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MULTI-JURISDICTIONAL GUIDE 2014/15
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Medicinal product regulation and product liability in Portugal: overview

Fernanda Matoso and Eduardo Maia Cadete

Morais Leitão, Galvão Teles, Soares da Silva & Associados, Sociedade de Advogados, R.L.

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REGULATORY OVERVIEW

1. What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

Legislation

The regulatory framework for the authorisation, pricing and reimbursement of drugs, biological and medical devices in Portugal is based on the application at a national level of EU legislation, including:

- Directive 2001/83, on the Community Code relating to medicinal products for human use (Code for Human Medicines Directive).
- Regulation 726/2004, laying down procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (EMA Regulation).
- Directive 93/42/EEC concerning medical devices (Medical Devices Directive).

The relevant legal framework at the national level is contained in the following legislation:

- Statute of the National Health Service (Decree-Law 11/93, 15 January 1993).
- Clinical Trials Act (Law 21/2014, 16 April 2014).
- Industrial Property Act (Decree-Law 36/2003, 5 March 2003).
- Human Medicines Act (Decree-Law 176/2006, 30 August 2006) (Medicines Act).
- Medical Devices Act (Decree-Law 145/2009, 17 June 2009).
- Price of Medicines Act (Decree-Law 112/2011, 29 October 2011).
- Price of Restrictive Use Medicines (Decree-Law 195/2006, 13 October 2006).
- Funding and Reimbursement of Medicines (Decree-Law 48-A/2010, 13 May 2010).

Regulatory authority

The national medicine regulatory authority (INFARMED) (*www.infarmed.pt*) is the authority responsible for the monitoring, supervision and enforcement of the provisions of the Medicines Act and the Medical Devices Act. Members of the respective Board of Directors are appointed for a three year period by the government.

2. Briefly outline how biologicals and combination products are regulated in your jurisdiction.

Medicinal products developed using one of the following biotechnological processes is subject to centralised approval by the European Medicines Agency under its centralised procedure:

- Recombinant DNA technology.
- Controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells.
- Hybridoma and monoclonal antibody methods.

In respect of combination products where a medical device is designed to administer a medicinal product:

- The placing on the market of the medical device is generally governed by the Medical Devices Act.
- The placing on the market of the medicinal product is governed by the Medicines Act.

If the medical device is placed on the market in such a way that the device and the medicinal product form a single integral unit which is intended exclusively for use in the given combination and which is not reusable, that single-unit product is governed by the Medicines Act.

3. Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of health IT issues and mobile medical applications?

Medical devices and diagnostics (medical devices) are governed by the Medical Devices Act (Decree-Law 145/2009, 17 June 2009).

INFARMED is the national competent authority on medical devices, including:

- Active medical devices.
- Custom-made devices.
- Implantable medical devices.
- Implantable active medical devices.
- *in vitro* diagnostic medical devices.
- Devices intended for clinical investigation.

Medical devices are divided into four different risk classes:

- Class I, low risk.
- Class IIa, medium risk.
- Class IIb, medium risk.
- Class III, high risk.

Each medical device risk class is calculated taking into account in particular the following factors:

- Length of time in contact with the human body (momentary, short-term and long-term).
- Degree of invasion of human body (invasive, non-invasive).
- Part of the body affected by its use (for example, hands, heart, and lower limbs).
- Potential risks stemming from technical design or manufacture.

Medical devices must have the CE marking, which is a prerequisite for medical devices to be placed on the market.

There is no specific regulation of health IT issues and mobile medical applications, although IT is extensively used in the health sector. For example, electronic prescription of medicines is, as a rule, mandatory for doctors, and INFARMED launched a mobile medicine price comparator application at the start of 2014.

PRICING, STATE FUNDING AND REIMBURSEMENT

4. What is the structure of the national healthcare system, and how is it funded?

The public national healthcare system (*Serviço Nacional de Saúde*) (NHS), comprises all the public services and units which provide healthcare services, including:

- Groups of health centres.
- Hospitals, irrespective of their legal designation.
- Local health units.

The Statute of the NHS is contained in Decree-Law 11/93, 15 January 1993. The Ministry of Health is responsible for planning, funding, directing, supervising, evaluating and auditing NHS activities.

The NHS is funded through the state annual budget and by moderating fees paid by users. The NHS also includes a centralised procurement system for hospitals addressed to the purchase of medical products, through the Central Purchasing Authority (*Serviços Partilhados do Ministério da Saúde*) (*SPMS*) (see *www.spms.pt*).

The NHS also has arrangements with private providers for the delivery of diagnostic and therapeutic services (including dialysis and rehabilitation).

5. How are the prices of medicinal products regulated?

The price of medicines which are not over-the-counter (OTC) medicines eligible for reimbursement is regulated by the government through INFARMED in association with the Directorate-General for Economic Activities (*Decree-Law 112/2011, 29 October 2011*). There are different pricing methods:

- The price of both prescription and OTC medicines eligible for reimbursement by the NHS is determined on the basis of the average price of the same medicine in specific reference countries (currently Spain, France and Slovakia) (*Order 91/2013, 28 February 2013*). The reference countries are subject to a yearly review by the Minister of Health.
- Medicines subject to strict medical prescription, when bought by hospitals, are usually subject to a price agreement between the marketing authorisation holders and INFARMED. The price agreement also governs the supply conditions which apply to NHS hospitals (*Decree-Law 195/2006, 13 October 2006*).
- The price of a generic medicine must be 50% of the sale price of the reference medicine of the same dosage and pharmaceutical form (*Decree-Law 112/2011, 29 November 2011*).
- Medicines which are the subject of parallel trade must, in principle, have a sale price 5% below the equivalent medicine for sale in Portugal.

The price of OTC medicines which are not subject to reimbursement by the NHS is not regulated by the public authorities.

6. When is the cost of a medicinal product funded by the state or reimbursed? How is the pharmacist compensated for his dispensing services?

The cost of a medicinal product can be funded by the state on the basis of either (*Decree-Law 48-A/2010*):

- Its technical-scientific and added therapeutic value.
- Evidence provided in relation to its economic advantage.

The scientific and economic assessment for funding by the NHS is carried out by

INFARMED. Medicines which receive upfront reimbursement of the pharmacy sale price by the NHS generally fall within one of four rating bands:

- Band A: 90%.
- Band B: 69%.
- Band C: 37%.
- Band D: 15%.

Decree-Law 48-A/2010 also establishes that special funding and reimbursement regimes apply to:

- Pensioners (by increasing the percentage of reimbursement they receive for medicines in any of the four bands).
- Patients with specific pathologies or included in special groups (by NHS upfront funding of 100% of the medicine sale price).

A pharmacist in a dispensing pharmacy is remunerated through a maximum legal margin based on the approved medicine authorised wholesale price (MAWP). The pharmacist's price margin varies according to the MAWP price, as follows (*Decree-Law 112/2011*):

- Up to EUR5: 5.58% over the MAWP (plus EUR0.63).
- EUR5.01 to EUR7: 5.51% (plus EUR1.31).
- EUR7.01 to EUR10: 5.36% (plus EUR1.79).
- EUR10.01 to EUR20: 5.05% (plus EUR2.80).
- EUR20.01 to EUR50: 4.49% (plus EUR5.32).
- Over EUR50: 2.66% (plus EUR8.38).

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Clinical trials are regulated by INFARMED. The Clinical Trials Act (Law 21/2014, 16 April 2014) enacts at a national level, Directive 2001/20/EC on the conduct of clinical trials.

Authorisations

Each clinical trial is subject to prior authorisation by INFARMED. Generally, decisions are made within 30 days of application. Additional requests for information suspend the applicable deadline until the requested information is provided by the sponsor.

Clinical trials must also receive a favourable binding opinion from the competent Ethics Committee (*Comissão de Ética competente*).

Consent

Clinical trial participants must provide written informed consent (*see below, Trial pre-conditions*).

Trial pre-conditions

The conditions which must be met before the trial can begin include:

- A satisfactory evaluation of the anticipated benefits and risks.
- The existence of a protocol.
- Complete details of the clinical trial sponsor, investigator or principal investigator or investigator-co-ordinator.
- Details of the qualifications of all the team members involved in the clinical trial.
- The existence of an investigator's brochure.
- Details of the clinical trial centre(s) and validation of the adequacy of the facilities.
- The provisions for indemnity or compensation in the event of injury or death attributable to the clinical trial.
- The existence of an insurance or indemnity to cover the liability of the investigator and sponsor.
- In the case of multicentre trials involving trial centres of other EU member states, the identification of the competent authorities and, if available, the opinions adopted by the respective ethics committees, translated into Portuguese.
- Details of the amounts and, where appropriate, the arrangements for rewarding or compensating investigators and trial subjects, and the relevant aspects of any agreement between the sponsor and the site.

In respect of trial participants, certain minimum conditions must be met:

- A prior interview with the investigator or team member, in which the participant must be informed of the:
  - clinical trial objectives;
  - risks and inconveniences;
  - associated conditions of performance;
  - the participant's right to withdraw from the clinical trial at any time.
- The protection of data privacy rights.
- Written informed consent, referring to the nature, scope, consequences and risks of the clinical trial.
- Details of the associated medical care to be provided during the clinical trial.
- Designation of a contact person to disclose detailed information to participants.

Procedural requirements

A clinical trial must be conducted in accordance with:

- Good clinical practice.
- The approved protocol.
- INFARMED's clinical trial authorisation.
- The decision of the competent Ethics Committee.

Amendments to the protocol can be made provided they:

- Do not affect the safety of participants.
- Do not alter the scientific evidence on which the conduct of the trial is based.

During the course of the trial, the investigator must report any adverse events to the sponsor, except those identified in the investigator's brochure or in the protocol as not requiring immediate (within a 24-hour period) notification. The sponsor must keep detailed records of all adverse events.

Serious unexpected adverse events that have caused or may cause the death of a participant must be registered and notified to:

- INFARMED.
- All the competent public authorities of all the participating EU member states involved in the trial.
- The competent Ethics Committee.

MANUFACTURING

8. What is the authorisation process for manufacturing medicinal products?

The national manufacturing authorisation process closely follows EU law (*Medicines Act*).

Application

The application must be submitted to INFARMED.

Conditions

The application can be made by a natural or legal person and must contain the following information:

- The specification and pharmaceutical form of the medicine.
- Details of where the manufacture of the medicine will be carried out.
- Evidence of compliance with the applicable technical requirements in relation to:
  - technical directors;
  - premises;
  - equipment; and
  - monitoring;
- Identity of the technical director.

Restrictions on foreign applicants

There are no specific restrictions on foreign applicants. The manufacturing facilities must, however, be located in Portugal.

Key stages and timing

The application for authorisation must be decided within a maximum period of 90 days from the date the request is submitted.

Fee

INFARMED applies a standard fee of EUR588.23 for each medicine manufacturing request (*Order 377/2005, 4 April 2005*).
INFARMED's fees are published online at *www.infarmed.pt/portal/page/portal/INFARMED/TAXAS*.

Period of authorisation and renewals

The manufacturing authorisation remains valid until INFARMED cancels it or the holder of the licence withdraws it.

Monitoring compliance and imposing penalties

A manufacturer's facilities are subject to ad hoc inspections by INFARMED. INFARMED can also request access to reports regarding each manufactured medicine lot.

In cases of non-compliance with the applicable manufacturing obligations, INFARMED can suspend or revoke the manufacturing licence (for example, if the manufactured medicine does not meet its declared qualities or quantities).

Where non-compliance can be attributed to the manufacturer's technical director, INFARMED can also suspend the technical director from his functions, or refer him to his professional association.

Without prejudice to potential criminal liability, breach of the relevant obligations is a misdemeanour under the Medicines Act, punishable with a fine for each infringement of up to:

- EUR44,891.81 in the case of manufacturing obligations.
- EUR35,000 in the case of the technical director.

MARKETING
Authorisation and abridged procedure

9. What is the authorisation process for marketing medicinal products?

Application

The application for authorisation to market a medicinal product in Portugal must be submitted to INFARMED. The Medicines Act follows EU law (*Code for Human Medicines Directive*).

A medicinal product must hold a marketing authorisation obtained through one of the following:

- The national procedure.
- The EU member states (including Portugal) procedure. This includes the:
  - decentralised procedure;
  - mutual recognition procedure.
- The centralised procedure of the European Medicines Agency. This is usually used for medicinal products for human use containing a new active substance for which the therapeutic indication is the treatment of any of the following diseases (*EMA Regulation*):
  - acquired immune deficiency syndrome;
  - cancer;
  - neurodegenerative disorder;
  - diabetes;
  - auto-immune diseases and other immune dysfunctions; and
  - viral diseases.

Authorisation conditions

An application for a marketing authorisation must include:

- The name or corporate name and permanent address of the applicant and, where applicable, of the manufacturer.
- The name of the medicinal product.
- Detailed qualitative and quantitative particulars of the constituents of the medicinal product in standard scientific terminology.
- A description of the medicinal product's manufacturing method.
- The medicinal product's:
  - therapeutic indications;
  - contra-indications;
  - adverse reactions;
  - posology;
  - pharmaceutical form;
  - method and route of administration; and
  - expected shelf life.
- If applicable, reasons for any precautionary and safety measures to be taken for the storage of the medicinal product, its administration to patients and for the disposal of waste products, together with an indication of any potential risks presented by the medicinal product for the environment.
- A description of the control methods used by the manufacturer.
- The results of physico-chemical, biological or microbiological tests, toxicological and pharmacological tests and clinical trials.
- A summary of the product's characteristics.
- One or more specimens or mock-ups of the product's outer packaging, immediate packaging and package leaflet.

Key stages and timing

INFARMED must make a final decision on a complete marketing authorisation application within a period of 210 days, without prejudice to potential time suspensions (for example, requests for information from the applicant due to detected deficiencies in the submitted file).

Fee

The applicable marketing authorisation base fees include for requests (*Order 377/2005, 4 April 2005*):

- Under the national procedure (per dosage and pharmaceutical form): EUR2915.55.
- From a member state with Portugal as the reference member state (per dosage and pharmaceutical form): EUR7672.50.
- For the parallel import of a medicine (per dosage and pharmaceutical form): EUR1,759.56.

INFARMED's applicable fees are published online at *www.infarmed.pt/portal/page/portal/INFARMED/TAXAS*.

Period of authorisation and renewals

The marketing authorisation is initially granted and valid for a period of five years. After the first renewal, following a formal request by the market authorisation holder, the subsequent authorisation is valid for an indefinite period. In exceptional cases, the renewal of the marketing authorisation may be subject to a limited five-year period.

Monitoring compliance and imposing penalties

INFARMED has the following powers to monitor compliance with marketing authorisations. It can:

- Execute inspections at the premises of manufacturers, wholesalers, pharmacies and entities responsible for laboratorial controls or a specific medicinal product's manufacturing stages, as well as any other facilities used for such purposes.
- Execute unannounced inspections of the manufacturers of active substances used in the production of medicines, as well as at the premises of holders of marketing authorisations, when there are grounds to suspect non-compliance with good manufacturing practices.
- Verify the facilities, records, documents and pharmacovigilance system of the marketing authorisation holder.
- Collect samples to carry out tests in a laboratory.

INFARMED can:

- Suspend, forfeit or alter the content of a marketing authorisation.
- Impose fines of up to EUR44,891.81 for each infringement, subject to judicial review.

Criminal liability may also apply.

10. What commitments and pharmacovigilance obligations apply after a company has obtained marketing authorisation? Are there further conditions concerning how the drug is distributed and accessible to patients?

Commitments and pharmacovigilance obligations

The market authorisation holder must have a qualified person responsible for:

- Pharmacovigilance.
- Maintaining a pharmacovigilance master file.
- Operating a risk management system (*see Question 20*).

INFARMED, in collaboration with the European Medicines Agency and other member states, must have a list of medicinal products that are subject to additional monitoring under the EMA Regulation (which sets out European Community procedures for the authorisation and supervision of medicinal products for human use). The list contains the names and active substances of both:

- Medicinal products authorised in the EU that contain a new active substance which, on 1 January 2011, was not contained in any medicinal product authorised in the EU.
- Any biological medicinal product not covered in the bullet point above that was authorised after 1 January 2011.

The medicinal products listed must include:

- A summary of product characteristics.
- The following statement on the package leaflet: "This medicinal product is subject to additional monitoring", preceded by a black symbol.

Other conditions

INFARMED can attach supplementary obligations to the marketing authorisation, for example, the execution of post-authorisation safety studies. In addition, a failure to effectively commercialise the medicine for a period of three consecutive years, regardless of the reasons, generally leads to forfeiture of the authorisation. Loss of the marketing authorisation is published on INFARMED's website.

11. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

The abridged procedure is set out in the Medicines Act. If the market authorisation applicant can provide evidence that the medicine's active substance has an established clinical use in the EU for a period of ten years with acceptable safety and recognised efficacy, the applicant is not required to provide pre-clinical and clinical trials data. It is sufficient if the applicant provides an adequate scientific bibliography.

INFARMED has 210 days to make a decision on the applicant's request. Requests for more information by INFARMED suspend this period.

12. Are foreign marketing authorisations recognised in your jurisdiction?

Marketing authorisation granted under the central community procedure by the European Medicines Agency is recognised in Portugal.

Marketing authorisations granted by the equivalent authorities of other EU member states are also, generally, recognised in Portugal. INFARMED usually makes its decision on marketing authorisation within 30 days of access to the assessment report of the equivalent regulatory authority of the other EU member state.

If INFARMED considers that there is a potential serious risk for public health, it can adopt an unfavourable opinion on the request for approval of the marketing authorisation. In the absence of any subsequent agreement between the relevant EU national agencies, an arbitration procedure can be initiated before the European Committee for Medicinal Products for Human Use (CMPH).

In the mutual recognition and decentralised procedures, the CHMP arbitrates in cases where there is a disagreement between member states concerning the marketing authorisation of a particular medicine. The CMPH consists of one member appointed by each EU member state.

Parallel imports

13. Are parallel imports of medicinal products into your jurisdiction allowed?

Parallel imports of medicinal products are allowed into Portugal, provided the following conditions are met:

- The medicine in the member state of origin must have a valid marketing authorisation.
- The medicine must have the same:
  - quantitative and qualitative composition in terms of active substances;
  - pharmaceutical form; and
  - therapeutic indications (different excipients can be used or different quantities of the same excipients if they have no therapeutic impact).
- The authorisation does not pose a risk to public health.

An applicant only needs to declare, not demonstrate, that differences in any inactive excipient do not affect the medicine's

therapeutic value or endanger public health, if the medicine has a common origin, namely:

- The medicine is manufactured in another EU member state.
- By a company:
  - contractually linked to the marketing authorisation holder in Portugal; or
  - in the same corporate group.

Generally, the holder of intellectual property rights in a medicinal product which has been placed on the market in the European Economic Area (EEA) is not legally able to impede further marketing of that product in another EEA country.

For information on pharmaceutical patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports, visit *Pharmaceutical IP and Competition Law in Portugal: overview.*

Restrictions on dealings with healthcare professionals

14. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

There are certain restrictions on advertising medicinal products (*see Question 16*). In addition, marketing authorisation holders or companies responsible for the promotion of medicines and distributors cannot offer or promise to offer, directly or indirectly, to health professionals any of the following (unless the offer relates to an object relevant to the practice of medicine and is of insignificant economic value) (*Medicines Act*):

- Gifts.
- Bonuses.
- Pecuniary benefits.

Both the sponsoring of scientific promotions addressed to health professionals and consultancy agreements engaging health professionals are allowed, provided payments are not conditional on the prescription or dispensing of medicines.

Anti-bribery legislation also applies to the life sciences sector, notably when dealing with public officials and state institutions.

The following provisions may apply:

- Receiving improper payment (*Article 372, Criminal Code*).
- Passive corruption (*Article 373, Criminal Code*).
- Active corruption (*Article 374, Criminal Code*).

Penalties can include imprisonment and fines for representatives of the company, public officials and other third parties for committing certain offences.

Portuguese anti-bribery provisions can apply to offences occurring outside Portugal but exceptions may apply.

SALES AND MARKETING

15. What are the restrictions on selling medicinal products? Are there specific regulations for the sale of medicinal products on the internet, by e-mail and by mail order?

Prescription medicines and over the counter (OTC) medicines reimbursed by the NHS are exclusively sold in pharmacies. OTC medicines not subject to reimbursement by the NHS can be sold in OTC retailers (*parafarmácias*).

The home delivery of medicinal products is allowed by (*Order 1427/2007, 2 December 2007*):

- Pharmacies in relation to prescription medicines.
- Pharmacies and OTC retailers in respect of OTC medicines.

Home delivery must be provided in the geographic municipality where the pharmacy or OTC retailer is located and in the surrounding geographic municipalities.

Orders can be delivered at a patient's residence or workplace by any of the following methods:

- Telephone.
- Fax.
- Online pharmacy.
- OTC retailer website.
- E-mail.

Pharmacies are governed by the rules of Decree Law 307/2007, 31 August 2007, as amended. OTC medicine retailers are governed by Decree Law 134/2005, 16 August 2005, as amended.

ADVERTISING

16. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

The advertising of medicinal products is governed by the Medicines Act. INFARMED is responsible for the supervision and enforcement of the provisions on advertising to healthcare professionals and the general public.

INFARMED will open an inquiry where non-compliance is suspected, either on its own initiative or based on a complaint. This can lead to penalties which include fines and loss of licences, authorisations or permits. Decisions are subject to judicial review.

Restrictions

Certain medicines cannot be promoted or advertised to the general public, only to healthcare professionals (for example, doctors, pharmacists and nurses). They must be advertised in scientific publications or other forms of communication with restricted use by health professionals. These medicines include:

- Prescription medicines.
- Medicinal products which contain psychotropic or narcotic substances.
- Medicines subject to reimbursement by the NHS.

Over-the-counter (OTC) medicines can be marketed to the general public.

The advertising of any of the above categories of medicinal products must:

- Comply with the particulars listed in the summary of product characteristics.
- Encourage the rational use of the medicinal product by presenting it objectively, without exaggerating its properties.
- Not be misleading.

All advertising to the general public of an OTC medicine must:

- Clearly indicate that it is an advertisement.
- Clearly identify the product as a medicinal product.

- Include the following minimum information:
  - the name of the medicinal product, as well as its common name if the medicinal product contains only one active substance;
  - the information necessary for correct use of the medicinal product;
  - a legible invitation to read the instructions on the package leaflet or the outer packaging (as the case may be) carefully.

The advertising of a medicinal product to the general public must not contain any material which:

- Gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail.
- Suggests that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product.
- Suggests that the health of the subject can be enhanced by taking the medicine.
- Suggests that the health of the subject could be affected by not taking the medicine.
- Is directed exclusively or principally at children.
- Refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products.
- Suggests that the medicinal product is a foodstuff, cosmetic or other consumer product.
- Suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural.
- Could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis.
- Refers, in improper, alarming or misleading terms, to claims of recovery.
- Uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts of it.

Advertising to persons qualified to prescribe or supply medicinal products must include the following:

- Essential information compatible with the summary of product characteristics. The supply classification of the medicinal product.
- The conditions for reimbursement by the NHS.

Measures or commercial practices related to margins, prices and discounts are not subject to the advertising rules of the Medicines Act.

The Portuguese Association of the Pharmaceutical Industry (*Associação Portuguesa da Indústria Farmacêutica*) (Apifarma) has produced a Code of conduct for promotional practices by the pharmaceutical industry with healthcare professionals. The Code reflects the rules and principles of:

- The Medicines Act.
- The European Federation of Pharmaceutical Industries Code on the Promotion of prescription-only medicines to and interactions with healthcare professionals.

Internet advertising

Advertising on the internet is subject to the same rules (*see above, Restrictions*).

DATA PROTECTION

17. Do data protection laws impact on pharmaceutical regulation in your jurisdiction?

The national data protection legislation (*Law 67/98, 26 October 1998*), enforced by the Portuguese Data Protection Agency (*Comissão Nacional Nacional de Proteção de Dados*) (CNPD) applies to personal health data, including within clinical trials, pharmacovigilance, adverse event reporting and patient data processing.

The access and treatment of personal data in these contexts is subject to prior notification and authorisation by CNPD.

There is also a specific legal regime which regulates the treatment of personal genetic information and health information (*Law 12/2005, 26 January 2005*). Under this regime, the collection of human biological samples or related derivatives, with the aim of establishing a database of biological products with personal information, is also subject to prior authorisation by CNPD.

A breach of the duty to submit an authorisation request to CNPD can incur an aggravated administrative penalty (up to EUR30,000 per infringement) and criminal liability (up to two years' imprisonment). Civil liability can also be incurred, depending on the existence of damage caused by the illegal processing of data.

PACKAGING AND LABELLING

18. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

The Medicines Act governs the packaging and labelling of medicinal products. INFARMED is responsible for the supervision and enforcement of the provisions applicable to the packaging and labelling of medicinal products.

Information requirements

The following information must appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:

- The name of the medicinal product followed by its strength and pharmaceutical form, and, when applicable, whether it is intended for babies, children or adults.
- Where the product contains up to three active substances, the international non-proprietary name must be included, or, if one does not exist, the common name.
- A statement of the active substances expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names when available.
- The contents by weight, volume or number of doses of the product.
- A list of those excipients known to have a recognised action or effect. If the product is injectable or a topical or eye preparation, all excipients must be stated.
- The method of administration and, if necessary, the route of administration.

- A space must be left for the prescribed dose to be indicated by the healthcare professional.
- A special warning that the medicinal product "must be stored out of the reach and sight of children" (*manter fora do alcance e da vista das crianças*).
- The expiry date in clear terms (month/year).
- Special storage precautions, if any.
- The name and address of the marketing authorisation holder and, where applicable, the name of the representative appointed by the holder to represent him.
- The number of the authorisation for placing the medicinal product on the market.
- The manufacturer's batch number.
- The sale price, through printing, label or stamp.
- When applicable "free sample" (*amostra gratuita*) or "sale to the public not authorised" (*proibida a venda ao público*).
- Safety features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to verify the authenticity of the medicinal product, and identify individual packs.

Other conditions

The packaging and labelling information referred to above must be:

- In Portuguese.
- Indelible.
- Easily readable and comprehensible.

Tests should be made by the marketing authorisation applicant in relation to the packaging and leaflet on target users, and the results taken into account. The labelling and the package leaflet can also be provided in other languages in addition to Portuguese.

PRODUCT LIABILITY

19. Outline the key regulators and their powers in relation to medicinal product liability.

INFARMED is the key regulator of medicinal product liability and its powers in this context are extensive. Under the Medicines Act, there is also a National Pharmacovigilance System of Medicines.

In this context, marketing authorisation holders, wholesalers, distributors and pharmacies must make their premises, installations, products and documents (including sensitive information and proprietary data) accessible at all times to INFARMED. In addition, market authorisation holder/wholesalers must have an emergency plan, which ensures effective implementation of any recall from the market ordered by INFARMED for the medicinal product concerned.

Non-compliance with the relevant provisions of the Medicines Act or with INFARMED's decisions is subject to a misdemeanour fine up to EUR44,891.81 per infringement imposed by INFARMED, without prejudice to potential criminal, tort and disciplinary liability,

INFARMED can also revoke, suspend or modify a marketing authorisation based, among other things, on a medicine being unsafe. As a rule, any of these three decisions, when the medicine is marketed in other EU member states, is co-ordinated with EMA and the competent national authorities of the other EU jurisdictions where the product is marketed.

20. Are there any mandatory requirements relating to medicinal product safety?

Under the Medicines Act, market authorisation holders must have a pharmacovigilance system that:

- Registers information on medicine risks for patients or public health, mainly relating to adverse reactions in human beings, arising from:
  - use of the medicinal product within the terms of the marketing authorisation;
  - use outside the terms of the marketing authorisation; and
  - occupational exposure.
- Evaluates all information scientifically, and considers options for risk minimisation and prevention, and adopts appropriate measures as necessary.
- Is subject to regular audits, including a note concerning the main findings of the audit on the pharmacovigilance system master file.

Marketing authorisation holders must:

- Submit information electronically to the Eudravigilance database and data-processing network referred to in the EMA Regulation (*https://eudravigilance.ema.europa.eu/human/index.asp*) on all serious suspected adverse reactions occurring in the EU and in third countries, within 15 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.
- Submit electronically to the Eudravigilance database information on all non-serious suspected adverse reactions that occur in the EU, within 90 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.
- Notify INFARMED immediately of any urgent safety decision or action to suspend or recall a medicinal product, when the medicine's efficacy or public health is at stake.

Public disclosure of a medicinal product warning directly by a marketing authorisation holder is, as a rule, subject to prior approval from INFARMED. The information contained in such notice must be objective and not misleading.

When applicable, INFARMED's public warning identifies the relevant medicinal product batch number.

In this context, non-compliance with the relevant rules of the Medicines Act is subject to penalties (*see Question 19*).

21. Outline the key areas of law applicable to medicinal product liability, including key legislation and recent case law.

Legal provisions

Medicinal product liability can arise under criminal law, contract and tort law.

Portugal has a specific legal regime for product liability set out in Decree-Law 383/89 of 6 November 1989, as amended (Product Liability Act) based on Directive 85/374/EEC on liability for defective products (Product Liability Directive).

Substantive test

The injured person must prove (*Product Liability Act*):

- Damage.
- The defect.
- A causal relationship between defect and damage.

The Civil Code also recognises tort liability based on:

- The infringement of legal provisions (*Article 483*).
- Joint and several liability (*Article 490 and Article 497*).
- Indemnity limitation in cases of negligence (*Article 494*).
- A general limitation period of three years (*Article 498*).

According to the Civil Code, liability depends on the fulfilment of five cumulative requirements:

- Conduct (act or omission) controllable by human resolution.
- The unlawfulness of the conduct.
- Imputation of the conduct to a natural or legal person.
- The existence of damages.
- A causal link between the conduct and the damage.

A damage claim can also be brought under contractual liability, where there is a contract between the wrongdoer and the natural or legal person suffering the damage.

22. Who is potentially liable for defective medicinal products?

The producer is liable for damage, independently of fault, caused by a defect in his product. The producer is defined as one of the following (*Product Liability Act*):

- Manufacturer of a finished product.
- Producer of any raw material.
- Manufacturer of a component part.
- Any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer.

In addition, without prejudice to the liability of the producer, any person who imports into the EU a product for sale or any form of distribution in the course of his business is also considered to be a producer and is responsible as a producer. If the producer cannot be identified, each supplier of the product is treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product.

23. What defences are available to product liability claims? Is it possible to limit liability for defective medicinal products?

Standard defences in a product liability claim include that:

- The defendant did not put the product into circulation.
- The defect which caused the damage did not exist at the time the product was put into circulation and came into being afterwards.
- The product was either not:
  - manufactured by the defendant for sale or any form of distribution for economic purpose; or
  - manufactured or distributed by the defendant in the course of his business.
- The defect is due to compliance of the product with mandatory regulations issued by the public authorities.
- The state of scientific and technical knowledge at the time the defendant put the product into circulation was not such as to enable the defect to be discovered.
- In the case of a manufacturer of a component, the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.

24. How can a product liability claim be brought?

Limitation periods

The limitation periods for bringing a product liability claim are (*Product Liability Act*):

- Three years from the day on which the claimant became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.
- Ten years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has since started proceedings against the producer.

Class actions

Law 83/95 of 31 August 1995 establishes the legal framework applicable to a representative action. The aim of this type of action is to represent collective or diffuse interests either for prevention (injunction) or for redress (claims for damages). A representative action for a product liability claim in the Portuguese courts can be brought by (*Law 83/95, 31 August 1995*):

- A natural person.
- An association or foundation (in cases which are directly connected with their scope).

Companies cannot use the representative action procedure.

The Portuguese procedure is an opt-out system. The claimant automatically represents all the holders of similar rights or interests at stake who do not opt out following, among others, a public notice of submission of the representative action before the court. The claimant can seek redress for damages suffered but compensation cannot be individually identified and will be determined globally. Representative actions in the context of product liability claims are rare in Portugal.

25. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

The claimant (or his estate) can claim damages for:

- Death.
- Personal injury.
- Damage to, or the destruction of, property (other than the defective product itself), provided the property:
  - is of a type ordinarily intended for private use or consumption; and
  - was mainly used by the injured person for his own private use or consumption.

Punitive damages are not available in Portugal for product liability claims.

REFORM

26. Are there proposals for reform and when are they likely to come into force?

Since 2011 Portugal has been under an EU/IMF Financial Assistance Programme (FAP) which involves a set of initiatives including structural legal measures relating to public finances, financial stability and competitiveness. In relation to the health sector the FAP, which is anticipated to cease in 2014, involves:

- Continuing with the reorganisation and rationalisation of the public hospital network through specialisation, concentration and downsizing of hospital services, joint management and joint operation of hospitals.
- Reduction of debt due to suppliers of the NHS, including pharmaceutical companies (in 2014, pharmaceutical expenditure must be limited to 1% of GDP).
- Improvements in the billing and collection of revenues from NHS moderating fees (taxas moderadoras), insurance companies and fees for the treatment of cross-border/foreign patients.
- Continuing to improve the monitoring and assessment system of doctors' prescription behaviour regarding medicines and diagnostic in terms of volume and value and as against prescription guidelines and peers.
- Additional centralised public tenders for active substances and medical devices, and establishment of an observatory for prices and acquisitions.
- Compulsory e-prescription and international non-proprietary name (INN) prescription.
- Changes in pharmacies' margins in the international reference price system and in the pricing of generics.
- The removal of administrative and legal hurdles to enhance the use of generics.

For information on pharmaceutical patents, trade marks, competition law, patent licensing, generic entry, abuse of dominance and parallel imports, visit *Pharmaceutical IP and Competition Law in Portugal: overview*.

ONLINE RESOURCES

Portuguese Mint and Official Printing Office (*Imprensa Nacional Casa da Moeda*)

W www.dre.pt

Description. Official website of the Portuguese Mint and Official Printing Office (*Imprensa Nacional Casa da Moeda*), where the official language version of the legislation referred to in this article can be accessed online (Portuguese version).

Practical Law Contributor profiles

Fernanda Matoso, Partner

Morais Leitão, Galvão Teles, Soares da Silva & Associados, Sociedade de Advogados, R.L.
T +351 21 381 74 31
F +351 21 381 74 98
E fmatoso@mlgts.pt
W www.mlgts.pt

Professional qualifications. Portugal, lawyer, 1984

Areas of practice. Life sciences; public and civil law litigation; regulatory; procurement.

Recent transactions

- Practises mainly in the health sector as a life sciences lawyer.
- Advising several pharmaceutical companies.
- Co-ordinating the firm's legal team representing companies in the pharmaceutical sector, in areas such as regulation (prices and reimbursement regulation, medicine legal framework, marketing authorisation procedures, promotion activities and clinical trials), commercial policies, litigation and arbitration.

Languages. Portuguese, English, French, Spanish

Professional associations/memberships. Portuguese Bar Association.

Publications. *European Lawyer, Pharma series.*

Eduardo Maia Cadete, Senior Associate

Morais Leitão, Galvão Teles, Soares da Silva & Associados, Sociedade de Advogados, R.L.
T +351 21 381 74 57
F +351 21 381 74 21
E maiacadete@mlgts.pt
W www.mlgts.pt

Professional qualifications. Portugal, lawyer, 2001

Areas of practice. Life Sciences; competition; EU law; regulatory.

Recent transactions

- Extensive legal assistance to companies active in life sciences.
- Advising and representing clients (both defendants and claimants) before the Portuguese Competition Authority, the European Commission, the General Court of the European Union, the Court of Justice and the European Court of Human Rights.
- Matters involving restrictive practices, merger control, state aids and sectoral inquiries.

Languages. Portuguese, English, French, Spanish

Professional associations/memberships. Portuguese Bar Association.

Publications. *European Lawyer; International European Law Tax Review; International Law Office; Portuguese Bar Association; Portuguese Bank Association; The Private Competition Enforcement Review.*