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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.

In Poland, legislative power is exercised by parliament, which consists of the Sejm and the Senate. Additionally, the Minister of Health, who is also responsible for supervising the pharmaceutical market, can issue regulations concerning life sciences products.

Other offices and regulatory bodies that oversee pharmaceuticals, medical devices, supplements, and cosmetics are: (i) the Chief Pharmaceutical Inspectorate (CPI) – responsible for the supervision and monitoring of the manufacture and marketing of medicinal products; (ii) the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (ORMP) – responsible for evaluation and authorisation of medicines, medical devices and biocidal products, supervision of clinical trials and collection of information on adverse reactions of medicinal products; and (iii) the State Sanitary Inspection (SSI) – overseeing the health standards of food, nutrition, cosmetic products, and dietary supplements.

Life sciences products are also subject to consumer protection supervision from the President of the Consumer Protection Authority (CPA). This exercises its powers through Trade Inspection authorities.

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?

Civil liability for injuries suffered as a result of product use is regulated in the 1964 Civil Code.

It is usually asserted on a strict liability basis as liability for damage caused by a dangerous product (i.e., a product that does not provide the safety that can be expected through its normal use). This regime provides facilities for the plaintiff compared to the fault-based regime. He must only prove damage, the existence of a dangerous product and an adequate causal link between the damage and placing of the dangerous product on the market.

Further, product liability can be asserted on the basis of fault, i.e., under Article 415 of the Civil Code. However, it is less favourable for the plaintiff. Indeed, apart from damage, the occurrence of a harmful event and a causal link between them, he must prove fault of the perpetrator (i.e., that he failed to exercise due care), which may be particularly complicated.

Approval of a product by the regulator does not provide protection from liability.

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

Liability for a dangerous product, as a rule, lies with the manufacturer of a product, not with the distributor. However, a distributor can quickly become a quasi-manufacturer, e.g., if there is a lack of clarity as to who is the manufacturer or if he makes significant modifications to a marketed product, which affect the safety of its use. In such circumstances, the distributor becomes liable for the product as if he were the manufacturer.

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 Polish market has many organisations that self-regulate the life sciences products sector. The Employers' Union of Innovative Pharmaceutical Companies (INFARMA), the Association of Polish Pharmaceutical Wholesale Employers, Polish Association of Employers in the Pharmaceutical Industry – National Pharmaceutical Manufacturers, and the Polish Chamber of Commerce 'Farmacja Polska' are associations relevant to the pharmaceutical market. The Polish National Chamber of Commerce of Medical Devices (POLMED) is the leading organisation of medical device manufacturers and distributors. The Polish Council for Supplements and Nutritional Foods brings together manufacturers of food supplements and functional foods, and the Polish Association of the Cosmetics Industry brings together entrepreneurs in the cosmetics industry.

These organisations develop ethical and industry codes, which are binding on their members. However, in the absence or ambiguity of legal provisions, such guidelines provide a general reference point as to what is acceptable and unacceptable in the market. Therefore, industry self-regulations are of subsidiary relevance in court proceedings when determining liability.

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?

Life sciences companies are required to provide warnings about any risks posed by their products directly to the consumers. The scope of information to be provided depends on the type of product.

As for medicinal products, the Regulation of the Minister of Health of 2009 determines what information must be placed on the label of a product and on the mandatory leaflet. The leaflet (a separate printed product attached to the medicinal product) contains information on indications and contraindications, precautions and interactions.

Regulation 2017/745 on medical devices requires, in turn, that the labels of medical devices contain relevant information on the safety and functioning of a product. The device should also be accompanied by instructions for use.

Whether the product label contains necessary warnings and information and is accompanied by an instruction/leaflet influences the liability of a producer. If they are missing, there is a substantial risk that the product will be considered dangerous.

2 Manufacturing

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

Under Article 38(2) of the 2001 Pharmaceutical Law, production of a medicinal product requires a permit from the CPI. It is issued following an inspection by the CPI inspectors for a period of five years (with the possibility of extension for an indefinite period).

Manufacturers of medical devices placing their products on the market for the first time must notify the President of the ORMP. Likewise, manufacturers who place or intend to place a dietary supplement on the market must notify the Chief Sanitary Inspector.

As for cosmetic products, no permit or notice is required. However, according to the 2018 Cosmetic Products Act, a responsible person, who guarantees that cosmetic products placed on the market meet the requirements set out in Regulation 1223/2009 on cosmetic products, must be appointed.

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?

As a rule, facilities manufacturing drugs in Poland are subject to inspections from CPI inspectors. However, the Mutual Recognition Agreement (MRA) between the EU and the U.S. on the recognition of inspections of facilities manufacturing drugs for human use in their respective territories allows for reduced duplication of inspections on reciprocal territories. Therefore, if drugs manufactured by a facility in Poland are intended for export to the U.S., FDA inspectors may carry out an inspection of such facility, and *vice versa*. Therefore, the MRA allows Polish authorities and their counterparts to rely on each other's Good Manufacturing Practices (GMP) inspection system, share information on inspections and quality defects, and waive batch testing of products on import into their territories.

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

Violation of manufacturing requirements may give rise to public law (administrative or criminal) liability. As for administrative liability, enforced by relevant public authorities, it is the company that risks fines, or – in the worst-case scenario – suspension or withdrawal of the manufacturing authorisation. Criminal liability, on the other hand, can be attributed by a court to natural persons, e.g., representatives of the company or its employees.

Where non-compliance with manufacturing requirements contributes to damage (e.g., of a third party such as a customer), the company also risks civil liability.

3 Transactions

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

Regulatory requirements to be met for life sciences mergers and acquisitions are determined by the type of transaction (e.g., whether it is a share deal or asset deal). Depending on that, the merger or acquisition of the company may trigger an obligation to notify the relevant authority, amend existing authorisations and permits, or obtain new ones.

Also, mergers or acquisitions of entities operating in the life sciences industry are subject to general procedures regarding the concentrations between undertakings. When a threshold of annual turnover is exceeded, the 2007 Competition and Consumer Protection Act requires the intention of such merger or acquisition to be reported to the President of the CPA. The President may consent or object to the concentration.

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?

Foreign ownership of life sciences companies or manufacturing facilities is restricted by general rules that apply to all foreign investors under the 2018 Act on the rules of participation of foreign entrepreneurs and other foreign persons in economic transactions in Poland.

Failure to comply with such rules is, however, unlikely to contribute to damage. Therefore, the risk that these restrictions will affect liability for injuries caused by use of a life sciences product is rather low.

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 of life sciences products in Poland is governed by statutory law and soft law.

With respect to statutory law, general rules for advertising are the 1992 Broadcasting Act, the 1984 Press Law, the 1993 Combating Unfair Competition Law, the 2007 Counteracting Unfair Market Practices Act and the 2007 Competition and Consumer Protection Act. Their overall aim is to protect consumers from misleading, unethical or aggressive actions of entrepreneurs (including advertising) and ensure fair competition. Specific advertising rules applicable to medicinal products and medical devices are also contained in the 2001 Pharmaceutical Law, the 2022 Medical Devices Act and implementing regulations of the Minister of Health. They define prohibited advertising practices, indicate information that must be included in advertising, and regulate inspections and sanctions.

As for soft law, resolutions of the Advertising Council are of great practical importance. The ethics and industry codes described in question 1.4 also address advertising and promotion.

Supervision over compliance with provisions on advertising of life science products is exercised by the National Broadcasting Council, the Pharmaceutical Inspection, the Trade Inspection and the SSI.

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 drugs or medical devices is not allowed in Poland. The advertisement of a medicinal product must contain information consistent with the Summary of Product Characteristics, which is of key importance for supervisory authorities.

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?

An entity that does not comply with advertising, promotion and sale regulations exposes itself to both administrative, civil and criminal liability. However, in practice, the greatest risk is that of administrative liability.

In particular, the Chief Pharmaceutical Inspector may issue a decision ordering the company: (i) to cease the advertisement of a medicinal product; (ii) to publish the decision in places where advertisement was shown and provide a correction of the misleading advertisement; or (iii) to rectify the infringements. It may also impose a fine.

Likewise, in case of a breach of rules regulating the advertising of medical devices, the President of the ORMP may issue a decision ordering: (i) rectification of the infringements found; (ii) cessation of the publication, appearance or conduct of the advertising in question; or (iii) publication of the issued decision in the places or media where the advertisement in question appeared. It may also impose a fine of up to PLN 5 million.

Furthermore, the President of the CPA may impose very high administrative financial penalties. For example, in August 2023, in connection with a case of surreptitious advertising of dietary supplements through social media, such penalty amounted to PLN 5 million. Such decisions are announced to the public.

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?

To implement data privacy standards, life sciences companies may be required to appoint a Data Protection Officer to ensure ongoing compliance. The Data Protection Officer should have expert knowledge of data protection, a good understanding of the way a company operates, and be able to perform his duties independently.

It is also recommended that the company follow guidelines published by the European Data Protection Board, the European Data Protection Supervisor, Article 29 Data Protection Working Party and the Polish Data Protection Authority, which specify GDPR provisions. Based on these, it should draw up internal data protection documents, e.g., codes of ethics, codes of good practice, etc.

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?

Under Article 9(1) of the 1964 Civil Proceeding Code, in line with the principle of publicity, parties to proceedings shall have the right to inspect a case file and to obtain copies or extracts from it. Further, pursuant to Article 525, anyone can access a case file, provided his request is sufficiently motivated and approved by the head of the court's civil division.

However, despite the lack of protection of trade information on file in the sphere of civil proceedings itself, the company still enjoys protection under the 1993 Combating Unfair Competition Law. Indeed, information on file may meet the conditions of Article 11(2), i.e., constitute a trade secret (information of economic value, not commonly known to or easily available for persons normally dealing with that type of information). If so, the other entity will not be able to use such information obtained during civil proceedings (e.g., communicate it to another entity, disclose it to the public or use it for its own business purposes). Otherwise, it will risk liability under the 1993 Combating Unfair Competition Law.

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

Poland is open to Digital Health solutions, as demonstrated by technological solutions implemented in previous years, such as e-prescriptions, e-referrals and e-sick leaves. The recent development is a pilot programme for central electronic registration in force from 23 August 2024.

Recent regulatory developments concerning Digital Health in Poland include a regulation on the possibility of using AI in the diagnostic and treatment process in the new Code of Medical Ethics. In particular, Article 12 introduces requirements to inform a patient of intention to use AI and to obtain the patient's consent. The Code of Medical Ethics, although not a universally binding act, in practice has a significant impact on litigation. Therefore, if damage occurs, a breach of

Article 12 may result in compensation proceeding for failure to provide the patient with sufficient information about treatment, as required by the 2008 Patients' Rights Act.

Further, the new Code of Medical Ethics places medical e-consultation on par with in-patient consultation. This change could potentially affect proceedings in cases involving the provision of e-health services and the exercise of due diligence in their course.

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.

The primary legal act regulating clinical trials in the EU and EEA is Regulation 536/2014 on clinical trials on medicinal products for human use. It introduces a uniform system for reporting clinical trials and a unified way of assessing applications at national level; strengthening the protection of trial participants and the transparency of trials.

To ensure the application of Regulation 536/2014 at a national level, the 2023 Act on clinical trials of medicinal products for human use was adopted. It introduces a detailed authorisation procedure for clinical trials, a procedure for ethical evaluation of trials, creates the Clinical Trials Compensation Fund, and regulates the supervision of trials.

Issues related to participation in clinical trials are regulated by the 1997 Medical and Dental Professions Act, which emphasises participant protection and ethical standards of medical practice. For example, it introduces conditions for the validity of a participant's consent to take part in a trial (and specifies information that must be provided to him) and establishes sanctions for violations of clinical trials laws.

In addition to legally binding provisions, clinical trials are also governed by soft law: Good Clinical Practice, which is an international code of ethics setting out principles for the design, conduct, documentation and presentation of results of clinical trials and guidelines of the Polish Agency for Medical Research.

As for the impact of regulatory standards and guidelines on litigation, compliance with them is of particular importance if the insurer refuses to cover potential compensation. In such cases, it is crucial to be able to counter the allegation of inadequate conduct of trials that it may raise.

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)?

When assessing an application for approval of a clinical trial, consideration should be given to whether groups of participants in the clinical trial are representative of the population to be treated. Otherwise, unless sufficiently justified, a study should not be approved by the ethics committee.

There is no publicly available information on any case law recognising liability for failure to test in certain patient populations. However, it cannot be ruled out that such cases will arise in the future.

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

Poland has not introduced detailed regulations enabling the efficient application of compassionate use under Article 83 of the Regulation 726/2004 procedures for the authorisation and supervision of medicinal products.

Therefore, at present, subject patient programmes are carried out under Article 4(8) of the 2001 Pharmaceutical Law. According to this, the Minister of Health may, in the event of a threat to human life or health, allow medicinal products to be marketed without authorisation for a limited period. An application to the Minister is submitted online via the Target Import Service System by a physician.

Supplementary use of the above provisions in the absence of regulations aimed at compassionate use, however, causes practical problems. Repeated attempts to pass a law regulating compassionate use in Poland have failed.

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

Waivers of liability are not utilised or effective in respect of doctors or patients.

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

Compassionate use programmes are currently not regulated in Poland. Instead, named patient programmes are carried out under Article 4(8) of the 2001 Pharmaceutical Law. However, this procedure is also not regulated in much detail, so a well-structured Named Patient Agreement is crucial for the company to protect itself from liability. Such an agreement should regulate, e.g., named patient use compliance requirements, adverse events reporting, product accountability or extent of financial support of the company.

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.

Under the 2001 Pharmaceutical Law, if a medicinal product does not meet the quality standards, the CPI can decide to withdraw it from the market. The CPI may issue such decision on its own initiative or at the request of the President of the ORMP (e.g., when the so-called 'urgent EU procedure' applies) or the Minister of Health. Furthermore, under the Regulation of the Minister of Health 2008 on principles and procedures for the suspension and withdrawal of medicinal products and medical devices from the market, the Provincial Pharmaceutical Inspector may issue a decision on the withdrawal of a medicinal product from the market in its territory.

Pursuant to the 2023 Medical Devices Act, a decision on the withdrawal of a medical device from the market is made by the President of the ORMP. As for dietary supplements, which do not meet requirements under the 2006 Food and Nutrition Safety Act and the 1985 State Sanitary Inspection Act, a product recall takes place on the decision of the District

Sanitary Inspector. The recall of cosmetic products, in turn, is decided by the Chief Sanitary Inspector.

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 process for recalling life science products differs by product type, as outlined in question 7.1, with the key distinction being the authority responsible for making the recall decision.

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

Product recall by a decision of an authority is usually the result of a product failing to meet safety requirements or other types of violations. Therefore, apart from withdrawal of a product from the market, these infringements may lead to criminal or administrative liability.

However, mere product recall, which occurs under an administrative procedure, does not prejudge civil liability. Indeed, to this end, it is necessary for the plaintiff to prove the premises for liability for damage caused by a dangerous product or liability on the basis of fault.

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?

As a rule, product recall in the U.S. or an EU Member State does not automatically lead to a recall in Poland. However, as for medicinal products authorised via the centralised procedure, recall is immediately enforceable in all Member States.

With regard to otherwise approved products, a so-called 'urgent EU procedure' applies, which can be initiated if there are concerns about the safety of pharmacotherapy. In its course, the European Commission may adopt a decision on measures to be implemented by Member States with regard to the marketing authorisations granted. Then, the President of the ORMP requests the CPI to issue a decision on product recall.

In any case, however, product recall in another country may trigger local authorities to initiate control measures in Poland.

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

As regards medicinal products, the Regulation of the Minister of Health from 2015 on the requirements of GMP states that the manufacturer must introduce and apply the Pharmaceutical Quality System in the manufacture of medicinal products. It covers GMP, Quality Review and Risk Management. Therefore, it determines that the manufacturer must control quality during production, carry out regular internal inspections and assess risks concerning the quality of a product. The Regulation of the Minister of Health of 2015 on GDP requirements also requires that wholesale distributors of medicinal products introduce and apply the quality management system and system for managing outsourced activities.

In accordance with Regulation 2017/745 on medical devices and Regulation 2017/746 on *in vitro* medical devices, the manufacturer must, in turn, introduce and apply an internal risk management system.

Also, the manufacturers of cosmetics products are, under Regulation 1223/2009, required to carry out production in accordance with good manufacturing practice.

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

After receiving a decision to withdraw a product from the market, the company should follow the Regulation of the Minister of Health of 2008 on defining detailed rules and procedure for suspending and withdrawing medicinal products and medical devices from the market, and cooperate with relevant authorities.

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 Poland, class actions, introduced in 2010 under the Act on Pursuing Claims in Group Proceedings, are used for cases like consumer protection and product liability. The act covers claims for damages from dangerous products, torts, contract issues, unjust enrichment, and consumer protection violations. A class requires at least 10 individuals with similar claims, represented by a class representative, with participation being opt-in. Group proceedings exclude personal rights claims, except those related to bodily injury or health impairment, including claims by family members of a deceased victim. In these cases, monetary claims are limited to establishing liability, with compensation determined in separate proceedings. A liability judgment in group proceedings serves as a precedent in individual cases.

From 29 August 2024, a new type of group proceeding addresses practices infringing on collective consumer interests, involving EU law violations like those in the Collective Redress Directive. A qualified entity files and conducts these lawsuits on behalf of the group. Besides class actions, mass torts can be addressed through consolidated individual claims for efficiency. The Consumer Ombudsman and certain organisations can initiate actions on behalf of consumers, protecting collective rights. Polish civil procedure allows joining claims by multiple plaintiffs if connected by the same legal or factual basis, with the court managing proceedings for collective treatment.

The Act on Liabilities of Collective Entities of 2002 remains applicable, especially for offences under the Pharmaceutical Law Act of 2001. A collective entity can be held accountable for unlawful actions by individuals representing it, if these actions benefited or could benefit the entity and resulted from negligence in selection or supervision. Legal proceedings must be initiated against the individual involved, and the court can levy fines up to PLN 5 million on the collective entity.

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

Personal injury/product liability claims, although suitable to be brought in class action (see question 8.1), are predominantly brought as individual plaintiff lawsuits.

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

In Poland, claims for injuries from life sciences products, such as pharmaceuticals or medical devices, are governed primarily by the Civil Code and the Act on the General Safety of Products. These allow claims against manufacturers, importers, and distributors for damages caused by defective products. A product is considered defective if it lacks the safety expected, considering its presentation, intended use, and the time it was circulated. The jurisdiction recognises strict liability claims, where claimants need not prove negligence but must show the product was defective, the defect caused the injury, and the injury resulted in damages. This framework facilitates consumer compensation by requiring proof only of the product's defectiveness and resulting harm, rather than fault. Liability for personal injuries caused by a product is broad, allowing for extensive claims. However, a manufacturer is liable for property damage only if the destroyed or damaged item is typically intended for personal use and was primarily used in that manner by the injured party.

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

In Poland, lawyers face restrictions on soliciting plaintiffs for litigation. Direct solicitation, especially aggressive or misleading advertising, is prohibited. Lawyers must uphold professional integrity and adhere to ethical codes set by the Polish Bar Council and the National Council of Legal Advisers. Violating these rules can lead to disciplinary actions.

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

There are no specific regulations governing litigation funding, but several forms are used. Self-funding is the most common, where parties use their own resources. Legal aid is available for those who qualify and cannot afford representation. Third-party litigation funding, where a third party finances litigation for a share of the proceeds if successful, is gaining traction but remains uncommon. Legal expenses insurance can cover costs, either as part of a broader policy or standalone. Contingency fees are allowed, but legal advisers cannot be compensated solely through success fees; these must supplement a standard fee. Specific regulations apply to funding entities in group proceedings for consumer protection claims. These entities can receive external funding but must remain independent and manage conflicts of interest. Courts ensure such funding does not compromise consumer interests.

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?

Res judicata prevents the re-litigation of cases that have been conclusively resolved, with a final judgment binding only on the same parties and legal issues. If a company is found liable, that finding is *res judicata* only in subsequent cases involving the same parties and issues. The binding effect applies to the judgment's operative part, not its reasoning, which includes evidence presentation and credibility assessment. Nonetheless, in practice, another party may cite a different judgment as evidence of rights or interests being violated in disputes based on the same circumstances.

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?

Efforts to improve a product or correct its deficiencies can be demonstrated through any admissible means of evidence, such as documents or witness testimonies, which are evaluated according to the general rules established by civil procedure. However, undertaking remedial actions after damage has occurred does not alter liability for any product-related harm.

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?

Adverse events allegedly experienced by product users other than the plaintiff can be demonstrated through any admissible means of evidence, such as documents or witness testimonies, which are evaluated according to the general rules established by civil procedure. They should therefore be relevant and reliable, and must directly relate to the case.

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?

In Poland, there are no specific 'blocking' statutes preventing depositions from being conducted in or out of the jurisdiction, but data protection and confidentiality laws must be considered. Companies can voluntarily produce witnesses, but they should evaluate the legal implications, such as confidentiality obligations and the strategic impact on the case and the employee involved. If a witness does not show up without a valid reason, they may be fined or the evidence may be disregarded, which can have a negative impact on the outcome of the proceedings. This does not apply to witnesses from outside the Polish jurisdiction. In some cases, the witness may also refuse to answer questions. With court approval, testimony can be given in writing or via videoconference.

To formally obtain testimony if a witness is not willing to provide the information voluntarily, parties generally need to use legal assistance instruments, which involves a formal request to Polish authorities to ensure compliance with local legal standards. In dealings with EU countries, except Denmark, Regulation 2020/1783 applies. For non-EU countries and Denmark, the 1970 Hague Convention or bilateral agreements are used. If these do not apply, Polish law governs.

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?

Attorney-client privilege covers everything the attorney has learned in the course of providing legal assistance. During litigation, privileged communications cannot be disclosed or used as evidence in court without the client's consent. In criminal proceedings, in exceptional situations, the court may exempt an attorney from the obligation to maintain attorney-client privilege, but in civil proceedings it is absolutely protected. Attorney-client privilege generally applies to in-house counsel. However, this privilege does not extend to lawyers employed under a labour contract in a company's legal department who serve only one client – their employer.

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

In Poland, as mentioned earlier, the attorney-client privilege is broad, providing significant protection for communications between clients and their legal counsel. To best protect the confidentiality of communications with counsel both within and outside the jurisdiction for litigation purposes, companies should take several steps. For foreign counsel, it is crucial to understand the scope of attorney-client privilege in their jurisdiction and ensure that communications are clearly marked as subject to legal privilege. Additionally, incorporating specific confidentiality provisions in legal service agreements can further safeguard sensitive information.

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

In Poland, there are no inherent limitations on suits against foreign defendants, with the primary consideration being national jurisdiction. Within the EU, Regulation (EU) 1215/2012 is crucial, while for EEA countries, the Lugano Convention applies. Generally, defendants should be sued in their domicile courts, with exceptions for contracts (place of performance) and torts (where the harm occurred). Consumers have the option to bring suits in the courts of their domicile. In other cases, the jurisdictional rules of the Polish Code of Civil Procedure apply, which are similar to these international regulations.

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

U.S. litigation has no direct impact on litigation in Poland. However, increasingly, though still rarely, Polish plaintiffs may initiate lawsuits based on the same factual circumstances as those in U.S. cases. In such proceedings, the outcome of the U.S. litigation can be used as evidence, potentially influencing the Polish court's assessment of the case.

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

While the likelihood of litigation evolving directly as a result of U.S. litigation is low, there is a growing, albeit still infrequent, trend wherein Polish plaintiffs initiate lawsuits based on similar factual circumstances as those in U.S. cases. These cases may use the outcomes of U.S. litigation as evidence, which can influence the development of litigation in Poland.

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.

In Poland, the Collective Redress Directive has been implemented by introducing a second type of class action for cases involving consumer interests. However, no such proceedings have been reported yet, and the Financial Ombudsman is listed as the only authorised entity for group actions. The Product Liability Directive has not been implemented, with the draft still under governmental review and expected to be adopted in 2025.

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Natalia Nieróbca provides regulatory advice, particularly for companies from the life science sector. She advises on the law of pharmaceuticals, medical devices, food, and healthcare.
She supports clients in matters involving procedures for market authorisation, classification, advertising, labelling, sales and distribution models, and systems for public financing of regulated products. She provides ongoing advice across the life cycle of products and supports companies in administrative proceedings.

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