International Comparative Legal Guides

Drug & Medical Device Litigation 2026

A practical cross-border resource to inform legal minds

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Expert Analysis Chapter

Q&A Chapters

Portugal


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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.

Infarmed, the authority for medicines and health products, oversees medicines, medical devices, food supplements, over-the-counter products and cosmetics.

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?

Legislation[1] and regulation define the required standards for product safety, quality, pharmacovigilance and post-authorisation, and marketing surveillance and product information. While regulatory approval can be evidence that a product met both the safety and information requirements at the time of approval, it does not provide immunity from liability if injuries occur. Manufacturers remain liable for harms caused by defects and insufficient or misleading information, regardless of regulator sign-off. Liability may still arise if there is negligence, inadequate warnings, or newly discovered risks after approval that the marketing authorisation holder of the product or the producer failed to disclose adequately.

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

Regulation broadly shapes litigation over life sciences products by defining legal standards for product safety, manufacturing, labelling, and post-marketing obligations. Courts use these regulatory benchmarks to assess whether all legal duties have been fulfilled, and compliance can serve as key evidence regarding product safety, or the adequacy of information provided. Advertising and promotion are also heavily regulated, increasing scrutiny of marketing practices and the risk of litigation over misleading claims. Engagement with regulators, such as incident reporting or recalls, may be relevant during litigation, but is not required as a precondition to bringing claims. Overall, regulation generally provides the framework within which courts may assess obligations, evidence, and liability regarding life sciences products.

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?

Yes. APIFARMA, the Pharma Industry Association, and APORMED, the Medical Device Company Association, have Codes of Ethics, which focus essentially on matters related to interaction with healthcare professionals, health care organisations and patients. The focus of these Codes of Ethics is promotion, understood in a broad sense – similarly to what happens with the equivalent Codes from EFPIA (European Federation of Pharmaceutical Industries and Associations) and MedTech Europe – and they do not affect litigation and liability.

There is also an Association of the Cosmetic, Personal Hygiene, and Perfume Industry; however, no public code of conduct exists.

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 inform both consumers and the prescribing physicians of the product's risks and instructions for use, directly in their label or leaflet or, in the case of medicines, in the Summary of the Products Characteristics ("SmPC") – a document specifically aimed at healthcare professionals. Such warnings are critical for litigation concerning the product. If the marketing authorisation holder or the manufacturer, whichever applicable, fails to include a known risk in the label, leaflet or SmPC, and the risk occurs, the product is often presumed defective, which greatly simplifies the claimant's case. Generally, manufacturers can only avoid liability for risks that are indeed derived from their product and were not included in the label if they prove that the risk was undiscoverable given the state of scientific knowledge when the product was placed on the market.

2 Manufacturing

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

Obtaining a medicines manufacturing authorisation in Portugal requires approval from the Portuguese Agency, Infarmed. Key requirements include having suitable premises,

equipment, and a qualified Technical Director. Applicants must comply with Good Manufacturing Practices ("GMP"). The licence is required for manufacturing, division, reconditioning, and repackaging operations. The licence to manufacture medical devices is simpler, and essentially depends on notification to Infarmed, or registration pursuant to the Medical Devices Regulation ("MDR").

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?

We are not aware of such agreements with the U.S. Food and Drug Administration. Regulation and guidance issued by the European Medicines Agency ("EMA") are integrated in Infarmed's regulatory practice, due to the EMA acting as a node in the European Union ("EU")'s medicines regulatory network. In addition, the legislation in Portugal applicable, amongst others, to manufacture is European-based, setting a common legal standard in the EU.

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

Violation of manufacturing requirements can be relevant for liability and litigation if there is a causal link between such violation and a product defect.

3 Transactions

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

There are no specific approvals required from local regulators. Nevertheless, licences are personal by nature and therefore, in the event of a merger/acquisition, the company gaining control must either already be the holder of the relevant authorisations (e.g. manufacturing authorisation) or satisfy all legal requirements that enable respective approval.

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

There are no specific restrictions on foreign ownership of life sciences companies or manufacturing facilities, apart from possible sanctions applied to specific countries. They do not affect liability for injuries caused by a product.

4 Advertising, Promotion and Sales

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

The main legislation is provided in the Medicines Act (enacted by Decree-Law no. 176/2006, and which transposed into Portuguese Law Directive 2001/83/EC)), SiNATS (the Health Technology Assessment System, enacted by Decree-Law no. 97/2015), the MDR (Regulation (EU) 2017/745), Decree-Law no. 145/2009 (which contains residual medical device regulation, specifically on what concerns advertising and promotion), and Decree-Law no. 29/2024, which executes the MDR in Portugal.

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")?

Such promotion is forbidden in the case of medicines. The same applies to medical devices that have not been object of CE marking.

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?

Such regulation is enforced independently by regulators and has limited impact on litigation. It can nevertheless constitute the basis of a claim or reinforce a defect claim, should the advertising be misleading or falsely represent that a product may be used for a purpose it was not able to meet.

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?

Life sciences companies face a complex data privacy landscape. Considering that jurisdictions such as Brazil and several US states have adopted GDPR-inspired data protection frameworks, life sciences companies often adopt a baseline privacy standard modelled on the GDPR to achieve broad compliance across multiple regulatory regimes. In practice, this involves establishing a lawful basis for processing and implementing comprehensive governance and technical mechanisms, including (i) appointing Data Protection Officers, (ii) conducting Data Protection Impact Assessments for high-risk processing activities, (iii) maintaining Records of Processing Activities, and (iv) performing detailed data mapping to track personal data flows across systems and jurisdictions. Because these organisations operate globally, they must also ensure that personal data transferred across borders complies with GDPR restrictions, often relying on mechanisms such as Adequacy Decisions issued by the European Commission, Standard Contractual Clauses or Binding Corporate Rules, often supported by Transfer Impact Assessments. In addition, they also manage relationships with third-party processors through strict contracts and due diligence, maintain breach response plans to meet notification obligations, and provide staff training to promote privacy awareness.

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?

Portuguese law[2] presumes publicity of judicial proceedings,

but this is limited by strong legal protections for trade secrets and non-pertinent personal data. A company may request confidentiality for documents that qualify as trade secrets under the Industrial Property Code or for sensitive personal data under data protection laws. Courts routinely grant measures such as restricted access, redacted versions, and confidential appendices to protect such information. However, confidentiality cannot override core principles of due process and the right to evidence. Material essential for the court and the opposing party to exercise rights of defence or reach a decision cannot be withheld, even if confidential; instead, courts will manage disclosure through protective orders. Blanket confidentiality claims are not accepted. Companies must clearly justify and specify the parts of documents to be protected and accept tailored disclosure rather than absolute secrecy. Information already public, or not meeting the legal standard of trade secret, must be disclosed. In summary, the court balances confidentiality with the need for transparency and fair trial, typically through proportionate, case-specific protective measures.

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

In February 2026, Portugal approved legislation to implement the EU Digital Services Act, setting up a framework for online intermediaries, creating a central coordination platform, and defining sanctioning powers.

The Portuguese National Strategy for the Health Information Ecosystem ("ENESIS") focuses on AI, cybersecurity, and data protection, pursuing a transition from traditional to smart health.

None of these changes seem to have a relevant impact on product 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.

Clinical trials with medicines are governed by the Clinical Trial Regulation ("CTR") (European Regulation 536/2014) and by Law no. 9/2026, which executes the CTR and has recently been enacted, coming into force in early April 2026. This law is generally governed by the Clinical Investigation Law (Law no. 21/2014). Additional guidance is issued by the Portuguese Agency, Infarmed and the National Ethics Committee for Ethical Research.

These rules are evidently relevant for litigation involving injuries associated with the products under trial. Under Portuguese Law, the trial sponsor is liable for the damages suffered by the participants, regardless of fault, unless it can prove that the damage is not caused by the trial. However, as far as we are aware, there has not yet been deemed relevant litigation involving injuries associated with the use of products within the context of clinical trials.

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)?

As far as we are aware, such liability has never been brought before Portuguese courts. In principle, and in theory, negligence for failure to test in a particular patient population could only occur if the population was predictably more prone to be subject to the medicine, or predictably more prone to suffer from certain adverse reactions.

Nevertheless, when a medicine is authorised, the relevant populations in which it was tested must be disclosed to the regulators. Not testing in a certain patient population may therefore restrict the label of the product, once approved, or entail the obligation of the marketing authorisation holder to put forward specific disclaimers in the product information (e.g. the information leaflet and/or the SmPC).

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

Yes. These are essentially governed in the Medicines Act and complementary regulation. Compassionate use of unapproved drugs requires prior authorisation from the Portuguese Agency, Infarmed.

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

No. Limitation of liability is limited in Portugal, and particularly so within clinical trials and compassionate use. Nevertheless, the informed consent provided to patients within the context of compassionate use programmes usually lays out the risks and limitations of an unapproved drug being used and of the particular drug in question.

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

Companies should clearly set out, in the informed consents provided to patients, the risks and limitations of an unapproved drug being used and of the particular drug in question. Similarly, companies should require physicians to obtain express informed consent from patients. Strict monitoring and pharmacovigilance obligations should also be put in place to allow for early interruption of treatment.

7 Product Recalls

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

The recall of medicines in Portugal is primarily regulated by the Medicines Act (enacted by Decree-Law no. 176/2006 and which transposed into Portuguese Law Directive 2001/83/EC).

Recall of medical devices is governed by the MDR (Regulation (EU) 2017/745) and by Decree-Law no. 29/2024, which executes the MDR in Portugal.

The competent authority, both for drugs and medical devices, is the Portuguese Agency, Infarmed.

Recalls can be triggered by the marketing authorisation holder, in the case of medicines, or the medical device manufacturer (voluntary recall). Infarmed, following reports of defects, adverse events, non-conformities, or non-compliance with legislation, may also order a recall and the withdrawal of the product from the market.

Infarmed will classify the recall based on its risk profile.

Once Infarmed approves the recall, such a recall is publicly disclosed by Infarmed – thus ensuring it reaches patients and users – and communicated to distributors, healthcare professionals and pharmacies. The marketing authorisation holder is responsible for withdrawing the products from the market.

In the case of medical devices, manufacturers and authorised representatives are required to notify Infarmed of any field safety corrective action, including recalls. Notification should be made as soon as possible, especially if there is a serious risk. Infarmed then decides on recall actions and oversees risk communications to users, distributors, and healthcare providers.

The manufacturer typically implements corrective actions, collects the affected devices, and communicates user instructions or safety notices.

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?

See above.

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

In Portugal, a product recall is treated as an evidentiary fact in civil litigation and does not, by itself, establish or exclude liability. The existence of a recall neither creates a presumption of defect nor operates as a standalone defence.

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?

Recalls in the U.S. or Europe do not have binding effect in Portugal and are not treated as evidence *per se* in local proceedings. However, international recalls can raise awareness and influence the behaviour of companies operating in Portugal, leading them to take preventive action or anticipate litigation risks. There is a clear spillover effect: foreign recalls may prompt increased regulatory scrutiny and encourage private claims, even if they play no direct role in establishing liability under Portuguese law.

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

Portuguese law does not provide a general guarantee of confidentiality for internal investigations or risk assessments. Such documents are not protected by privilege and may be subject to disclosure in future judicial proceedings if relevant to the dispute. Companies should be aware that internal reports, assessments and communications can be requested and used as evidence in litigation unless they fall under specific legal confidentiality regimes.

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

A product recall often increases the risk of litigation, as it may constitute an acknowledgement of a defect (even if limited to specific batches) or at least be perceived as an implicit admission of a defect. To mitigate exposure, companies should ensure that internal communications, investigations, and risk assessments related to a recall are kept confidential, to the greatest extent permitted, ideally under the legal privilege of external counsel. Handling sensitive aspects in this manner can limit their disclosure in future proceedings. It is also important to avoid unnecessary admissions in recall documentation and restrict access to internal analyses. These measures help companies control the legal risks associated with conducting a recall, but do not eliminate liability.

It should be noted, however, that companies are subject to regulatory obligations, which often require disclosure of adverse effects or implementation of corrective actions, and compliance with these requirements cannot be withheld for litigation strategy purposes. Meanwhile, companies may internally be assessing the potential liability implications of an adverse event or a recall; in certain circumstances, a recall might be pursued solely as a precautionary measure, rather than as an admission of any safety issue. The fact that regulatory and/or internal discussions occur does not constitute an admission of defect, and companies may need to defend the safety of a product even after a recall has been implemented. It is therefore important that discussions relating to litigation risk are kept confidential as far as permissible, since informal or open internal communications may later become subject to disclosure in litigation and be mischaracterised as admissions, even if they only reflect preliminary or open internal debate.

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.

Portuguese law[3] permits collective actions ("*ações populares ou coletivas*"), which allow qualified entities such as consumer associations to represent the interests of a group of affected individuals. Portuguese law adopts an "opt-out" regime for class actions, making it attractive for collective claims. These actions can address various areas, from consumer and competition law to other fields, and there are no significant substantive limitations on the types of class actions that may be brought, so long as the requirements for representative standing are met.

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

In Portugal, although the collective action regime is opt-out, there have been no known collective actions specifically related to product liability. Litigation in the drug and medical device sectors is significant and well established, but so far, claims have been pursued through individual plaintiff lawsuits. One

reason for this may be the greater difficulty in establishing a sufficiently homogeneous class to satisfy standing requirements for a collective action in product liability cases. Another explanation is that the collective system is still maturing and has not yet been tested in this area. There is, however, a clear trend towards collective actions in other sectors, such as consumer protection and antitrust, including cases within the pharmaceutical area, but not relating to product liability. Looking forward, and with the transposition of the new Product Liability Directive, it is likely that, in time, an association may test the regime with a product liability collective action.

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

Product liability claims are permitted under Portuguese law, which follows the EU framework. Strict liability is recognised for damages caused by defective products, including drugs, medical devices and other healthcare products, meaning that liability can arise without proof of fault if a product is defective and causes harm.

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

Yes. Under Portuguese law, there is a strict prohibition on lawyer solicitation of plaintiffs for litigation. According to Article 90, paragraph 2, item h) of the Statute of the Portuguese Bar Association[4] (*Estatuto da Ordem dos Advogados*), lawyers are expressly forbidden from soliciting clients, either directly or through third parties. This rule is designed to uphold the integrity and dignity of the legal profession. Violations of this prohibition constitute disciplinary offences and may lead to sanctions imposed by the Bar Association. Possible disciplinary sanctions include a warning, censure (reprimand), monetary fines (the amount depends on the seriousness of the infraction), suspension from the practice of law for up to 10 years, or, in the most severe cases, expulsion from the Bar. The type and severity of the penalty will depend on the gravity of the misconduct and any harm caused, and all sanctions are formally recorded. In addition, disciplinary procedures may require restitution of fees or assets received as a result of the breach.

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

Third-party litigation funding is permitted and has recently transformed the Portuguese class actions market. The applicable legislation (Decree-Law 114-A/2023, implementing the EU Collective Redress Directive) imposes requirements to maintain the independence of the claimant from the funder, such as: (i) the funding agreement must disclose financing sources and ensure independence and absence of conflicts of interest; (ii) decisions related to the litigation must rest exclusively with the claimant (the association or representative), and funders cannot influence or control these decisions; and (iii) funders' remuneration must be fair and proportionate.

Should these requirements be violated, courts may order amendments to the funding agreement, or otherwise deny standing to the claimant.

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

A final court decision (*transitado em julgado*) in Portugal has *res judicata* effect, binding only the parties to the proceedings and on the specific matters decided. However, in practice, findings can influence similar or follow-on claims.

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 are no specific obstacles under Portuguese law to introducing evidence during the proceedings that a manufacturer has made improvements or corrective measures to a product to enhance its safety. The main requirements are that such evidence must be presented before the end of the evidentiary stage in the trial. There is no predetermined rule on how this evidence will be assessed or for what purpose it may be used, and it will be up to the court to determine its relevance and impact in each case.

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?

There are no general obstacles to a plaintiff seeking the testimony of another affected individual in an action. Subject to confidentiality safeguards and the third party's consent, documents concerning another affected person that are relevant to the case may also be submitted as evidence. However, the admissibility and access to such evidence depend heavily on the third party's consent, especially when sensitive health information is involved. Portuguese law strictly protects medical and health-related confidentiality for all parties involved, including physicians and hospitals. Therefore, it would not be possible, for example, for a plaintiff to broadly request all information about similar cases from every hospital or healthcare provider in the country without appropriate consent.

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?

There is no specific procedure under Portuguese law for conducting depositions, similarly to what happens in the U.S., for use in foreign proceedings. Portuguese law does not contain any statutes that expressly prohibit a company from voluntarily making witnesses available for deposition, and such informal cooperation is possible if the individuals consent and all relevant obligations, such as labour law and data protection, are respected. However, if formal, compelled testimony or the

production of documents is required for use in foreign litigation, parties must follow international judicial cooperation mechanisms, primarily the Hague Evidence Convention, to which Portugal is a party. Under this Convention, the foreign court submits a request to the Portuguese central authority, and the Portuguese courts will execute the request according to domestic procedural rules and safeguards, particularly those related to privileged information and personal data. In practice, the use of the Hague Convention process is advisable to maximise the likelihood that testimony or documents will be recognised as enforceable and valid in foreign litigation, although their ultimate admissibility and evidentiary value will always depend on the evidentiary thresholds that apply in the requesting jurisdiction.

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 Portugal, attorney-client privilege (legal professional privilege) is recognised and protected for communications between clients and external, independent lawyers, especially when legal advice is provided in the context of litigation. This privilege is enforced under the Portuguese Bar Association Statute and remains robust in civil matters, making such communications inadmissible as evidence if obtained or disclosed in breach of confidentiality. However, in line with the 2010 *Akzo Nobel v Commission* (C-550/07 P) judgment of the Court of Justice of the European Union ("CJEU"), legal professional privilege does not extend to communications with in-house counsel in the context of EU competition investigations and related proceedings. The CJEU held that in-house lawyers do not possess the necessary independence from their employer to benefit from this protection. As a result, in-house counsel communications are generally not privileged in regulatory and competition contexts and may be subject to disclosure during discovery. In purely domestic civil matters, Portuguese law could theoretically recognise privilege for in-house lawyers if they are duly registered and act independently, but the prevailing EU standard takes precedence in areas governed by EU law or where disclosure in cross-border proceedings is at issue.

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?

To best protect the confidentiality of communications with counsel in Portugal and internationally for purposes of litigation, companies should engage external, independent lawyers for sensitive matters, as only communications with external counsel are protected by legal professional privilege under both Portuguese and EU law. All legal communications should be clearly marked as confidential and subject to attorney-client privilege, and their dissemination within the company should be strictly limited to those who truly need access. Companies should ensure that in-house counsel are registered with the Portuguese Bar Association, or its EU equivalent if the in-house counsel is not Portuguese. If the in-house counsel is qualified in a non-EU jurisdiction, there is no clear or immediately applicable rule on confidentiality/privilege under Portuguese or EU law, and significant uncertainty may exist as to the protection of such communications.

It is also important that the legal role is well defined and separated from business functions, while being mindful that, in the context of EU competition law, privilege will generally not extend to in-house lawyers' communications. It is essential to segregate legal advice and documentation from purely business or technical materials, as only documents prepared for the purpose of legal advice or containing legal advice are likely to be privileged. When involved in cross-border disputes, companies should be aware that the scope and recognition of privilege may differ in other jurisdictions, and it is advisable to coordinate with local counsel to adapt privilege strategies as needed. Internally, data management protocols should ensure that legal communications, including emails and digital records, are securely stored to avoid inadvertent disclosure during discovery or regulatory requests.

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

There are no significant limitations on suits against foreign defendants in Portugal. As long as the cause of action is clearly set out and there is a sufficient connection to Portuguese jurisdiction, a foreign defendant is treated in the same manner as a domestic defendant. While foreign defendants may benefit from additional time to respond and from the right to have documents translated, there are no structural differences compared to proceedings against local defendants.

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

In Portugal, the impact of U.S. litigation on "follow-on" is quite distinctive. Due to Portugal's opt-out system and openness to representative actions, there have been several cases where disputes that exist or are anticipated in the U.S. have also been litigated in Portugal, sometimes as follow-on cases, but sometimes even in anticipation of litigation in the U.S. This phenomenon is probably explained not only by the opt-out class action regime but also by the procedural principle of concentration of defence, which requires the defendant to present their full defence in the initial statement of defence. As a result, there have been situations in Portugal involving exploratory or anticipatory litigation related to matters pending or expected to arise in U.S. courts.

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

It is likely that significant U.S. litigation trends, such as class actions in product liability or consumer protection, may result in increased litigation in Portugal, especially with the ongoing maturation of the collective redress regime and growing experience with litigation funding.

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.

Portugal has transposed the EU Collective Redress Directive, modernising and clarifying the framework for collective actions, including in the life sciences sector (pharmaceuticals and medical devices). With new rules coming from the anticipated

revision of the Product Liability Directive, which should be transposed into Portugal Law on 9 December 2026, claimants will benefit from lowered evidential thresholds and increased opportunities for collective claims, suggesting an increase in drug and medical device litigation in the coming years.

Endnotes

1 Decree-Law no. 383/89 (as amended by DL 131/2001); Decree-Law no. 176/2006 (Medicines Act).

2 Code of Civil Procedure (publicity, access limits, evidence and secrecy measures: e.g. arts 3, 547, 417–423); Industrial Property Code (trade secrets: arts. 311–317); Constitution, art. 20 (access to justice and effective judicial protection) and art. 32 (rights of defence).

3 Constitution, art. 52; Law no. 83/95 (Popular Action Act); Law no. 24/96, art. 19 (Consumer Protection Act); Directive (EU) 2020/1828 on representative actions — transposed by Decree-Law no. 114A/2023.

4 Statute of the Portuguese Bar Association (*Estatuto da Ordem dos Advogados*), art. 90(2)(h); disciplinary sanctions framework therein (warning, censure, fine, suspension up to 10 years, expulsion).

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