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Portugal: Law & Practice
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PORTUGAL

Law and Practice

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Contents

Morais Leitão, Galvão Teles, Soares da Silva & Associados is a leading full-service law and consultancy firm in Portugal, with decades of experience. It has earned broad recognition in several branches and sectors of the law at both a national and international level. The firm's reputation amongst peers and clients alike stems from the excellence of the legal services provided. The firm combines unique technical expertise with a distinctive approach to reach cutting-edge solutions that often challenge some of the most conventional practices. With a team comprising more than 250 lawyers, Morais Leitão is headquartered in Lisbon and has additional offices in Porto, Funchal and Singapore. Due to its network of associations and alliances with local firms and the creation of the Morais Leitão Legal Circle in 2010, the firm can also offer support through offices in Angola, Mozambique, Cape Verde and Timor-Leste.

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1. Applicable Product Safety Regulatory Regimes

1.1 Medical Devices

The Portuguese product safety regulatory regimes for medical devices and other healthcare products are essentially defined by EU law, which is implemented or transposed by national legislative acts. Following the solutions adopted by EU law, Portuguese law regulates each product category through specific pieces of legislation. In addition, specific topics related to certain products are regulated by administrative regulations issued by local regulatory authorities or by the Portuguese government.

Medical Devices

The safety of medical devices (including software-based medical devices) is primarily ruled by:

- Regulation (EU) No 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices;
- Regulation (EU) No 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices;
- Decree-Law No 29/2924, of 5 April 2024, which approves the Portuguese Medical Devices Act; and
- Decree-Law No 189/2000, of 12 August 2000, as amended, which approves the Portuguese In Vitro Medical Devices Act.

Special measures on safety are established in Decree-Law No 29/2024, which states that local regulatory authorities shall adopt the necessary measures to ensure the protection and safety of health and/or compliance with public health requirements. As such, the authority may decide on a withdrawal from the market or suspension, or may restrain or impose specific conditions on the placement into the market and the putting into service of medical devices; any such measures shall be notified to the European Commission.

Medical Instruments

Medical instruments are legally qualified as medical devices, so the above-mentioned medical devices regimes apply.

Personal Protective Equipment (PPE)

PPE may be qualified as a medical device and thereby become subject to the medical devices regimes.

Other product safety regulatory regimes that apply to PPE include:

- Regulation (EU) No 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment; and
- Decree-Law No 118/2019, of 21 August 2019, as amended, which ensures the implementation of Regulation (EU) 2016/425 into the Portuguese legal order.

1.2 Healthcare Products

The Portuguese legal framework on healthcare products is essentially defined by EU law and the respective national acts of implementation or transposition, and eventual administrative regulations.

Cosmetics

The safety of cosmetics is primarily ruled by:

- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products; and
- Decree-Law No 23/2025, of 19 March 2025, which approves the Portuguese Cosmetics Act.

Biocides

The safety of biocides is primarily ruled by:

- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products; and
- Decree-Law No 140/2017, of 10 November 2010, as amended, which ensures the implementation of Regulation (EU) 528/2012 into the Portuguese legal order.

Food

The safety of food, including genetically modified organisms (GMOs) and nutrition supplements, is primarily ruled by:

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs;
- Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin;
- Decree-Law No 113/2006, of 12 June 2006, as amended, which ensures the implementation of Regulation (EC) 852/2004 into the Portuguese legal order;
- Decree-Law No 136/2003, of 28 June 2003, as amended, which approves the Portuguese Food Supplements Act;
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food; and
- Decree-Law No 102/2005, of 23 June 2005, which ensures the implementation of Regulation (EU) 1829/2003 into the Portuguese legal order.

Several other acts may also be applicable to specific foodstuffs.

1.3 Medicines

The Portuguese legal framework on medicines is essentially defined by EU law and the respective national acts of implementation or transposition, and eventual administrative regulations.

Pharmaceuticals

The safety of pharmaceuticals is primarily ruled by Decree-Law No 176/2006, of 30 August 2006, as amended, which approves the Portuguese Medicines Act.

The clinical trials of medicinal products are primarily ruled by:

- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicines for human use; and
- Law No 21/2014, of 16 April 2016, as amended, which approves the Portuguese Clinical Investigation Law.

Blood Products

Blood products are partially subject to the Portuguese Medicines Act (Decree-Law No 176/2006, of 30 August 2006, as amended), which is the safety regulatory regime applicable to pharmaceuticals, as stated above, and to a specific piece of legislation: Decree-Law No 267/2007, of 24 July 2007, which approves the legal framework applicable to the quality and safety of human blood and blood components.

Psychedelics

Psychedelics are partially subject to the Portuguese Medicines Act (Decree-Law No 176/2006, of 30 August 2006, as amended), which is the safety regulatory regime applicable to pharmaceuticals, as stated above, and to specific pieces of legislation: Decree-Law No 15/93 of 22 January 1993, as amended, which approves the regime applicable to trafficking and consumption of narcotic drugs and psychotropic substances, as well as Regulation-Decree No 61/94, of 12 October 1994, as amended, which regulates the Decree-Law No 15/93.

Cannabis for medicinal purposes is subject to specific legislation:

- Law No 33/2018, of 18 July 2018, which regulates the use of medicines, preparations and substances based on the cannabis plant for medicinal purposes; and
- Decree-Law No 8/2019, of 15 January 2019, which regulates the use of medicines, preparations and substances based on the cannabis plant for medicinal purposes.

CBD

CBD, as a cannabinoid, when intended to be used for medicinal purposes, is subject to the legislation outlined above applicable to medicinal products and, specifically, to the legislation applicable to medicines, preparations and substances based on the cannabis plant for medicinal purposes.

1.4 Technologies and Digital Health

Medical Apps, Telemedicine and Wearables

Portugal follows the discussions on the regulation of new products/technologies that occur at an EU level.

Therefore, medical apps or the software, apps or instruments used in telemedicine (the regulation of which, in Portugal, is limited to some ethical standards that apply to physicians), as well as wearables with medical purposes, are not subject to specific product safety regulatory regimes. However, once those apps, software or instruments fall within the legal definition of "medical device", the medical devices regulatory regime becomes applicable.

Stem Cells

The safety of stem cells is primarily ruled by Law No 12/2009, of 26 March 2009, as amended, which approves the legal framework on quality for the donation, procurement, testing, processing, preservation, storage, distribution and application of human tissues and cells.

1.5 Borderline Products

Due to their characteristics, some products may fall within the scope of more than one of the regimes identified in previous sections, which determine the applicable regulatory obligations (see **2. Commercialisation and Product Life Cycle**).

In general terms, the regime applicable to a specific borderline product is defined by taking into consideration the intended purpose of the product in question and the mechanism by which the main intended effect is achieved in the human body. Some specific rules may be applied.

European entities and INFARMED, I.P. (the local Regulatory Authority – see **3.1 Regulatory Authorities**) usually issue some guidance on how to define which specific regime the product comes under.

2. Commercialisation and Product Life Cycle

2.1 Design and Manufacture

Entities that manufacture medical devices, pharmaceuticals, cosmetics and food products of animal origin are subject to specific requirements, as established in the legal acts outlined in **1. Applicable Product Safety Regulatory Regimes**, as follows.

Medical Devices

The manufacture of medical devices is subject to previous registration under Regulation (EU) No 2017/745.

The manufacturer is required to appoint a qualified person to be technically responsible for assuring the compliance with the applicable regulations.

Medicines

The manufacture of medicines in Portugal is subject to previous authorisation from INFARMED, I.P.

Authorisation shall only be granted if the applicant has duly licensed facilities and adequate equipment with the characteristics established in the applicable legislation, and complies with the good manufacturing practices established by law.

Manufacturing operations are to be carried out in compliance with the Good Manufacturing Practices and the granted manufacturing authorisation.

The manufacturer must appoint a qualified person to act as a technical director, and must have sufficient competent and appropriately qualified personnel.

The manufacturing premises and equipment shall be located and designed, constructed, adapted and maintained in a manner appropriate to the operations to be carried out, minimising the risk of error and also to allow effective cleaning and maintenance to avoid contamination, cross-contamination and, in general, any adverse effect on product quality.

Cosmetics

The manufacture of cosmetic products shall comply with the Good Manufacturing Practices.

Food Products of Animal Origin

These products shall be prepared and handled exclusively in premises that comply with the hygiene requirements set out in Annex II of Regulation (EC) No 852/2004. The manufacturing premises shall be registered with the Regulatory Authority and, in some cases, previous approval of such premises may be required.

2.2 Corporate Social Responsibility, the Environment and Sustainability

There are no specific legal obligations regarding corporate social responsibility, environment and sustainability throughout the life cycle of medical devices and consumer health products.

2.3 Advertising and Product Claims

The products listed in **1. Applicable Product Safety Regulatory Regimes** are subject to the general advertising legal regime, approved by Decree Law No 330/90, of 23 October 1990, as amended (the "Advertising Code").

According to the Advertising Code, advertising should be governed by the principles of lawfulness, identifiability, truthfulness and respect for consumer rights. Testimonials and comparative advertising are subject to specific and strict requirements.

In addition, the advertising of products listed in **1. Applicable Product Safety Regulatory Regimes** is subject to some specific requirements. The advertising of medicines and medical devices is subject to very detailed and restrictive advertising regimes, which are approved by the acts outlined in **1. Applicable Product Safety Regulatory Regimes**, among others.

Medical Devices

Specifically in what concerns to medica devices, despite the approval and entry into force of Decree-Law No 29/2024, Decree-Law No 145/2009 remains in force with regard to the regulation of advertising for medical devices.

Decree-Law No 145/2009 establishes specific prohibitions on the advertising of medical devices, as follows:

- it is prohibited to advertise medical devices that do not possess a conformity assessment and were not notified to the competent authority; and
- it is generally prohibited to advertise medical devices whose use requires the assessment and decision of healthcare professionals – eg, implantable devices, long-term invasive devices, devices that include a medicine or stable derived from human blood or plasma, and devices that are manufactured with cells and tissues of animal origin.

Specific rules are also imposed on the advertising of medical devices to the general public and healthcare professionals, as follows.

Advertising to the general public

The advertising of devices shall be unequivocally identified as such and shall expressly indicate that it is related to a medical device, and shall contain the following:

- the name of the device or respective commercial brand;
- indispensable information on the safe use of the device, including the respective purpose and special precautions; and
- advice for the user to carefully read the labelling and instructions of use.

The advertisement cannot contain any reference that:

- might lead to the conclusion that a consultation or surgery is unnecessary, in particular by offering a diagnosis or by suggesting a treatment by correspondence;
- suggests that the effect of the device is guaranteed, without adverse reactions or secondary effects, with superior or equivalent results in comparison to another treatment or with other medicine;
- suggests that the average health condition of a person may be harmed if the device is not used;
- is exclusively or mainly targeted at children;
- mentions the recommendations of scientists, healthcare professionals or other individuals who could, because of their celebrity status, encourage the consumption of the device;

- addresses the device as food, cosmetic or body hygiene product or as any other product;
- suggests that the safety or efficacy of the device is due to it being a natural product;
- induces an incorrect self-diagnosis, through a description or detailed representation of the anamnesis;
- mentions statements or guarantees of recover in an abusive, daunting, or misleading way; or
- contains visual representations of human body changes caused by diseases or lesions, or by the effect of a medical device on a human body or parts of it.

Any form of comparative advertising is prohibited.

Advertising to healthcare professionals

Medical devices, the use of which requires the assessment and decision of healthcare professionals – eg, implantable devices, long-term invasive devices, devices that include a medicine or stable derived from human blood or plasma, and devices manufactured with cells and tissues of animal origin – can be advertised solely to healthcare professionals.

Medicines

The Medicine Act establishes separate sets of rules for the advertising of medicines to the general public and to healthcare professionals.

Advertising to the general public

Only non-prescription medicines may be advertised to the general public, provided they are not under state reimbursement and the advertisement complies with the same specific requirements as those listed above for the advertising of medical devices to the general public.

The advertising should be unequivocally identified as such and shall expressly state that it corresponds to a medicinal product. It shall include the following information:

- the name of the medicine, as well as the common name if the medicine contains only one active substance, or the brand name;
- essential information on the rational use of the drug, including therapeutic indications and special precautions; and
- advice for the user to read the information contained in the secondary packaging and the package leaflet carefully, and a warning to consult a doctor or pharmacist in case of doubt or if symptoms persist.

Comparative advertising is not permitted.

Advertising to healthcare professionals

Advertisements of medicines shall include the following in a comprehensible way in the respective advertising material:

- the name of the medicine;
- the essential information compatible with the Summary of Product Characteristics;
- the classification of the medicine in terms of its dispensation regime, namely if it is a prescribed medicine, when applicable;
- the respective reimbursement regime; and
- the date of the issuance of the advertising material in question and the date of its last revision.

The information contained in the advertising material must be accurate, up-to-date, verifiable and sufficiently complete to allow the correct assessment of the therapeutic value of the medicine. The references and the illustrative material of medical publications or scientific works shall be correctly reproduced and should mention the respective source.

Cosmetics

In the advertising of cosmetics, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions they do not have.

Biocides

The following is to be noted in the advertising of biocides:

- the sentences “Use biocides safely. Always read the label and product information before use” should be included and shall be clearly distinguish-

able and legible in relation to the remaining advertisement;
- advertisers may replace the word "biocides" in the prescribed sentences with a clear reference to the product type being advertised;
- the advertisement shall not refer to the product in a misleading manner in terms of the risks of the product to human health, animal health or the environment, or in terms of its efficacy; and
- the advertising of biocides shall not mention "low-risk biocidal product", "non-toxic", "harmless", "natural", "environmentally friendly", "animal friendly" or any similar indication.

Food

The advertising of food shall be accurate, clear and easy for the consumer to understand.

It shall not be misleading, particularly:

- as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production;
- by attributing effects or properties to the food that it does not possess;
- by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients; and
- by suggesting, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient.

Food Supplements

The labelling and advertising of these products shall not include any mention that:

- attributes prophylactic, treatment or curative properties of human diseases to the product, nor makes reference to such properties; and
- expressly or implicitly states that a balanced and varied diet is not a sufficient source of nutrients in general.

The labelling, presentation and advertising of food supplements, whether written, audiovisual or broadcast only by auditory means, shall include the term "Food Supplement" with sufficient and appropriate prominence, which unequivocally identifies the product as such.

Nutrition and health claims shall be subject to the specific EU legal requirements.

2.4 Marketing and Sales

The placing on the market of some of the products outlined in **1. Applicable Product Safety Regulatory Regimes** is subject to compliance with specific requirements, ranging from previous notification to conformity assessments by independent third parties or obtaining administrative authorisations.

Medical Devices

The following requirements are to be followed.

- Before they are placed on the market, medical devices should undergo a conformity assessment procedure. The specific applicable assessment procedure varies according to the category of device. In some cases, the conformity assessment procedure should be carried out by a notified body (ie, a third-party entity able to carry out conformity assessment tasks under the applicable regulation).
- Conformity with the general safety and performance requirements shall be demonstrated, including through a clinical evaluation.
- CE marking is affixed to medical devices that conform with the applicable requirements.
- The regulatory authority is to be notified when the medical devices are placed on the market, and a Unique Device Identifier is assigned to each medical device.

Medicines

Only medicines with Marketing Authorisation may be placed onto the market.

Marketing Authorisations may be granted by national regulatory authorities or by the European Medicines Agency, subsequent to the valid submission of the respective request applications and documentation listed by the applicable law, including the results of pharmaceutical, pre-clinical and clinical trials.

The decision to grant a Marketing Authorisation shall be based on objective scientific criteria regarding the quality, safety and therapeutic efficacy of the medicinal product.

The Marketing Authorisation is valid for five years and is renewable; after the first renewal it can be renewed for an indefinite time.

Personal Protective Equipment

Before being placed on the market, PPE should undergo a conformity assessment procedure, to be carried out by a notified body (ie, a third-party entity able to carry out conformity assessment tasks under the applicable regulation). The PPE shall be classified according to the risk categories set out in Regulation (EU) No 2016/425; the conformity assessment procedures vary according to each of the risk categories.

CE marking is affixed to PPE that conforms with the applicable requirements.

Cosmetics

Cosmetics are subject to safety assessment before they are placed on the market.

Prior to placing the cosmetic product on the market, a notification shall be submitted to the European Commission, by electronic means.

Biocides

Only authorised biocidal products may be made available on the market.

Authorisation can be requested from the national or the European regulatory authority, and may be granted for a single biocidal product or for a biocidal product family.

The authorisation shall be granted for a maximum period of ten years.

Biocidal products shall be used in accordance with the terms and conditions defined by the authorisation.

Food Supplements

The placing on the Portuguese market of a food supplement is to be previously notified to the regulatory authority.

If the regulatory authority does not issue a decision within 60 business days of receiving the notification, its decision shall be deemed favourable.

GMO

GMO for food use, food containing GMO or food produced from or containing ingredients from GMO may only be placed on the market if they are covered by an authorisation granted in accordance with the applicable European legal framework.

2.5 Internationalisation

The increasing approximation between the legal systems of the EU, driven by EU legislative initiatives, is an important factor in promoting the internationalisation of products.

Some difficulties may arise from the need to comply with some local requirements that are indispensable for the respect of consumer rights (such as compliance with language requirements), and from the limitations that are sometimes imposed on the free movement of goods between EU member states, on the grounds of the need to safeguard public health.

2.6 Post-Marketing Obligations, Including Corrective Actions and Recalls

The regulatory regimes outlined in **1. Applicable Product Safety Regulatory Regimes** contain the following post-marketing obligations.

Medical Devices

As an integral part of the manufacturer's quality management system, for each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is appropriate for the risk class and the type of device.

The post-market surveillance system is aimed at actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device, addressing the necessary conclusions, and at determining, implementing and monitoring any preventative and corrective actions.

Manufacturers shall prepare post-market surveillance and safety update reports.

Manufacturers of devices made available on the EU market shall report to the relevant competent authorities any serious incident involving such devices and any field safety corrective action, as well as any statistically significant increase in the frequency or severity of incidents.

Following the reporting of a serious incident, the manufacturer shall perform the necessary investigations in relation to the serious incident and the devices concerned, including a risk assessment of the incident and field safety corrective action. During the investigations, it shall co-operate with the competent authorities and with the notified body concerned (where relevant).

Medicines

All agents that act in the commercialisation of medicines have a general duty of collaboration and information regarding post-market surveillance. However, specific obligations are imposed on different agents, as stated in the Portuguese Medicines Act.

Manufacturers

The specific obligations for manufacturers are as follows:

- they shall establish and maintain a documentation system based on specifications, manufacturing formulae, processing and packaging instructions, procedures and records of the various manufacturing operations, complaints registration and complaints analysis;
- they shall immediately inform the regulatory authority of any quality deficiency that may lead to a recall or abnormal restrictions in the supply of medicines; and
- the manufacturer or the Marketing Authorisation holder shall inform the regulatory authority immediately of any action taken to suspend or withdraw a medicinal product from the market, as well as the reasons for such action, if it relates to the effectiveness of the medicinal product or the protection of public health.

Marketing Authorisation Holders

Marketing Authorisation holders should adopt and operate a pharmacovigilance system that includes a set of rules and material and human resources aimed at collecting information on the risks of medicines for patients or public health, the scientific evaluation of all the information obtained, the consideration of appropriate safety measures to prevent or minimise risks, and the compliance with reporting duties.

Blood Products

Blood products are subject to a specific hemovigilance system that includes a system of traceability and notification of adverse reactions.

Personal Protective Equipment

Manufacturers, importers or distributors who consider or have reason to believe that PPE they have placed on the market does not conform with the applicable regulation shall immediately take the necessary corrective measures to bring that PPE into conformity, to withdraw it or to recall it, as appropriate.

Manufacturers shall immediately inform the competent national authorities of the member states in which PPE is available on the market whenever such equipment presents a safety risk, and shall provide the details, particularly concerning non-conformity and any corrective measures taken.

Cosmetics

Manufacturers, importers or distributors who consider or have reason to believe that a cosmetic product they have placed on the market does not conform with the applicable Regulation shall immediately take the corrective measures necessary to bring that product into conformity, or to withdraw or recall it, as appropriate.

In the case of non-compliance, manufacturers, importers or distributors may be required by the competent authorities to execute such measures.

Manufacturers, importers or distributors shall cooperate with the competent authorities on any action to eliminate the risks of the products they have made available on the market, namely by providing all the information and documentation necessary to demonstrate the conformity of the product with the applicable requirements.

In the event of serious undesirable effects, the manufacturer or importer and distributors shall, without delay, notify the competent authority of the member state where the serious undesirable effect occurred.

Biocides

The holder of an authorisation to place a biocide on the market shall notify the authorities of the information that may affect the authorisation, namely:

- new data or information on the adverse effects of the active substance or biocidal product for humans (particularly vulnerable groups), for animals or for the environment;
- any data indicating the potential of the active substance for the development of resistance; and
- new data or information demonstrating that the biocidal product is not sufficiently effective.

Food

Food business operators shall put in place, implement and maintain permanent procedures based on the Hazard Analysis and Critical Control Point principles.

3. Regulator Engagement and Enforcement

3.1 Regulatory Authorities

The relevant regulatory authorities for the product categories outlined in **1. Applicable Product Safety Regulatory Regimes** are as follows.

- INFARMED, I.P. (*Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.* – National Authority of Medicines and Health Products), which regulates and supervises pharmaceuticals for human consumption, medical devices and cosmetics.
- *Direção-Geral da Saúde* (DGS – General Directorate of Health) and *Inspeção-Geral das Atividades em Saúde* (IGAS – General Inspectorate of Health Activities) regulate and supervise compliance with the blood products regime.
- *Instituto Português da Qualidade, I. P.* (IPQ – Portuguese Institute for Quality) and *Autoridade de Segurança Alimentar e Económica* (ASAE – Authority for Economic and Food Safety) regulate and supervise compliance with the PPE regime.
- DGS and ASAE are responsible for regulating and supervising compliance with the biocides regime.
- *Direção-Geral da Alimentação e Veterinária* (DGAV – General Directorate of Food and Veterinary Medicine) and ASAE regulate and supervise compliance with the legal framework applicable to food.

3.2 Regulatory Enforcement Mechanisms

INFAREMD, I.P., IGAS and ASAE

These agencies have supervisory powers over market agents' compliance with the applicable laws and regulations and the compliance of their respective products; they also have enforcement powers.

They may execute inspections and audits of the agents under their supervision and impose preventative or corrective measures. They may also initiate administrative offences procedures and, consequently, impose fines and eventually accompanying sanctions (see **4.1 Product Safety Offences**).

4. Liability

4.1 Product Safety Offences

In Portugal, offences against the product safety regulatory regimes outlined in **1. Applicable Product Safety Regulatory Regimes** are essentially sanctioned through administrative offences procedures, which culminate in the imposition of fines and, whenever applicable, accompanying sanctions.

The sanctions regimes are framed by:

- the specific acts outlined in **1. Applicable Product Safety Regulatory Regimes**;

- the General Regime on Administrative Offences, approved by Decree-Law No 433/82, of 14 September, as amended; or
- the Regime on Economic Administrative Offences, approved by Decree-Law No 9/2021, of 29 January 2021.

Specific sanctions are established by the legal framework applicable to the following products.

Medical Devices

The sanctions framework is established by the Portuguese Medical Devices Act and the Portuguese In Vitro Medical Devices Act.

According to the Portuguese Medical Devices Act, violation of the respective legal provisions is qualifiable as serious administrative offence, sanctioned by the fines provided for in the Regime on Economic Administrative Offences:

- from EUR650 to EUR1,500 (if the infringer is a natural person); or
- from EUR1,700 to EUR24,000 (if the infringer is a legal person).

According to the Portuguese In Vitro Medical Devices Act violation of the respective legal provision is sanctioned by fines varying from EUR2,000 to 15% of the business volume of the infringer, or EUR180,000, whichever is lower (the maximum amount is reduced to EUR3,700 if the infringer is a natural person).

Ancillary sanctions may apply.

Personal Protective Equipment

In the specific case of PPE, Decree-Law No 118/2019, as amended, and the Regime on Economic Administrative Offences provide for fines of between EUR65,000 and EUR150,000 if the infringer is a natural person, or between EUR170,000 and EUR2.4 million if the infringer is a legal person, depending on the size of the company.

The following accompanying sanctions may be imposed, depending on the seriousness of the infraction and the level of fault:

- loss of objects in favour of the state;
- prohibition on engaging in professions or activities whose exercise depends on administrative permission (for a maximum period of two years);
- deprivation of the right to participate in conferences, fairs or markets, national or international, with the purpose of transacting or advertising products or activities (for a maximum period of two years);
- deprivation of the right to participate in any public procurement procedure, as a candidate, competitor or member of a candidate or competitor group (for a maximum period of two years);
- closure of an establishment whose operation is subject to any type of administrative permission (for a maximum period of two years);
- deprivation of the right to tax benefits, credit benefits and credit financing lines (for a maximum period of two years);
- deprivation of the right to benefits or subsidies granted by national or EU public entities or services (for a maximum period of two years);
- suspension of licences, permits or authorisations related to the exercise of the respective activity (for a maximum period of two years); and
- publication of the condemnation.

Medicines

The sanctions framework is defined by the Portuguese Medicines Act, according to which fines may vary from EUR2,000 to 15% of the business volume of the infringer or EUR180,000, whichever is lower.

The following accompanying sanctions may also be imposed, depending on the seriousness of the infraction and the level of fault:

- loss of illicit objects, equipment and devices in favour of the state;
- prohibition of the business activity of the infringer, for a maximum period of two years;
- deprivation of the right to participate in public tenders for a maximum period of two years; and
- suspension of authorisations, licences and other titles attributing rights for a maximum period of two years.

In the infringement of legal provisions regarding advertising, the specific following accompanying sanctions may also apply:

- the decision on the imposition of fines may also determine the publication on social media of the essential elements of the condemnation;
- the suspension of advertising of the relevant medicine, for a maximum period of two years;
- a procedure to exclude the relevant medicine from the reimbursement regime by the state may be initiated; and
- the infringer's medical sales representative may be prevented from visiting national health service hospitals and services, in case of violation of the legal regime of such visits.

Blood Products

The respective specific regime provides for fines of between EUR500 and EUR1,500 if the infringer is a natural person, or EUR44,000 if the infringer is a legal person.

Cosmetics

The sanctions framework is defined by the Portuguese Cosmetics Act, according to which the fines may vary from EUR2,000 to 15% of the business volume of the infringer or EUR180,000, whichever is lower.

Biocides

The sanctions framework is defined by Decree-Law No 140/2017, as amended, and by the Regime on Economic Administrative Offences. The established fines may vary between EUR150 and EUR7,500 if the infringer is a natural person and depending on the seriousness of the infraction, or between EUR250 and EUR90,000 if the infringer is a legal person and depending on the seriousness of the infraction and the size of the company.

The following accompanying sanctions may also be imposed, depending on the seriousness of the infraction and the level of fault:

- the loss of active substances, biocidal products, treated articles or other objects belonging to the infringer;
- suspension of the commercialisation of biocidal active substances, biocidal products or treated articles;
- suspension of authorisations, licences and permits; and
- deprivation of the right to a subsidy or benefit granted by public entities or services.

Food

Several sanctions are provided for each specific regime outlined in **1. Applicable Product Safety Regulatory Regimes**, as follows:

- for violation of the regime regarding the hygiene of foodstuffs, the applicable fines vary from EUR500 to EUR3,740 if the infringer is a natural person, or EUR44,890 if the infringer is a legal person; and
- for violation of the food supplements regime or the GMO regime, the applicable fines vary between EUR65,000 and EUR150,000 if the infringer is a natural person, or between EUR170,000 and EUR2.4 million if the infringer is a legal person and depending on company size.

Accompanying sanctions may be imposed in each case.

4.2 Product Liability

The legal bases for product liability claims in Portugal are:

- Decree-Law No 383/89, of 6 November 1989, as amended, which approves the Liability Regime for Defective Products and transposes Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products into the Portuguese legal order; and
- the Portuguese Civil Code.

Under these acts, product liability claims may be grounded on the Liability Regime for Defective Products or on the general civil liability mechanisms (non-contractual or contractual) contained in the Civil Code. Civil liability may occur whenever damages arise from the infringement of civil law (non-contractual) or of contractual provisions (contractual).

According to the Liability Regime for Defective Products, the following applies:

- the producer is liable, regardless of guilty behaviour, for damage caused by defects in the products it puts into circulation;
- a product is considered to be defective when it does not provide the safety conditions which may legitimately be expected, taking into account all the circumstances, namely its presentation, the use that can reasonably be made of it, and the moment it went into circulation on the market;
- the producer is not liable if it proves that:
  (a) it has not put the product into circulation;
  (b) in regard to the circumstances, the defect could reasonably be assumed not to have existed when the product was put into circulation;
  (c) it has not manufactured the product for sale or for any other form of distribution with an economic purpose nor produced or distributed it in the course of its business activity;
  (d) the defect is due to the compliance of the product with mandatory standards established by the public authorities;
  (e) the state of scientific and technical knowledge at the time when the product entered into circulation did not allow the detection of the existence of the current defect; or
  (f) in the case of the defect of a component part, the defect is attributable to the design of the product in which the component was incorporated or to the instructions given by the manufacturer of the product.

Damages resulting from death or personal injury and damage to something other than the defective product are compensable.

Under the civil liability mechanisms, all damages are compensable. The requirements for a civil liability claim, which must be proved by the claimant, are as follows:

- action or relevant omission (wilfully or by negligence);
- breach of law or of contractual provisions;
- the occurrence of damage;
- guilty behaviour (presumed in the case of contractual civil liability); and
- causality between the damage and the defective conduct.

4.3 Judicial Requirements

As a rule, the Portuguese courts have jurisdiction to resolve claims if the defendants are domiciled in Portugal.

Under Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, the following applies:

- in claims based on the Liability Regime for Defective Products or on civil liability (non-contractual) (see **4.2 Product Liability**), Portuguese courts also have jurisdiction if the damaging event took place in Portugal;
- in claims based on civil liability (contractual), Portuguese courts have jurisdiction if the claim arises from a contract performed in Portugal; and
- consumers can always file a claim in Portugal if they are domiciled in Portugal, regardless of the location of the other party's registered office or domicile.

According to the internal legal order (the Civil Procedure Code), the territorial jurisdiction is defined by the domicile of the defendant.

4.4 Costs

In terms of costs, product liability claims are subject to the rules that apply to judicial claims in general, which means that they are subject to trial costs as established by law.

Trial costs include the judicial fee (a fee paid by the claimants and by the opponents to the court) and all the costs of the process – ie, all the expenses resulting from the process, such as the fees for interpreters or translators, or for experts appointed by the judge.

The trial costs are to be paid by the losing parties in proportion to their lack of success, which means the

trial costs may be split between the parties according to their respective lack of success.

In addition, the losing parties shall pay compensation to the successful parties, corresponding to 50% of the judicial fees paid by all the parties.

4.5 Product-Related Contentious Matters

Besides product liability claims (see **4.2 Product Liability**), the most common product-related contentious claims are those arising from the judicial review of decisions made by regulatory authorities.

Final decisions made by regulatory authorities may be challenged before the courts, whether they are of a sanctioning nature (decisions imposing fines and, eventually, accompanying sanctions) or not.

4.6 Class Actions, Representative Actions or Co-Ordinated Proceedings

Portuguese law provides for the popular action (governed by Law No 83/95 of 31 August 1995, as amended) of a collective claim that can be brought by those seeking compensation for offences against public health, quality of life or the consumption of goods.

4.7 ADR Mechanisms

Besides judicial dispute resolution, the following ADR mechanisms are available in the context of civil liability legal actions in Portugal:

- arbitration;
- mediation or conciliation; and
- recourse to justices of the peace.

4.8 Interrelation Between Liability Mechanisms

The same facts may constitute one or more administrative offences and, furthermore, grounds for product liability claims.

If the facts constitute several administrative offences, several sanctions may be imposed.

If the facts constitute several administrative offences and are investigated by different regulatory authorities, the simultaneous investigations should proceed, since each regulatory authority should act and decide on the facts in accordance with the scope of its specific responsibilities and legal competence.

On the other hand, there is no direct interrelation between administrative offence procedures and judicial claims.

If potential criminal conduct is found by the regulatory authorities in the context of the respective investigations or by the court in the context of the judgment of the liability claim, the facts should be reported to the public prosecutor for criminal enforcement purposes.

5. Applicable Product Safety Regulatory Regimes

5.1 Policy Development

In relation to product safety and the liability of the products referred to in **1. Applicable Product Safety Regulatory Regimes**, Portugal follows currently the discussions and initiatives that occur at an international and EU level.

5.2 Legislative Reform

There is currently no public information on legislative reforms in progress in respect of products listed in **1. Applicable Product Safety Regulatory Regimes**.

However, considering the relevant recent developments, the following legislative reforms may be expected.

- Adoption of a law to implement the Regulation (EU) No 2017/746 into domestic law.
- Reform of the regulation of advertising for medical devices.
- Changes to the legal framework applicable to the assessment of health technologies, taking into account the application of Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment.

5.3 Impact of Artificial Intelligence

Artificial intelligence (AI) has played an important role in the development of new products falling within

the categories listed in **1. Applicable Product Safety Regulatory Regimes**.

At the regulatory level, once products incorporating AI fall within the legal definition of any of the listed products, the respective regulatory regime becomes applicable.

Portugal follows the discussions and initiatives on AI that occur at an international and EU level.

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