International Comparative Legal Guides

Drug & Medical Device Litigation 2020

A practical cross-border insight into drug & medical device litigation

First Edition

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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 principal legislative body for the regulation of medicinal products, including over-the-counter (OTC) medicinal products and medical devices, is the Federal Ministry of Health (*Bundesministerium für Gesundheit* – BMG).

Within the remit and scope of the BMG, the competent higher federal authorities responsible for vaccines and biomedicines are the Paul-Ehrlich-Institut (PEI) and the Federal Institute for Vaccines and Biomedicines (*Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel*) in Langen; while the competent higher federal authority responsible for all other medicinal products, as well as for all medical devices, is the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte* – BfArM) in Bonn. The local supervisory authorities of the Federal States (*Bundesländer*) are responsible for monitoring the placing on the market of medicinal products and medical devices.

For cosmetics and all other life sciences products, the Federal Office of Consumer Protection and Food Safety (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* – BVL) is responsible for the coordination of their supervision. The German competent authorities for market surveillance of cosmetics, in accordance with Article 34 of Regulation (EC) No 1223/2009, are the local authorities of the Federal States.

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?

With respect to medicinal products, according to the absolute liability provision of Section 84 of the German Medicinal Products Act (*Arzneimittelgesetz* – AMG), last amended on 22 March 2020, the pharmaceutical entrepreneur is liable if a person is killed or the body or health of a person is substantially damaged as a result of the use of an approved medicinal product. In this case, the pharmaceutical entrepreneur shall be obliged to compensate the injured person for the damage caused. However, the obligation to compensate exists only if the medicinal product has been used in accordance with its intended purpose and the harmful effects do not exceed the limits considered tolerable in the light of 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 the pharmaceutical entrepreneur with protection from liability. Liability pursuant to Section 84 AMG is limited to certain maximum amounts (see Section 88 AMG).

Apart from liability pursuant to Section 84 AMG, the pharmaceutical entrepreneur may be liable pursuant to the general provisions on compensation for damages pursuant to Sections 823 *et al.* German Civil Code (*Bürgerliches Gesetzbuch* – BGB), last amended on 19 March 2020. Liability pursuant to the provisions is unlimited, may also encompass compensation for immaterial damage (Section 847 BGB), and the approval of a medicinal products does not provide any protection in this respect.

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

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 advertising and promotion of pharmaceuticals and medical devices in the area of unfair competition. The provisions of the AMG and of the Law on Advertising in the Field of Health Care (*Heilmittelwerbegesetz* – HWG), last amended on 10 February 2020, are also intended to regulate market conduct in the interest of market participants. By that, infringements of the AMG and/or the HWG are generally also considered to be unfair within the meaning of the Law against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb* – UWG), last amended on 18 April 2019.

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 collaboration in the pharmaceutical industry with partners in the healthcare system, there are two self-regulating

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bodies: Voluntary Self-Regulation of the Pharmaceutical Industry (*Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.* – FSA); and Pharmaceuticals and Cooperation in the Healthcare Sector (*Arzneimittel und Kooperation im Gesundheitswesen e.V.* – AKG). The FSA Code of Conduct on Collaboration with Healthcare Professionals and the AKG Code of Conduct (*AKG-Verhaltenskodex*) are only binding on their member companies. The FSA Code of Conduct reflects the requirements of the Code of Conduct of the European Federation of Pharmaceutical Industries and Associations (EFPIA). In the long run, these Codes of Conduct will lead to a change in companies' behaviour, but they will generally not have any influence on jurisdiction, liability or whether certain conduct is considered to be misleading pursuant to the UWG.

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?

With respect to medicinal products, warnings are normally part of the PIL for patients and the SmPC containing information for HCPs. If new findings give rise to additional warnings, this is done by means of so-called 'red-hand letters' (*Rote-Hand-Brief*) to specialist circles. If the facts of the case that are the subject of the warning are of any relevance in an ongoing lawsuit, this can of course influence the outcome of the proceedings.

Concerning medical devices and other life sciences products, there is no such obligation to provide warnings of the risks of the products to the consumer and/or the HCP.

2 Manufacturing

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

Manufacturers of pharmaceuticals and active ingredients require a manufacturing authorisation according to Section 13 AMG. The decision on the granting of the manufacturing authorisation is made by the competent authority of the Federal State in which the manufacturing site is located. In the case of blood preparations, sera and vaccines, the decision on the manufacturing authorisation is made in consultation with the Paul-Ehrlich-Institut as the competent higher federal authority. According to Section 14 AMG, the prerequisite for the granting of the manufacturing authorisation is that a Qualified Person is available and that the manufacturer is able to guarantee that the manufacture or testing of the medicinal products is carried out in accordance with the state of the art in science and technology, in line with the Good Manufacturing Practice (GMP) requirements. The details of this are regulated in the Ordinance on the Manufacture 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?

Within the EU, the competent national authorities are responsible for the inspection and approval of manufacturing sites located within their own territories. Manufacturing sites outside the EU are inspected by the competent national 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.

In this respect, the EU has concluded such MRAs with Australia, Canada, Israel, Japan, New Zealand, Switzerland and the United States (U.S.). With the recognition of Slovakia, as the latest EU Member State, by the U.S. Food and Drug Administration (FDA) on 11 July 2019, the EU and the United States have fully implemented the MRA with respect to inspections of manufacturing sites. This means that inspectors from the FDA or EU Member States will be able to 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?

Violation of, or deviation from, the manufacturing regulations for approved drugs or certified medical devices affects liability.

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) of the German MPA. According to Section 5 of the Germany MPA, the marketing of unsafe drugs is prohibited and will result in liability. In case of a violation of the manufacturing rules and regulations, pursuant to the strict liability rules under § 84 AMG, it is assumed that the medicinal product is capable of causing the damage claimed in the liability suit, so 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.

Concerning medical devices, 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*; hereafter "FCO") like any other merger and/or acquisition. The German merger control rules are laid down in Sections 35 to 43 of the Act against Restraints of Competition (*Gesetz gegen Wettbewerbsbeschränkungen* – GWB) (ARC), last amended on 19 December 2018. Mergers and acquisitions may only be implemented after clearance by the FCO. Joint ventures are also reviewed under the rules for regulating restrictive agreements.

In addition, Sections 55 to 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 25% or more of the voting rights of a German 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

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order or security of the Federal Republic of Germany. The same applies if such a shareholding is acquired by an EU-based investor and an investor from outside the EU holds 25% or more of the voting rights. A threshold of 10% of the voting rights applies in certain cases, where the acquisition of a domestic company may be deemed a threat to public order or security.

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 is mainly governed in Germany by the Law on Advertising in the Field of Healthcare (*Heilmittelwerbegesetz* – HWG), last amended on 10 February 2020. 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, contrary to a lot of other countries, there is no requirement for advertising, promotion and sales of medicinal products, medical devices and other life sciences products to gain prior approval by a public authority, either in general or in specific circumstances.

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 and medical devices is strictly prohibited: the promotion of any indication or use of a medicinal product which is not covered by its marketing authorisation is considered to be inadmissible pursuant to Section 3a HWG. In addition, an off-label promotion with respect to both medicinal products and medical devices is considered to be misleading pursuant to Sections 3 HWG, 5, 3 UWG and therefore inadmissible too.

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?

Due to the fact there is no regulation of, or approval requirement for, advertising, promotion and sales by a supervisory authority, competitors usually take action to prohibit alleged inadmissible advertising. Competitors may seek to obtain a cease-and-desist declaration by sending a warning letter to the company in question and, if not successful, may take legal action in front of the civil courts and seek to obtain injunctive relief against unlawful advertisements.

In addition, intentional breach of the HWG provisions on misleading advertising constitutes a criminal offence punishable by imprisonment for a term of up to one year or a fine. All other intentional or negligent breaches of explicitly listed provisions of the HWG may result in administrative fines of up to EUR 50,000. In practice, however, such public prosecutions for infringements of the HWG are 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 in scope is a member of the FSA, and may thereby result in a fine of at least EUR 5,000 to EUR 400,000.

5 Data Privacy

5.1 How do life sciences companies which distribute their products globally comply with GDPR 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), effective as of 25 May 2018, applies directly in each EU Member State. In order to implement the GDPR requirements into national law, Germany enacted the new Federal Data Protection Act (*Bundesdatenschutzgesetz* – BDSG) on 5 July 2017, effective as of 25 May 2018, which also included derogations from several GDPR requirements. These requirements apply to any life sciences company operating in Germany. As a result, those life sciences companies have to comply with GDPR requirements in the form in which they were implemented by the BDSG on 5 July 2017.

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 produced in litigation in Germany are not confidential: pursuant to Section 299 (1) and (2) of the Code of Civil Procedure (*Zivilprozessordnung* – ZPO), the content of procedural files is open to all parties and, in general, publicly accessible to a limited extent. The protection of trade or business secrets or confidential data must be taken into account when granting third parties access to files in accordance with Section 299 (2) ZPO, but not in relation to the counterparty. If a party requests the court to maintain confidentiality of submitted documents *vis-à-vis* the other side, the court must not include these documents in the court files and, due to the necessity of preserving the right to be heard on the other side, must not use them in its decision. The party can only exploit confidential information in the process if the documents are also made available to the other party. There is only the possibility to make access dependent on suitable security measures in order to protect one's confidentiality interests.

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 provide for the possibility of obtaining classification of specific documents as confidential, with the result that, amongst other things, the number of persons who have access to evidence, the oral hearing or the right to inspect the court files is limited.

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

In the area of Digital Health, the BfArM provides clear guidance on the differentiation between apps (i.e. software that is not incorporated into a medical device, e.g. as control software) and medical devices or other devices, as well as on the subsequent risk classification in accordance with the Medical Devices Act (*Medizinproduktegesetz* – MPG). The recent Law for Better Care through Digitalization and Innovation (*Digitale-Versorgung-Gesetz* – DVG), effective as of 19 December 2019, enables, amongst other things, the use of medical apps by patients, providing support, e.g., for the compliant taking of medicines, video consultations by the treating physician and access from anywhere to a secure healthcare data network for treatments. There are currently no observations that these regulatory considerations and developments in Digital Health are having 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 Sections 40–42b AMG. Design, conduct and documentation of clinical trials in humans, and reporting on such trials, must comply with the Guidelines on Good Clinical Practice (GCP). They have to be approved by the competent higher federal authority – either BfArM or PEI, depending on the type of product. In addition, a favourable opinion from the competent Ethics Committee is required. A general condition for the conduct of a clinical trial in Germany is that there is an insurance policy in place which 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 his/her body or health is injured during the course of the clinical trial. Its scope must be reasonably commensurate with the risks involved in the clinical trial and determined on the basis of the risk assessment in such a way as to ensure that, for every case of death or permanent occupational disability of persons involved in the clinical trial, at least EUR 500,000 will be available. Insofar as benefits are paid by the insurance, all claims for damages shall be extinguished.

Clinical testing for medical devices is governed in Germany by Sections 20–24 MPG. The requirements are similar to the criteria that exist for clinical trials for medicinal products, and include the requirement for an adequate insurance policy to be in place for the person participating in the trial.

With respect to both medicinal products and medical devices, the approval of the trial by the responsible authority does not provide protection against third-party claims due to injuries associated with the use of the product, whereas there is financial coverage to a certain extent due to the mandatory insurance policies.

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?

Since July 2009, the German law has provided for the legal basis of compassionate use programmes (CUPs) for medicinal products, pursuant to Section 21(2) No 6 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). However, the AMHV is only applicable to cohort programmes which are intended for a group of patients (cohort compassionate use). A 'named patient compassionate use' is not in the scope of the notification procedure as laid down in the Ordinance on Medicinal Products for Compassionate Use, and is therefore currently not regulated in Germany.

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

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

The main responsibility for a CUP lies with the person notifying the competent higher federal authority about the conduct of the CUP (the so-called 'responsible person') – which normally is the pharmaceutical company that develops the medicinal product. The responsible person has to ensure, in particular, that: the CUP is properly conducted; all conditions and restrictions with respect to the safe and effective use of the medicinal product at hand are observed; the persons involved – in particular, the treating physician and the patient – receive the information necessary to this end; the medicinal product is properly labelled as defined in the AMHV; and the quality of the product is ensured. The decision to administer the non-approved product lies with the treating physician. Based on that, waivers of liability for 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 market surveillance and for taking any product-related measures – such as a prohibition on marketing or the recall of products due to quality defects – are the local authorities of the Federal States. The authorities have broad discretion as to whether the criteria to take any action are met, as well as which measure to take (see Section 69 AMG).

The framework for medical devices is laid down in Section 26 MPG and further detailed in the General Ordinance for

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the Execution of the Medical Device Act (*Medizinprodukte-Durchführungsvorschfirt* – MPGVwV). The competent authorities for market surveillance and for taking any product-related measures are again the local authorities of the Federal States. The authorities have broad discretion as to whether the criteria to take any action are met, as well as which measure to take (see 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. The same is true for litigation 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, are in a close and transparent relationship with the responsible supervisory authority, and also that they align potential measures and related communications to HCPs and/or to patients with the 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.

In the area of medicinal products and medical devices, to date, there has neither been aggregate litigation, nor mass tort, nor class actions. 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 have filed claims with the court registry within two months of the public announcement. So far, however, there are no corresponding procedures and experience in the field of medicinal products and medical devices.

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.

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 is only permitted to the lawyer if he/she factually informs about the professional activity in form and content, and if such advertising is not aimed at the granting of an assignment in individual cases. Therefore, the solicitation of plaintiffs is restricted.

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 the 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 to be over 50%, and the defendant has a solid credit rating.

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?

There is no direct legal effect in German law of a court ruling on the liability of a pharmaceutical company in one case on the cases of other plaintiffs. The substantive legal validity of a judgment only has a binding effect in terms of content in personal, factual and temporal terms. The binding effect does not extend to third parties who were not involved in the proceedings. In practice, however, a court will follow the findings of a higher court, provided the facts of the case are comparable.

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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?

There is no direct effect of subsequent remedial measures on the question of liability in pending civil proceedings. If improvement measures contribute to the reduction of the damage incurred, they will be taken into account accordingly in the liability process. The pharmaceutical company may, in principle, use all evidence admissible in civil proceedings.

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 found in civil 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?

The sovereign powers of a German court essentially end at the national borders. The admissibility of voluntary witness statements in Germany for civil proceedings abroad is governed by the Code of Civil Procedure of the other jurisdiction. Whether a company can voluntarily present witnesses for questioning also depends 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 (EC) No 1206/2001 of 28 May 2001 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 European Union, the attorney-client privilege is also comprehensively recognised as a general principle of law. According to the decision of the European Court of Justice 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 over domestic defendants by the German Code of Civil Procedure. Limitations are therefore more likely to arise due to potential difficulties surrounding access to the defendant domiciled abroad or his assets.

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

Liability proceedings in the USA 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, due to the differences in damage calculation and damage amounts in the German jurisdiction.

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Dr. Alexander Meier has more than 19 years of relevant professional experience as an external attorney and in-house lawyer in the field of pharmaceutical law. He is specialised in European and German regulatory law relating to chemical and biological pharmaceuticals (including advanced therapies) and medical devices. Alexander Meier advises and represents national and international pharmaceutical and medical device companies in all areas of pharmaceutical law (including GxP and Medical Affairs), competition law and compliance-related aspects. A particular specialisation is in the field of biopharmaceuticals; in particular, advanced therapy medicinal products (ATMPs). With over 18 years of experience in Germany and Europe, he has particularly extensive practical experience in the area of Regulatory Data Protection (RDP), Orphan Drugs and the Paediatric Regulation.
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Peter von Czettritz is the author of a variety of specialised publications and is a regular speaker on all topics of pharmaceutical law. He is a lecturer at the Philipps-Universität Marburg. He is a member of the German Medicines Manufacturers Association of the BPI – committee on material medical devices – and of the "Medical Devices Law" network of the German Medical Technology Association.

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