical devices is governed in Germany by Articles 62–82 MDR and Sections 24–70 MPDG. The requirements are similar to the criteria that exist for clinical trials for medicinal products and also include the requirement for an adequate insurance policy to be in place for the person participating in the trial (Section 26 MPDG).

With respect to both medicinal products and medical devices, the approval of the clinical trial by the responsible authority does not provide protection against third-party claims due to injuries associated with the use of the product.

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)?

No, it does not.

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

German law provides the legal basis for compassionate use programmes (CUPs) for medicinal products (Section 21 (2) no. 3 AMG) in conjunction with the Ordinance on Medicinal Products for Compassionate Use (*Arzneimittelhärtefallverordnung* – AMHV), effective since 22 July 2010. The AMHV contains the so-called "confirmed notification procedure" for CUPs according to which the commencement of any new CUP requires a confirmation of notification by the competent higher federal authority (BfArM or PEI). The AMHV is only applicable for cohort programmes that are intended for a group of patients (cohort compassionate use). A "named patient compassionate use" is not in the scope of the AMHV.

With respect to medical devices, Germany does not allow compassionate use.

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

The decision to administer a non-approved product lies with the treating physician. Based on that, waivers of liability with the treating physicians and/or patients are in general not utilised.

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, there is no such regulatory or other guidance available.

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.

Sections 64–69b AMG contain the regulatory framework for the surveillance of medicinal products. The competent authorities

for the market surveillance and for taking any product-related measures – such as the prohibition of marketing or the recall of products due to quality defects – are the local authorities of the Federal States. The authorities have broad discretion with respect to whether the criteria to take any action are met, as well as which measure to take (Section 69 AMG).

The framework for medical devices is laid down in Section VII MDR and further detailed in Chapter 2 of the MPDG. The competent authorities for market surveillance and for taking any product-related measures are the local authorities of the Federal States. The authorities have broad discretion with respect to whether the criteria to take any action are met, as well as which measure to take (Section 69 AMG).

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?

The regulatory scheme for product recalls with respect to medicinal products and medical devices is similar.

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

In Germany, product recalls do not have a legal but a factual effect on litigation and government actions concerning the product.

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?

Product recalls in the U.S. or other EU Member States do not have a legal impact on recall decisions, as this lies in the discretion of the responsible authority, but of course decisions in other states are taken into account in the assessment. The same is true for litigations in Germany, as this lies with the independent courts. Irrespective of that, a recall may well have a factual impact, as they are usually noticed and taken into account.

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

The German jurisdiction does not provide for protection of internal investigations and/or risk assessments unless they are carried out under and protected by legal privilege.

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

It is, in general, recommended that companies when conducting a product recall keep and maintain a close and transparent relationship with the responsible supervisory authority and align potential measures and communication to HCPs and/or patients with the competent authority.

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.

Since 1 November 2018, consumer protection organisations have been able to file so-called "model declaratory actions" at the higher regional court in the first instance at the seat of the defendant company. The prerequisite for this is that at least 50 consumers must have filed claims with the court registry within two months of the public announcement. So far, however, no corresponding procedures in the field of medicinal products and medical devices have been published. However, under German competition law, it is possible for consumer protection organisations in particular to assert claims for injunctive relief. These organisations are independently authorised to take legal action of their own accord against competition law infringements that naturally affect a large number of consumers, including in the healthcare sector.

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

Personal injury/product liability claims are brought as individual plaintiff lawsuits to the competent district courts.

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 Germany, product liability claims are permitted. These are the normal claims to recover for injuries as a result of use of a life sciences product. For pharmaceuticals, there is in Section 84 AMG a strict liability claim regulation. Further bases for claims exist for medical devices in the provisions of the ProdHaftG, as well as generally in accordance with Sections 823 *et seq.* BGB, which postulate a fault-based liability for damages that is unlimited in terms of the possible amount of damages (see question 1.2).

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

According to Section 43 lit. b of the Federal Lawyers Regulation (*Bundesrechtsanwaltsordnung* – BRAO), advertising of lawyers is only permitted if it consists of factual information about the professional activity in form and content and is not aimed at the granting of an assignment in individual cases.

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

In Germany, there is the possibility of financing legal costs. These are partly stock exchange quoted companies, financing the court proceedings against a performance-related revenue share, i.e. they bear the lawyers' court costs and the expert costs. The prerequisite is usually that the amount of costs in dispute is above EUR 100,000, the chances of success are assessed by the plaintiff's lawyer at over 50% and the defendant has a solid credit rating. In addition, Sections 114 *et seq.* ZPO stipulate that a party whose personal and financial circumstances mean that they cannot afford the costs of legal proceedings, can receive legal aid on application if the intended legal action or legal defence offers sufficient prospect of success and does not appear to be unreasonable. Legal aid covers the court costs and the costs of their own lawyer. However, it does not cover the costs incurred by the opposing party in the event of loss of a case.

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?

In Germany, decisions of a court ruling on the liability of a pharmaceutical company in one case have no binding effect on the cases of other plaintiffs. In practice, however, a court will take the findings of another court into account, provided the facts of the case are comparable.

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 have no influence on the question of liability in pending civil proceedings. However, if improvement measures contribute to the reduction of the damage incurred, they will be taken into account in the liability process. The pharmaceutical company may, in principle, use all evidence admissible in civil proceedings. Evidence can therefore be obtained in particular through the submission of documents, the hearing of witnesses and experts and – to a lesser extent – through the hearing of parties.

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?

The competent higher federal authority generally records centrally all risks arising from the use of drugs, in particular side effects and interactions with other drugs. According to Section 84a AMG, the injured party has a right to information from the responsible higher federal authority (BfArM or PEI). In this respect, corresponding incidents can be used in civil proceedings in favour of the plaintiff.

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?

The sovereign powers of a German court basically end at the national borders. The admissibility of voluntary witness statements in Germany for civil proceedings abroad is governed by the foreign Code of Civil Procedure. Whether a company can voluntarily present witnesses for questioning depends in turn on the foreign Code of Civil Procedure and the willingness of the employee to give a witness statement.

If a voluntary witness statement is not possible or not wanted, foreign courts can turn to German courts by way of legal assistance. Within the EU, legal assistance proceedings are governed by Council Regulation (EU) 2020/1783 of 25 November 2020 on cooperation between the courts of the Member States in the taking of evidence in civil or commercial matters. The foreign trial court can directly request the competent court in Germany to hear the witness.

If there is no international mutual legal assistance agreement between the Federal Republic of Germany and the foreign state, legal assistance is only provided on a voluntary basis.

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?

In German law, the attorney's duty of confidentiality is regulated by professional law in addition to the principles of attorney independence and the prohibition of representation of conflicting interests and is the most important basic duty of the lawyer. The procedural implementation of the attorney-client privilege is essentially effected by means of rights to refuse to testify, prohibitions of seizure and the use of evidence. Both constitutionally and in the EU, the attorney-client privilege is also comprehensively recognised as a general principle of law. According to the decision of the ECJ in the *Akzo Akros* case (C-550/07 P), there is no legal privilege for in-house lawyers in European law. Internal company documents that are exchanged between an in-house lawyer and company employees can therefore be used as evidence.

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?

Correspondence between the client and the external lawyer is generally subject to secrecy under German law. An additional confidentiality agreement is therefore not required. For communication with foreign lawyers, the legal regulations applicable in the respective country of the foreign lawyer should be determined and, where permissible, contractual confidentiality obligations should be concluded.

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

Foreign defendants are not privileged compared to domestic defendants by the ZPO. Limitations are therefore more likely to arise in cases where a defendant domiciled abroad is difficult to reach or his assets difficult to access.

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

Liability proceedings in the U.S. have no direct legal effect on corresponding proceedings in Germany. Insofar as the facts of the case are comparable, a German court will take note of the U.S. proceedings but must not allow itself to be influenced by them in its decision making.

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

The likelihood of litigation evolving in Germany as a result of U.S. litigation is not very high as damages are calculated differently in the German jurisdiction.

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.

See question 8.1.

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