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Portugal

LIFE SCIENCES

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This country-specific Q&A provides an overview of life sciences laws and regulations applicable in Portugal.

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1. Please briefly summarize your country's legislative framework for medicinal products (including biologicals), medical devices, food, and food supplements

i. Medicines

Medicines are ruled in Portugal by Decree-Law n. 176/2006, of 30 August ("**Medicines Law**") which regulates most of the aspects relating to medicines, namely marketing authorisation ("**MA**"), advertising, pharmacovigilance, import, export, labelling and promotion of medicines, transposing, among others, Directive 2001/83/CE of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use ("**Medicines Directive**").

ii. Medical Devices

Medical devices are regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices ("**MDR**") and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices ("**IVMDR**"). Aspects such as notification of manufacturing, wholesaling distribution, vigilance and advertising are provided by Decree-Law n. 145/2009 of 17 June ("**Medical Device Law**") and Decree-Law n. 189/2000, of 20 August ("**In Vitro Medical Device Law**"), which are respectively applicable to all aspects that are not governed by MDR or IVMDR.

iii. Food

In what concerns to food, it is applicable Regulation (EC) 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 and which frames all the laws and regulations applicable to food safety.

From the national law point of view, several laws and regulations are applicable to specific sectors of activity related with food safety and quality.

iv. Food Supplements

Legal framework applicable to food supplements in Portugal is provided by Decree-Law n. 136/2003 of 30 June ("**Food Supplements Law**"), transposing to the national law the Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

2. With regards to medicinal products and medical devices, how is the regulatory process structured in your jurisdiction from R&D through market approval until post-marketing vigilance, and what rules does it follow? Please briefly describe.

i. Medicines

To obtaining an MA for a medicine, applicants should follow one of the following procedures:

- A national procedure, if the medicine is intended to be approved only for placing on the Portuguese market.
- A mutual recognition procedure, in which an authorisation obtained in a member state is used to apply for authorisation in a new member state.
- A decentralized procedure, when the application is submitted in several member states simultaneously and when the medicine does not have an MA in any member state.
- A centralized procedure, managed by the European Medicines Agency ("**EMA**"), leading to an MA that is valid in all member states.

Any change in the terms of an MA must be subject to an application for a variation of the MA, including changes to the summary of product characteristics and any conditions, obligations or restrictions affecting the MA, or

changes to the labelling or package leaflet in connection with changes to the summary of product characteristics.

An MA may be transferred to a new holder through the submission of a transfer application by the MA holder.

ii. Medical Devices

Medical devices do not need authorisation for placing medical devices on the market. The manufacturer must submit the medical device to a conformity assessment, affix "CE" marking and notify the competent authority that the medical device has been made available on the market. Infarmed may withdraw a product from the market or may suspend, restrict or subject to certain conditions the placing on the market and putting into service of a device or group of medical devices under certain conditions – namely, when the use of medical devices could compromise the health and safety of patients or other persons, or for public health reasons.

3. What is the regulatory process for food supplements, from first notification to the competent authorities until post-marketing vigilance in your country, and what regulations are applicable here? Please briefly describe.

As per Food Supplements Law, only food supplements complying with its provisions may be commercialized in Portugal.

The marketing of food supplements should be electronically notified by the applicant to *Direção-Geral de Alimentação e Veterinária* (Directorate General for Food and Veterinary) ("**DGAV**") and should be instructed with the following elements:

(i) Notification table (model available at DGAV's website which includes information relating to the manufacturing and commercialization of the product and information relating to the product itself). (ii) Copy of the label of the product and (iii) Copy of the consumer information leaflet.

In case of any doubt related to the product, DGAV may request additional information to the applicant, which should make such information available within 15 days. DGAV may also request opinions or studies relating to the safety and quality of the product to the applicants, which should be performed by accredited entities included in the public list provided by DGAV for this purpose.

In case DGAV does not answer and/or request additional information within 60 days after the application, the product is deemed approved.

The market of food supplements in Portugal is supervised by ASAE – *Autoridade de Segurança Alimentar e Económica* (Authority for Food and Economic Safety) ("**ASAE**").

4. What are the ongoing obligations in your country after a marketing authorization for medicinal products has been obtained or a conformity assessment been carried out for medical devices?

Once an MA is granted or a conformity assessment is carried out, there are several obligations to be observed by the MA holder or manufacturer of the medical device. Such obligations are mainly related to the following aspects:

i. Marketing

MA holder should ensure the marketing of the medicine under the terms of the MA and comply with the obligation to notify Infarmed about the starting of the effective commercialization of the medicine for all the authorized presentations. MA holder should also notify Infarmed with two months in advance (except for urgent circumstances) about the date of suspension or cessation of effective marketing of the medicine, for each authorized presentation.

Concerning medical devices, once the conformity assessment has been carried out, manufacturer should ensure that the medical device comply the requirements provided by MDR, including those applicable to labelling and instructions for use.

ii. Pharmacovigilance

MA holders and/or manufacturers of medical devices are subject several obligations once the products are available in the market.

Holders of MA of medicines are subject of obligations of pharmacovigilance provided by Medicines Law, which closely follows the framework provided by Directive 2010/84/EU and Directive 2012/26/EU. In Portugal, National System of Pharmacovigilance is managed by Infarmed. To comply with those obligations, MA holders must implement a pharmacovigilance system allowing the report of adverse reactions and the mitigation and management of risks emerging from the use of medicines. MA holders should have a qualified person responsible for all the obligations established by law relating to pharmacovigilance.

Healthcare professionals are also subjected to reporting obligations of adverse reactions of medicines, which should be performed through the platform available in Infarmed' s website.

Requirements applicable to vigilance of medical devices are provided by MDR. However, until Eudamed is fully in place, the rules governing the vigilance of medical devices provided by Medical Devices Law should apply.

Within the National System of Vigilance of Medical Devices, manufacturers, authorized representatives, distributors, healthcare professionals and users should report to Infarmed all the information related to incidents occurred within the use of medical devices in Portugal, namely those related to:

(i) Malfunction, breakdown or deterioration of characteristics or performance, as well as any inaccuracy, omission or inadequacy in the labelling or instructions for use of a device, which may cause or have caused death or serious deterioration in the state of health of a patient, user or third party. (ii) Indirect damage following an incorrect medical decision related to a medical device, when used in accordance with the instructions for use provided by the manufacturer. (iii) Any technical or medical reason related to the characteristics or performance of a device that has led to corrective safety action being taken on the Portuguese market for devices of the same type by the manufacturer.

iii. Advertising and transparency

Advertising of medicines and medical devices are subject to significant restrictions. MA holders of medicines and medical devices should comply with all the regulatory requirements applicable to advertising and promotion of these products. The rules governing advertising of medicines are provided by Medicines Law. Concerning advertising of medical devices, the rules are provided by Medical Devices Law.

In what concerns to transparency requirements, the MA holders, companies responsible for information or promotion of a medicinal product or the distributor are prohibited from giving or promising directly or indirectly to health professionals or their patients, prizes, gifts, bonuses or benefits in cash or in kind, except in the case of objects of insignificant value and relevant to the practice of medicine or pharmacy (the insignificant value has been set out as EUR 60 by Order of the Secretary of State of Health).

On the other hand, healthcare professionals are prohibited to request to an MA holder, companies responsible for information or promotion of a medicinal product or distributors any prizes, gifts, bonuses or benefits in cash or in kind – even if they are earned abroad or under foreign legislation –, regardless of whether or not there is any consideration for the supply, prescription, dispensation or sale of medicines.

Additionally, any entity covered by Medicines Law sponsoring congresses, symposia or any actions or events of a scientific nature or the direct or indirect dissemination of medicinal products, such sponsoring (i) must be included in the promotional documentation related to such event, as well as the documentation of the participants and the works or reports published after the realization of the event and (ii) must notify Infarmed about the sponsorship in advance of the event.

Advertising to medical devices is regulated by Medical Devices Law, establishing advertising rules very similar to those applicable to medicines. Additionally, Medical Devices Law sets out equal transparency requirements as to medicines, with the same reporting obligations.

5. Which are the competent national authorities having the regulatory oversight over medicinal products, medical devices, food, and food supplements and what are their respective responsibilities?

Infarmed is the regulatory authority with competence for regulation and surveillance of the market. Infarmed has as a role to ensure the quality, safety and effectiveness of medicines and health products, thus protecting and ensuring high standards of public health.

Among other attributions, Infarmed is responsible for regulating and supervising the research, production, distribution, marketing and use of medicines for human use and health products, including medical devices, cosmetics and body care products as well as monitoring the use and consumption of medicines, medical devices and health products. Infarmed could be assisted by ASAE in the exercise of their attributions of regulation and surveillance.

In what concerns to food and food supplements, DGAV is the competent authority for regulation of the market having as mission the execution and evaluation of the food safety politics. DGAV is also the competent authority to manage the adverse reaction of food supplements report system. As to surveillance of the market, the competent authority is ASAE.

6. Please briefly describe the procedure of

challenging regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food supplements.

Decisions regarding medicines and medical devices may be challenged through administrative and/or judicial channels, within a given period.

Individuals and entities who are affected by decisions of administrative bodies may react against them, mainly on the grounds of breach of the law. These means of reaction are common to decisions that affect other products such as food supplements, although there may be specific details.

7. Please briefly describe the legal framework and the relevant regulatory procedure (e.g., application process, requirements, approval, denial) that applies in your jurisdiction to clinical trials for medicinal products and medical devices.

i. Medicines

Clinical trials on medicines are regulated by Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 ("**Clinical Trials Regulation**").

The entry into force of the Clinical Trials Regulation on 31 January 2022 involved the entry into force of the Clinical Trials Information System ("**CTIS**"), through which all clinical trial submission, assessment and supervision processes in the EU are to be submitted. The Clinical Trials Regulation has provided for a three-year transition period, with the following timeline:

- From 31 January 2022 to 31 January 2023, clinical trial sponsors were able to choose to submit their clinical trial applications under the Clinical Trials Directive or through the CTIS.
- From 31 January 2023, new applications for clinical trials in the EU and the European Economic Area must be submitted under the CTIS.
- By 31 January 2025, all ongoing trials will have to be transferred to the CTIS under the Clinical Trials Regulation.

As such, all the new applications for clinical trial should be submitted through CTIS, under the rules and requirements provided by Clinical Trials Regulation and the ongoing trials should be transferred to CTIS by 31 January 2025.

ii. Medical Devices

Interventional clinical studies with medical devices of Classes III, implantable medical devices and invasive medical devices of classes II-A and II-B for long-term using must be authorized be Infarmed and are also subjected to a favourable opinion of the competent ethics committee. Once the application is submitted by the sponsor, Infarmed should resolve on the application within 30 days. Infarmed may request additional information to the applicant, being the deadline suspended until such additional information is made available by the sponsor. In case of objections by Infarmed, the sponsor may amend the application to accommodate the objections. The refuse to amend the application by the sponsor under the terms requested by Infarmed implies the refuse of authorization to conduct the study.

Interventional clinical studies for medical devices other that those referred above depends on the favourable opinion of the competent ethics committee and notification to Infarmed.

8. Is there a public database for clinical trials in your country, and what are the rules for publication?

Clinical trials of medicines and clinical studies of medical devices are available on the National Clinical Trials Register ("**RNEC**") website, available at www.rnec.pt.

RNEC has two user profiles allowing different degrees of access to information. The general access area includes relevant information about clinical studies and the database of clinical trials ongoing in Portugal and the entities involved in such clinical trials. The restricted area implies the creation of a profile and allows the communication between the sponsors of clinical studies and the status of the applications submitted by the sponsors.

9. Please briefly summarize the rules that must be observed in your jurisdiction when using data from clinical trials?

Data used for clinical trials of medicines and clinical studies of medical devices may be qualified as personal data, particularly falling under the category of sensitive data. As a result, any data processing activities must adhere to the General Data Protection Regulation

("**GDPR**") and local regulations governing health data.

In cases where the data derived from these clinical trials and studies is identified as personal data, there is a possibility of transferring it to third parties or affiliates. However, such transfers must strictly align with the GDPR requirements.

This includes ensuring a lawful basis for processing, like obtaining consent, and fulfilling obligations related to information disclosure, ensuring the security of the processing, meeting joint-controllership requirements, having sub-processing agreements in place, and complying with regulations for international data transfers.

It is important to highlight that if the data undergoes full anonymization (not just pseudonymization), it loses its status as personal data, rendering GDPR requirements inapplicable. Nevertheless, it is crucial to emphasize that the anonymization process itself needs to align with the guidelines set forth in the GDPR.

10. Are there any trends and/or legislative proposals in your country on digitizing the process of conducting clinical trials (e.g., digitalization of the application process, decentralization of clinical trials)?

Covid-19 has evidenced weakness and obsoletism in traditional processes of clinical trials. Within the constraints imposed by the pandemic, Infarmed has issued guidelines to mitigate the impact of the pandemic on clinical trials that were in progress or about to start. These measures did not specifically target clinical trials of medicines to treat COVID-19, but all clinical trials ongoing during the pandemic period. Infarmed stressed the possibility of remote visits through technological means, ensuring the collection and recording of the information foreseen for the presential visits.

In addition, considering the technological evolution that has been taking place, it is necessary to progressively support clinical trials with safe technology, making it possible to improve the quality of the data collected and the comfort of the participants, without jeopardising the quality of the results of the study. The use of technology will also allow optimizing the costs involved in the clinical trials.

11. What are your country's legal requirements for the authorization of manufacturing plants for medicinal products, medical devices, food, and food supplements? Please briefly describe.

The manufacture of medicines, experimental medicines and medical devices requires authorisation from Infarmed.

The manufacture of medicines requires the existence of facilities licensed for the purpose, and compliance with good manufacturing practices. The facilities are subject to periodic inspections by Infarmed, which certifies their compliance and issues a certificate of good manufacturing practices, which is valid for three years.

For medical devices, facilities must obtain an industrial activity license in accordance with the applicable legislation and have an industrial activity code associated with the categories of medical devices produced in conjunction with the respective manufacturing activities performed.

Facilities for manufacturing food supplements should be licensed with an industrial activity license in accordance with the applicable laws and have an industrial activity code associated with the categories of manufactured products.

12. Please briefly describe the typical process of distributing medicinal products, medical devices, and food supplements in your country, encompassing, if applicable, the wholesale distribution of products.

Authorisation for the wholesale of medicines is issued by Infarmed and covers the activities of supplying, holding, storing or delivering medicines for processing, resale or use in medical services, healthcare facilities and pharmacies, excluding the supply to the public. It specifies the facilities from which distribution is carried out and is subject to the validity of the certificate of good distribution practices, which must be renewed every five years.

The wholesale of medical devices is subject to prior notification to Infarmed and covers the activities of supplying, holding, storing or supplying medical devices for resale or use in medical services, healthcare facilities, pharmacies and other points of sale to the public, excluding supply to the public. The application must be submitted at least 60 days before the start of the distribution activities and must include the full address of the distribution facilities. It does not have an expiration date.

For dispensing to the public, medicines are classified into

prescription-only medicines (MSRMs) and non-prescription medicines (MNSRMs). MSRM prescriptions can also be classified as renewable, special or for restricted use in specialized monitored conditions. MNSRM include the MNSRM *latu sensu*, which may be dispensed at pharmacies and points of sale of non-prescription medicines (being the latter subject to a communication to Infarmed and the compliance with the applicable rules) and MNSRM of exclusive pharmacy dispensing which, despite being MNSRM, may only be dispensed in pharmacies.

13. Please briefly describe the pricing and reimbursement rules, if any, for medicinal products, medical devices, and food supplements in your jurisdiction?

i. Medicines

Non-reimbursed medicines have free pricing arrangements, but all other medicines have their prices regulated and are subject to maximum price rules or notified price rules. They cannot be sold unless the MA holder obtains a retail price ("**RP**").

The RP of the medicine is composed of:

- The ex-factory price ("**EFP**"), which is the maximum price at the stage of production or import and has fixed rules for its determination.
- The wholesalers' and retailers' selling margins, as fixed by ministerial order.
- The tax on the sale of medicines.
- Value-added tax ("**VAT**").

The MSRMs intended to be dispensed and used in National Health Service ("**NHS**") establishments are also subject to maximum price rules, and their final price is composed of the EFP, the sale tax and VAT.

The prices of medicines subject to the maximum price rules are reviewed annually. The pricing rules for medicines are set out in Decree-Law 97/2015 of 1 June 2015 establishing SiNATS – *Sistema Nacional de Avaliação de Tecnologias de Saúde* (National System of Evaluation of Health Technologies) ("**SiNATS**") and regulated by several Ministerial Orders (in particular, Ministerial Order 195-C/2015 of 30 June 2015 and Ministerial Order 154/2016 of 27 May 2016).

Requests for price authorisation and price reviewing communications follow their own procedures and are submitted to INFARMED by the MA holder.

ii. Medical Devices

As a rule, medical devices financed by the State have fixed maximum prices. Medical devices not financed by the State have free pricing.

The pricing rules for medical devices are set out in SiNATS, and there are Ministerial Orders that define the maximum prices applicable to certain devices or groups of medical devices, which usually include the marketing margins and VAT. In these cases, the RP proposed is indicated by the manufacturer at the time of the request for reimbursement to Infarmed, which follows its own procedure.

iii. Food Supplements

In some special cases, food supplements may be reimbursed by the State. As example, food supplements suitable for the treatment and/or mitigation of special health needs of special groups. This is the case of reimbursement of the price of health technologies for children with respiratory, neurological and/or alimentary sequelae secondary to extreme prematurity, where milk formula after hospital discharge and breast milk strengthener until 12 months old are fully reimbursed.

14. What legislative framework applies to the advertising for medicinal products, medical devices, and food supplements in your country?

i. Medicines

Advertising of medicines in Portugal is ruled by Medicines Law which stems from the Directive 2001/83/CE. Subsidiarily, is applicable Decree-Law n. 330/90 of 23 October ("**Advertising Code**"). For an overview of the regime applicable to medicines, please refer to question 14 above.

ii. Medical Devices

In contrast to advertising of medicines, advertising of medical devices is not harmonized to EU level and is ruled in Portugal by Medical Devices Law. Advertising Code is also subsidiarily applicable. For an overview of the regime applicable to medicines, please refer to question 14 above.

iii. Food Supplements

Framework applicable to advertising of food supplements arises from Food Supplements Law and, subsidiary, from Advertising Code. For an overview of the regime applicable to food supplements, please refer to question 14 above.

15. What laws apply to patents and trademarks for medicinal products, medical devices, and food supplements in your country?

The Portuguese Industrial Property Code ("**IPC**") contains the most relevant provisions for patents, including for patent prosecution and enforcement.

Special inhibitory actions relating to pharmaceutical patents and generic medicines are available under Law 62/2011 of 12 December 2011.

The most common issues encountered by pharmaceutical companies in Portugal relate to patent disputes between originator and generic companies under Law 62/2011. Other issues that usually arise relate to the validity of patents and supplementary protection certificates ("**SPCs**").

There are no specific patentability requirements for medicines or medical devices per se. However, according to the IPC, processes for cloning human beings, processes for modifying the germinal genetic identity of the human being and uses of human embryos for industrial or commercial purposes are not patentable.

Methods of surgical or therapeutic treatment are also not patentable, but the products, substances or compositions used in any of these methods may be patented.

16. Please briefly describe how patent infringements in relation to medicinal products and medical devices are addressed in your jurisdiction, including possible defense strategies and legal proceedings against patent infringements.

Specific defenses to patent infringement in relation to medicines and medical devices in Portugal include an experimental use exemption and, in particular, the Bolar exemption.

Compulsory licenses on patents are provided for in the IPC in general terms, but there are no relevant precedents in Portugal regarding the granting of compulsory licenses. In any case, compulsory licenses may be granted in Portugal in the following circumstances:

- Lack or insufficient exploitation of the invention;
- Dependency between patents;
- Public interest;
- Under EU and Portuguese Competition law; and
- Under Regulation (EC) 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of medicines for export to countries with public health problems.

Patent infringement proceedings may be brought by the patent-holder or by the licensee. The licensee's right to bring an action depends on the specific terms of the corresponding license agreement and on the record of the license at the INPI – *Instituto Nacional da Propriedade Industrial* (National Institute of Industrial Property).

Although patent infringement is a crime under Portuguese law, the typical procedure for patent infringement actions is a civil lawsuit at the IP Court. Special inhibitory actions relating to pharmaceutical patents and generic medicines are available under Law 62/2011 and must also be filed at the IP Court or, upon agreement of the parties, before an institutional or ad hoc arbitral tribunal.

Civil remedies include preliminary and permanent injunctions granting the patent-holder the right to prevent any imminent infringement or to prohibit the continuation of the infringement. There is also the possibility of requesting the IP court to order the infringer to pay a periodic penalty for breach of the judgment, and to order the destruction, recall or definitive removal of the infringing goods from the channels of commerce. Damages claims for infringement are also possible.

Invalidity is available as a defense in civil infringement proceedings on the merits, through the filing of a counterclaim for revocation of the patent or SPC.

17. Does your jurisdiction provide for restrictions on the use of trademarks for medicinal products, medical devices, food, and food supplements?

Besides the general requirements and impediments provided for in the IPC with respect to trademark distinctiveness (that apply to all marks), Decree-Law 176/2006 of 30 August further provides that the name of a medicine may consist of a trademark, as long as that trademark is not misleading with regard to the therapeutic properties and nature of the medicine.

Furthermore, the EU Regulations on medical devices also

prohibit the use of trademarks or other signs that may mislead the user or the patient regarding the device's intended purpose, safety and performance.

Under trademark law, genuine medicine or medical device products that are non-counterfeit may face limitations on using their trademark if there is a prior trademark in Portugal that prevents the use of the mark by the importer (e.g., based on likelihood of confusion).

18. Please briefly describe the product liability regime for medicinal products, medical devices, and food supplements in your country.

General product liability rules are provided by Decree-Law n. 389/89 of 6 November, transposing to national law Directive 85/374/EEC of the Council of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. In the case of medicines, depending on whether the damage occurs before or after they are placed on the market, the applicable legal framework will be different.

In case the damage occurs during the clinical study or trial, the Clinical Research Law establishes that the sponsor and the researcher are jointly and severally liable, irrespective of fault, for any pecuniary and non-pecuniary damages caused to the participant by the clinical study or trial. In what concerns to interventional clinical studies, Clinical Research Law establishes that damage that affecting the participant's health during the clinical study and in the year following its completion is presumed to have been caused by the clinical trial.

In case the damage occurs after the medicine is in market, the Decree-Law n. 389/89 of 6 November will apply. As general rule, the producer is liable for the damages caused by a defect in his product, being producer defined as the manufacturer of the finished product, component part or raw material, and anyone who presents themselves as such by affixing their name, trademark or other distinctive sign to the product. Decree-Law n. 389/89 of 6 November also sets out the situations in which the producer's responsibility is excluded.

Concerning medical devices, Clinical Research Law is also applicable to the clinical studies involving medical devices. Thus, the responsibility for damages caused by the medical device during the clinical study applies in similar terms as those provided for medicines and referred above.

Finally, for medical devices after the placement in the market and for food supplements, Decree-Law n. 389/89 of 6 November is applicable.

19. Please provide a short overview of risks of liability (criminal liability, serious administrative / civil liability) and enforcement practice with regards to medicinal products (including biologicals), medical devices, foods, and food supplements.

Relating to administrative liability, the law applicable to medicines, medical devices and food supplements provides for an administrative offences' regime.

In case of medicines, administrative offences are considered very serious or serious. Very serious administrative offences are punishable with a fine between EUR 2.000 and 15% of the turnover or EUR 180.000, whichever is lower and serious administrative offence are punishable with a fine between EUR 2.000 and 10% of the turnover or EUR 120.000 whichever is lower. Additionally, ancillary sanctions such as prohibition from exercising the activity up to a maximum of two years, loss of objects in favor of the state, prohibition of participation in public tenders up to two years and suspension of licenses and authorizations up to two years may also be applied.

Concerning to medical devices, infringements to the rules provided by Medical Devices Law are qualified as administrative offences are punishable with a fine between EUR 2.000 and 15% of the turnover or EUR 180.000, whichever is lower.

Relevant law establishes as administrative offence the manufacturing and commercialization of food supplements which are not in compliance with Food Supplements Law and without complying with the labelling, information, presentation and notification requirements as provided by the same law. Such infringements are qualified as serious administrative offences as per *Regime Jurídico das Contraordenações Económicas* (Legal Framework for Economic Administrative Offences) ("**RJCE**"), punished with a fine between EUR 650 and EUR 24.000, depending on the offender's qualification.

From the criminal point of view, article 282 of Portuguese Criminal Code establish the crime of corruption of food and medicinal substances, punished with 1 to 8 years of prison. Article 283 establish the crime of spread of disease, change of analysis or prescription, also punished with 1 to 8 years of prison.

Additionally, Decree-Law n. 28/84 of 20 January relating to anti-economic and public health offences, providing specific crimes related to public health offences.

Relating to civil responsibility, please see answer to question 18 above.

20. Does your jurisdiction provide for a specific legislative and regulatory framework for digital health applications (e.g., medical apps)? If yes, please briefly describe the relevant framework.

As software, digital health applications fall within the RDM, being qualified as active medical devices.

However, some apps are borderline between medical devices and wellbeing apps. In those cases, it is essential to assess to what extent the app in question falls within the definition of a medical device provided by the MDR and should therefore be qualified as such or, alternatively, is just a wellbeing app and not subject to the requirements set by the MDR.

21. Does your jurisdiction provide for laws or certain legal measures to ensure the supply of medicinal products and medical devices, or are such rules envisaged in the future? If yes, please briefly describe those rules.

Access to medicines is an essential public service and cannot be limited by MA holders, wholesalers, pharmacies or any other entity or person authorized to dispense medicines to the public. Medicines Law provides the obligation of supply by MA holders, importers, wholesalers, pharmacies, hospital pharmaceutical services and retailers of non-prescription medicinal products are obliged to supply, dispense or sell the medicinal products requested of them under the conditions established by law. In addition, MA holders, manufacturers, wholesalers, and dispensers of medicines must respect the principle of continuity of service to the community to ensure that the prescriptions are fulfilled.

Portuguese law also establishes mechanisms to avoid shortage of medicines in the national market ensuring the permanent monitoring of the market and the shortage of medicines. For this purpose, Infarmed provides an electronic platform for notification of marketing interruptions and cessations by marketing authorisation holders (SIATS), classifying the medicines in three classes of risk, depending on the existence of therapeutical alternatives.

In this same sense, Infarmed has published the regulation on prior notification of medicines transactions to outside the country, aiming to ensure the availability of medicines and improve the procedure for revising the prior notification list so that it better reflects the state of supply in the market. This regulation imposes to MA holders and wholesalers to report through the platform SIEXP the quantities of medicines included in the prior notification list established by Infarmed that they have supplied, including quantities exported or distributed to other member states of the European Union, indicating the respective country of destination. Such list is quarterly updated by Infarmed.

Additionally, Infarmed monthly defines the list of medicines whose export is suspended. The list includes medicines that were disrupted in the previous month and whose impact of the disruption was considered medium or high according to the criteria established by the availability regulation. The suspension is intended to ensure supply to the national market after a disruption has occurred and applies to all players in the medicines circuit, including manufacturers.

22. Are there any specific compliance standards in your jurisdiction for the marketing of medicinal products and medical devices (e.g., codes of conducts of industry associations, etc.)? If yes, please give a brief overview of the relevant standards.

Yes. Sectorial associations usually have codes of conduct applicable to its associates. In Portugal, the most relevant associations are APIFARMA – *Associação Portuguesa da Indústria Farmacêutica*, (Portuguese Pharmaceutical Industry Association) ("**Apifarma**"), APOGEN – *Associação Portuguesa de Genéricos e Biosimilares* (Portuguese Association of Generic and Biosimilar Medicines) ("**Apogen**") and APORMED – *Associação Portuguesa das Empresas de Dispositivos Médicos* (Portuguese Association of Medical Devices Companies ("**Apormed**").

Apifarma has in place the Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interaction with Healthcare Professionals and Health Organizations, applicable to all of Apifarma members ("**Apifarma Ethics Code**"). The regime provided by Apifarma Ethics Code closely follows the code provided by European Federation of Pharmaceutical Industries and Associations ("**EFPIA**").

Relating to Apogen, its code of conduct establishes the ethical standards ruling the interactions between

pharmaceutical companies which are member of Apogen and the players involved in the healthcare sector in Portugal.

Apormed's code of ethics establish the ethical standards of good business practices, promoting greater transparency and independence between companies in the medical device sector, professionals and healthcare institutions. The code of ethics of Apormed is based on the European Code of Ethics of MedTech Europe, the European association representing medical devices companies).

23. Please state 3-5 key decisions by courts or regulatory authorities that have been issued recently and that are relevant for the life sciences sector.

Portugal has not a great track record of court decisions related to life sciences. Decisions are mainly related to prices and reimbursement and are not publicly disclosed by the parties. As such, the court decisions relevant for life sciences market are usually those issued by European courts, namely Court of Justice of European Union.

24. What, if any, are the key legal and regulatory trends in your jurisdiction with regards to the digitalization of the local healthcare system and with regards to the use of artificial intelligence in the life sciences sector? Please briefly describe.

Decree-Law 128/2023 of 26 December introduces significant changes to information on the price of medicines. Among other things, the Decree-Law aims to improve the information provided to users when medicines are dispensed. It also removes the reference to the retail price (PVP) on the packaging, as this reference has proved to be of little relevance or even difficult to interpret.

It is justified by the fact that the retail price on the packaging does not usually correspond to the cost of the medicine to the citizen, due to the variables that influence the price, such as (possible) reimbursement and its different application criteria.

The removal of the retail price from the packaging therefore aims to avoid providing information that does not correspond to reality. It also aims to avoid outdated information due to price changes and to promote other ways to access the information that appear to be more up-to-date and therefore more reliable.

Pharmacies are obliged to provide users with detailed information on the price of medicines on the invoice or receipt issued.

With this amendment, the law now recognizes Infarmed's responsibility to make information on the price of medicines publicly available on its website and through other digital tools. These digital tools include the Infarmed database and the *Poupe na Receita* (Save on your Prescription) app available on the Infarmed website.

25. Please briefly highlight 3-5 key developments or trends in your jurisdiction with regards to the life sciences sector as you consider them relevant. This may include legislative proposals, market activity, etc.

During the last months several measures were taken to develop and simplify the access to healthcare services by citizens.

One of the most relevant is the possibility introduced by Ministerial Order 264/2023 of 17 August, which has set out the vaccination model for Autumn-Winter season. Communitarian pharmacies had already been a partner of the NHS in flu vaccination for several years. With the new rules, pharmacies are now able to administrate Covid-19 vaccines, allowing to speed-up the vaccination coverage using the great territory coverage of communitarian pharmacies.

Pharmacies wishing to participate in the vaccination campaign must meet have a service for the administration of vaccines in accordance with Infarmed Resolutions 139/CD/2010 of 21 October and 145/CD/2010 of 4 November and have qualified staff with specific training in vaccine administration.

Vaccination must comply with the governance model of the National Vaccination Program established by Ministerial Order 248/2017 of 4 August and should be based on the principles of free of charge to the user, accessibility, fairness, comprehensive coverage, targeting all people in Portugal who have an indication for vaccination and taking advantage of all vaccination opportunities.

Other relevant measure is the proximity dispensing of medicines and other health products prescribed for hospital outpatients. Usually, patients need to travel significant distances to have the medicines prescribed to their treatments, as such medicines may only be dispensed in the relevant hospital. With the new regime, patients may obtain their medicines in (i) any services of

NHS, (ii) communitarian pharmacies or (iii) other places, in dully justified cases.

This regime will highly enhance the comfort of the patients, avoiding long travels to obtain its medicines, improving the life quality of patients by optimizing the existing resources.

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