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DISTRIBUTION AND MARKETING OF DRUGS

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Distribution and marketing of drugs in Portugal: overview

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DISTRIBUTION

Pre-conditions for distribution

1. What are the legal pre-conditions for a drug to be distributed within the jurisdiction?

Authorisation

The Portuguese Medicine Act, enshrined in Decree Law No. 176/2006, 30 August 2006, as amended (Medicine Act), establishes the national legal framework applicable to medicines for human use. The Medicine Act implements Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) (as amended) at national level.

Under the Medicine Act, a medicinal product to be distributed in Portugal must hold a marketing authorisation obtained via any of the following methods:

- The centralised procedure before the European Medicines Agency.
- The Decentralised Procedure.
- The Mutual Recognition Procedure.
- A strictly national procedure.

See *Question 4*.

Exceptions

Under special and exceptional circumstances, medicines without a marketing authorisation (including medicines for compassionate use) can be allowed to be used to treat patients in Portugal. This is subject to an authorisation granted with a temporary and transitory nature by the Portuguese Medicine Regulatory Authority

(*Autoridade Nacional dos Medicamento e de Produtos de Saúde*) (INFARMED) (*www.infarmed.pt*).

The rules applicable to the authorisation of medicinal products for compassionate use are provided in Articles 92 and 93 of the Medicine Act and in INFARMED's Decision 139/CD/2014, 6 November 2014, and Deliberation 1546/2015, 6 August 2015. See also *Question 2*.

2. Do any types of named patient and/or compassionate use programmes operate? If so, what are the requirements for pre-launch access?

There are several programmes in place, which are mainly internal and reserved to specific patients of healthcare institutions that are part of the National Health Service (NHS), and this type of information is not publicly disclosed to the general public. The Portuguese Medicine Regulatory Authority (INFARMED) can authorise the pre-launch access by patients to such medicines when any of the following conditions are met:

- Where, for reasons of urgency and clinical justification, the medicines are considered to be indispensable for the treatment or diagnosis of certain pathologies.
- Where the medicines are necessary to avoid a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation, any of which could cause harm.
- In exceptional cases, where the medicines are acquired by a pharmaceutical service or a hospital pharmacy and are dispensed to a specific patient.

Article 5(1) of Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) (as amended) has been enacted in Portugal and is reflected in Article 92 of the Medicine Act. The rules applicable to the authorisation of medicinal products for compassionate use are set in INFARMED's Decision 139/CD/2014, 6 November 2014 and in Deliberation 1546/2015, 6 August 2015.

Licensing

3. What is the procedural structure regarding licensing a drug for distribution?

Structure

The applicant's request for a marketing authorisation must include the information and documentation listed and detailed in Chapter II of the Medicine Act. Such information includes the following data (among others):

- The name or corporate name and permanent address of the applicant and (where applicable) the manufacturer.
- The proposed name of the medicinal product.
- The qualitative and quantitative particulars of all the constituents of the medicinal product, including active substances and excipients.
- The therapeutic indications, contra-indications and adverse reactions.
- The posology, pharmaceutical form, method and route of administration and expected shelf life.
- The 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 potential risks presented by the medicinal product for the environment.
- A summary of the product characteristics, and a mock-up of the outer and inner packaging.

- A copy of a manufacturing licence valid in Portugal or, if the medicine is not manufactured in Portugal, a certificate of a valid manufacturing licence by the manufacturer in the applicable country.
- The data regarding the medicine manufacturing, including description of the manufacturing method.
- The description of the control methods employed by the manufacturer.
- A written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of the active substance with principles and guidelines of good manufacturing practice by conducting audits. Such written confirmation must contain a reference to the date of the most recent audit and a declaration that the outcome of the audit confirms that the manufacturing complies with the principles and guidelines of good manufacturing practice.
- The results of pharmaceutical, pre-clinical and clinical trials.
- A summary of the applicant's pharmacovigilance system.
- A risk management plan describing the risk management system which the applicant will introduce for the medicinal product concerned (together with a related summary).
- A statement to the effect that clinical trials carried out outside the EU meet the ethical requirements applicable to clinical trials.
- A copy of any authorisation, obtained in another member state or in a third country, to place the medicinal product on the market, a summary of the safety data including the data contained in the periodic safety update reports, where available, and suspected adverse reactions reports, together with a list of those member states in which an application for authorisation is under examination.
- A report on potential environmental risks posed by the medicinal product, accompanied, when deemed needed, by specific arrangements to limit such risks.
- A copy of any designation of the medicinal product as an orphan medicinal product under Regulation (EC) 141/2000 on orphan medicinal products (Orphan Medicinal Products Regulation).
- Proof of payment of the applicable fee to the Portuguese Medicine Regulatory Authority (INFARMED).

On receiving the authorisation request, the 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, where the INFARMED requests further information from the applicant due to detected deficiencies in the submitted file).

The marketing authorisation is initially granted for a period of five years. After the first renewal, the marketing authorisation will, as a rule, be valid for an indefinite period of time.

Regulatory authority

The INFARMED is the national licensing agency for medicinal products.

4. Is there a simplified licence proceeding, or relaxed licensing conditions, for drugs which have already been licensed for distribution in another jurisdiction?

There are simplified licensing proceedings where the Portuguese Medicine Regulatory Authority (INFARMED), in accordance with the Medicine Act, participates in the Mutual Recognition Procedure or the Decentralised Procedure as a "Reference Member State".

For parallel imports, there is a legal presumption that a medicine subject to EU parallel trade will have the same qualitative and quantitative composition, pharmaceutical form and indications, and will therefore not represent a risk to public health. This presumption is applicable either:

- When the medicine to be imported has a common origin.
- Where there is a connection between the companies that hold the marketing authorisation in Portugal and in the member state of origin.

The outcome is that an applicant must only declare (not demonstrate) that any differences in any inactive carrier substances (excipients) do not affect the medicines' therapeutic value or endanger public health. The parallel import authorisation is granted within a period of 45 days from the date the application is submitted before the INFARMED.

5. Is virtual drug distribution possible from your jurisdiction?

"Virtual" distribution does not appear to be possible under the rules of the Medicine Act. This is because, under the applicable provisions:

- The distribution activity must be physically carried out in the national territory.
- The distributor, through the maintenance of an adequate stock, must be capable of immediately supplying the Portuguese market.

6. What is the procedure to appeal (legal remedy) a licensing decision?

The licensing decisions of the Portuguese Medicine Regulatory Authority (INFARMED) can be subject to judicial review before administrative courts. The appeal must be filed before the INFARMED within a period of three months from the date the decision is notified to the addressee.

7. What are the costs of obtaining licensing?

Pursuant to Order No. 377/2005, 4 April 2005, which establishes the fees for the services rendered by the Portuguese Medicine Regulatory Authority, the applicable base fees are the following (among others):

- Marketing authorisation requests under the national procedure (per dosage and pharmaceutical form) cost about EUR2,916.
- Marketing authorisation requests that Portugal be the Reference Member State cost about EUR7,673 (per dosage and pharmaceutical form).
- Marketing authorisation requests for the parallel import of a medicine costs about EUR1,760 (per dosage and pharmaceutical form).

Distribution to consumers

8. What are the different categories of drugs for distribution?

In terms of access by the general public, medicines for distribution are classified into two main categories:

- Medicines subject to medical prescription.

- Over-the-counter medicines (that is, medicines not subject to medical prescription).

Prescription drugs

Medicines are classified as "subject to medical prescription" if any of the following are applicable:

- They are likely to present a danger (directly or indirectly) even when used correctly, if utilised without medical supervision.
- They are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health.
- They contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation.
- They are normally prescribed by a doctor.

Medicines subject to medical prescription can be further classified as:

- **Medicines subject to a renewable medical prescription.** These are medicines that address specific diseases or prolonged treatments that may, in compliance with safety in their use, be acquired more than once, without requiring a new medical prescription (as the original medical prescription, contains two identical copies, which can be used within a period of six months).
- **Medicines subject to a special medical prescription.** These are medicines that meet one of the following criteria:
  - the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the applicable legislation;
  - the medicinal product is likely, if incorrectly used, to present a substantial risk of medicinal abuse, or to lead to addiction or be misused for illegal purposes; or
  - the medicinal product contains a substance which, by reason of its novelty or properties, could be considered as belonging to the group envisaged in the second indent as a precautionary measure.
- **Medicines restricted to a medical prescription, reserved for use in certain specialised areas.** These are medicines that meet one of the following conditions:
  - the medicinal product, because of its pharmaceutical characteristics or novelty or in the interests of public health, is reserved for treatments which can only be followed in a hospital environment;
  - the medicinal product is used in the treatment of conditions which must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere; or
  - the medicinal product is intended for outpatients, but its use may produce very serious adverse reactions requiring a prescription to be drawn-up as required by a specialist and special supervision throughout the treatment.

Over-the-counter drugs

Medicines which do not fulfil the conditions provided in the previous paragraphs are classified as over-the-counter medicines.

9. Who is authorised to distribute prescription drugs and over-the-counter drugs to consumers?

Prescription drugs

According to Decree Law 307/2007, 31 August 2007, as last amended by Law 51/2014, 24 August 2014, which governs the rules applicable to pharmacies, the sale of prescription drugs to consumers can only be made through pharmacies.

Pharmacies are subject to strict monitoring and supervision and must be registered with the Portuguese Medicine Regulatory Authority (INFARMED). Each pharmacy must have a pharmaceutical technical director and an additional pharmacist.

For pharmacies, a serious offence to the applicable legal regime (and without prejudice to any tort, contractual or criminal liability) can be subject to misdemeanour fine of up to 10% of its annual turnover or EUR75,000 (whichever is the lower).

Over-the-counter drugs

Over-the-counter medicinal products can be distributed by pharmacies and over-the-counter medicine retailers (the latter are also subject to registration with the INFARMED).

Over-the-counter medicine retailers are governed by the rules of Decree Law 134/2005, 16 August 2005, as last amended by Law 51/2014, 25 August 2014, and also subject to the supervision of the INFARMED.

For over-the-counter medicine retailers, a serious non-compliance with the governing rules (and without prejudice to potential contractual, tort or criminal liability) is sanctionable with a misdemeanour fine of up to 30% of its annual turnover or EUR100,000 (whichever is lower).

10. What drugs can an attending physician distribute and under what circumstances?

In accordance with the Portuguese Medical Association Code of Ethics, physicians must not sell medicines or other medical articles or products to the respective patients.

Free-of-charge supply can only be made in strict and duly justified cases, notably in an emergency situation.

11. Who is authorised to prescribe prescription drugs to consumers?

In accordance with the Medicine Act, a prescription drug can be prescribed by a doctor or, in cases specifically provided in the legislation, a dentist or an orthodontist (*odontologista*).

12. Is direct mailing/distance selling of drugs permitted in your jurisdiction?

Conditions

Home delivery of medicines is allowed, specifically by pharmacies in relation to medicines subject to medical prescription and by over-the-counter retailers regarding over-the-counter medicines (*Order 1427/2007, 2 December 2007*). Therefore, drugs can be sold at a pharmacy/over-the-counter retailer or through a pharmacy/over-the-counter retailer distance selling system. Delivery to a patient's residence or workplace can be arranged by telephone, fax, online or via e-mail.

Cross-border sales

Cross-border sales are allowed. However, such activity is subject to prior communication to the Portuguese Medicine Regulatory Authority (INFARMED), as detailed in Decree Law 307/2007, 31 August 2007, as last amended by Law 51/2014, 24 August 2014. In a cross-border sale, the destination country rules must also be taken into account by the supplying entity.

13. What regulatory authority is responsible for supervising distribution activities?

The Portuguese Medicine Regulatory Authority (INFARMED) is the agency responsible for the supervision and enforcement of the provisions applicable to distribution activities.

The INFARMED ensures that the legal requirements governing medicinal products are complied with through the use of:

- Inspections of the facilities of pharmacies or over-the-counter retailers (which may be unannounced if necessary).
- Audit and reporting requirements, including of adverse reactions under the pharmacovigilance rules.

In the use of its supervision and enforcement powers, the INFARMED can adopt decisions, including interim measures, leading to the suspension or revocation of medical authorisations.

14. What is the procedure to appeal (legal remedy) a distribution decision?

Decisions from the Portuguese Medicine Regulatory Authority (INFARMED) can be subject to judicial review before national courts.

As a rule, if the subject matter of the INFARMED's decision is the application of a misdemeanour fine, the criminal courts are competent to review the decision. In addition, administrative courts are competent to review cases of INFARMED decisions related to the grant, suspension or revocation of authorisations or licences.

In such setting, interim measures can be triggered by the addressee of the INFARMED decision before administrative courts, which are followed by the main proceedings.

15. What are the legal consequences of non-compliance with consumer distribution laws?

Non-compliance with consumer distribution laws may cause the non-compliant entity to be subject to misdemeanour fines and accessory sanctions by the Portuguese Medicine Regulatory Authority (INFARMED) (the product owner and/or distributor may also be subject to criminal, contractual, tort or disciplinary liability).

The INFARMED's fines can reach 15% of the infringing company's annual turnover or EUR180,000 (whichever is the lower) per each piece of illicit conduct committed.

Wholesale distribution

16. What is the legal regime regarding wholesale distribution of drugs?

The Medicine Act sets out the rules applicable to the wholesale distribution of medicinal products. Wholesale distribution of medicinal products is subject to prior authorisation from the Portuguese Medicine Regulatory Authority (INFARMED).

To obtain a distribution authorisation, the applicant must fulfil the following minimum requirements:

- The applicant must have suitable and adequate premises, installations and equipment to ensure proper conservation and distribution of the medicinal products.
- The applicant must have staff, and in particular, a qualified technical director designated as responsible.
- The applicant must undertake to fulfil the following obligations:
  - to make the premises, installations and equipment accessible at all times to the person responsible for inspecting them;
  - to obtain medicinal products supplies only from persons who are themselves in possession of the distribution authorisation or who are exempt from obtaining such authorisation under the applicable derogation;
  - to supply medicinal products only to persons who are themselves in possession of the distribution authorisation or who are authorised or entitled to supply medicinal products to the public;
  - to have an emergency plan which ensures effective implementation of any recall from the market ordered by the INFARMED or carried out in co-operation with the manufacturer or medical authorisation holder for the medicinal product concerned;
  - to keep records in the form of purchase/sales invoices, or on computer, or in any other form, giving for any transaction in medicinal products received or dispatched at least the following information: the date, name of the medicinal product, quantity received or supplied, name and address of the supplier or consignee, as appropriate;
  - to keep the records of the information referred to in the point above that are available to the INFARMED, for inspection purposes, for a period of five years; and
  - to comply with the principles and guidelines of Good Distribution Practice for medicinal products as set out in INFARMED's Decision 47/CD/2015, 19 March 2015, which adopts the European Commission Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01).

The wholesale supply of medicinal products can only be executed to either:

- Persons who are themselves in possession of the distribution authorisation (that is, other distributors).
- Persons who are authorised or entitled to supply medicinal products to the public (for example, pharmacies, over-the-counter retailers, and healthcare centres authorised to acquire medicines directly from distribution wholesalers).

17. What regulatory authority is responsible for supervising wholesale distribution activities?

Regulatory authority

The Portuguese Medicine Regulatory Authority (INFARMED) is the agency responsible for the supervision and enforcement of the provisions applicable to wholesale distribution activities.

The INFARMED ensures that the legal requirements governing the wholesale distribution of medicinal products are complied with, by means of:

- Inspections (which may be unannounced if necessary) of the facilities of pharmacies and over-the-counter retailers.

- Audit and reporting requirements, including under the national guidelines of Good Distribution Practice for medicinal products as provided in INFARMED's Decision 47/CD/2015, 19 March 2015.

When using its supervision and enforcement powers, the INFARMED can adopt decisions, including interim measures, leading to the suspension, withdrawal and revocation of wholesale distribution authorisations.

Supervision

See above, *Regulatory authority*.

Rights of appeal

INFARMED decisions in the setting of wholesale distribution authorisations can be subject to judicial review before administrative or criminal courts, depending on the factual matter and legislation taken into account in the relevant decision.

18. What are the legal consequences of non-compliance with wholesale distribution laws?

The legal consequences of non-compliance with wholesale distribution laws are the same as for non-compliance with consumer distribution laws (*see Question 15*).

MARKETING
Promotion

19. What is the general legal regime for the marketing of drugs?

Legal regime

The marketing of medicines is regulated by:

- The Medicine Act.
- Portuguese Medicine Regulatory Authority (INFARMED)'s:
  - Decision 44/CD/2008, 7 February 2008;
  - Informative Note 13/CD/8.1.6, 17 January 2014;
  - Informative Note 29/CD/8.1.6, 12 February 2014;
  - Informative Note 12/CD/8.1.6, 17 January 2014;
  - Informative Note 105/CD/8.1.6, 10 May 2013; and
  - Informative Note 24/CD/8.1.6, 14 February 2013.
- The National Advertising Code, established in Decree Law 330/90, 23 October 1990 (as amended) (Advertising Code).

The following activities are not considered to be "advertising":

- The labelling of the medicinal product and the accompanying package leaflets.
- Any correspondence to answer a specific question about a particular medicinal product.
- Any factual, informative announcements and reference material relating to the medicinal product (for example, information relating to pack modifications, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists), provided such information does not include any product claims.
- Any statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.

In addition, any measures or commercial practices related to margins, prices and discounts are not subject to the advertising rules of the Medicine Act.

Limits to marketing activities

The following cannot be marketed to the general public, and can only be marketed to healthcare professionals (doctors, pharmacists and nurses and so on):

- Medicines subject to medical prescription (*see Question 8, Prescription drugs*).
- Medicinal products which contain psychotropic or narcotic substances.
- Medicines subject to reimbursement by the National Health Service (NHS).

However, over-the-counter medicines can be advertised to the general public.

Advertising of any of the categories of medicinal products identified above, before the applicable addresses, must fulfil the following requirements:

- The advertising must comply with the particulars listed in the summary of product characteristics.
- The advertising must encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties.
- The advertising must not be misleading.

In addition, all advertising activities to the general public of an over-the-counter medicine must:

- Be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product.
- Include the following minimum information:
  - the name of the medicinal product, and the common name if the medicinal product contains only one active substance;
  - the information necessary for the correct use of the medicinal product; and
  - an explicit, legible invitation to read the instructions on the package leaflet carefully or outer packaging.

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 (for example, by offering a diagnosis or 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 (however, this does not apply to vaccination campaigns provided in the Medicine Act).
- 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, a 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 inadequate, 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 human body parts.

Advertising of a medicinal product to persons qualified to prescribe or supply such products must include:

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

In accordance with Article 164(4) of the Medicine Act and INFARMED's Decision 44/CD/2008, 7 February 2008, advertising elements regarding prescription drugs and over-the-counter medicines, addressed to healthcare professionals, must be communicated to the INFARMED within ten days, counting from the date the marketing campaign is initiated.

20. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organisations)?

Since 1987, the Portuguese Association of the Pharmaceutical Industry (*Associação Portuguesa da Indústria Farmacêutica*) (API) has developed a Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interactions with Healthcare Professionals and Institutions, Organisations or Associations comprising Healthcare Professionals (API Code).

The current version of the API Code, which entered into force on 1 January 2014, takes into account and is aligned with the rules of:

- The Medicine Act.
- The International Federation of Pharmaceutical Manufacturers Code.
- The European Federation of Pharmaceutical Industries and Associations Code on promotion of prescription-only medicines to, and interactions with, healthcare professionals.

Compliance with the provisions of API's Code by the respective associated members is monitored and supervised by the association Council of Ethics. In the case of an alleged breach, the complaint is submitted by the associated member to the API's Council of Ethics. If it is found that a company did not act in accordance with the provisions of the API Code, the API can request the associated member to cease the irregular activity and to undertake, in writing not to repeat such practice. A breach of the API Code by a company is considered a disciplinary offence and the applicable sanctions are provided for in API statutes. Where a breach is found, the applied sanction, as well as the nature of the offence, can be publicised by the API.

Marketing to consumers

21. What is the legal regime for marketing to consumers?

Legal regime

The relevant rules are set out in the Medicines Act and in Portuguese Medicine Regulatory Authority (INFARMED) Decision 44/CD/2008, 7 February 2008, which approves the regulation governing specific issues related to medicines marketing.

Products

The following products cannot be marketed to the general public and can only be marketed to healthcare professionals (doctors, pharmacists and nurses):

- Prescription drugs.
- Over-the-counter medicines subject to reimbursement by the National Health Service.
- Medicinal products which contain psychotropic or narcotic substances.

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

In accordance with the INFARMED's Decision 44/CD/2008, 7 February 2008, all advertising elements regarding medicines addressed to healthcare professionals must be communicated to the INFARMED within a period of ten days, counting from the date in which the marketing campaign is initiated. See also *Question 19*.

22. What kinds of marketing activities are permitted in relation to consumers and the products which may be advertised to them?

Over-the-counter medicines can be subject to most common types of marketing activities, including through the use of communication platforms such as television, internet, radio, magazines and newspapers.

23. Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers (for example, "buy-one-get-one-free")?

Consumers cannot be provided with free samples of medicinal products. Samples can only be provided to healthcare professionals under strict conditions (*see Question 31*).

A special offer of the type "buy-one-get-one-free" could potentially be qualified as a breach of the samples regime and as an incentive for the non-rational use of medicinal products. Therefore, such a special offer is not permitted under the Medicine Act.

However, pharmacies can grant discounts to consumers, under the principle of equality (*see INFARMED Informative Note 13/CD/8.1.6, 17 January 2014*), when acquiring medicinal products, as discounts, as a rule, are not subject to the advertising rules of the Medicine Act.

Furthermore, Decree Law 97/2015, 1 June 2015, which regulates (among others) the price regime for medicines subject to medical prescription and over-the-counter medicines reimbursed by the National Health Service (NHS), specifically states that discounts are allowed in all stages of medical distribution, from the manufacturer to the retailer. The Decree Law also provides that discounts applied by pharmacies to the price of medicines partially reimbursed by the NHS are applicable only to the part of the price not subject to reimbursement.

24. Are there particular rules of practice on the use of the internet/social media regarding drugs and their advertising?

There are no specific rules on the use of the internet or social media other than the rules provided in relation to consumers above (*see Questions 21 to 23*).

In relation to healthcare professionals, the Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interactions with Healthcare Professionals and Institutions, Organisations or Associations comprising Healthcare Professionals (API Code) specifically states that the internet promotion of medicinal products targeting healthcare professionals must be based on technical, scientific and professional principles. The API Code also provides that pharmaceutical companies should adopt measures to guarantee that the promotion is accessed exclusively by healthcare professionals (and not by the general public).

Following the European Court of Justice judgment in *MSD Sharp & Dohme GmbH v Merckle GmbH (Case C-316/09) [2011] ECR I-03249*, INFARMED confirmed in Informative Note 229/CD (9 November 2011) that a pharmaceutical undertaking is not prohibited from disseminating information relating to medicinal products on a website if the:

- Medicinal products are available by prescription only.
- Information is accessible on the website only to someone who seeks to obtain it.
- Dissemination consists solely in the faithful reproduction of the packaging of the medicinal product and in the literal and complete reproduction of the package leaflet or the summary of the product's characteristics, which have been approved by the authorities with competence in relation to medicinal products.

However, it is prohibited to disseminate on a website medicinal product information that:

- Has been selected or rewritten by the manufacturer.
- Could only have an advertising purpose.

25. What regulatory authority is responsible for supervising marketing activities to consumers?

Regulatory authority

The Portuguese Medicine Regulatory Authority (INFARMED) is the agency responsible for the supervision and enforcement of the provisions applicable to consumer marketing activities.

The INFARMED ensures that the legal requirements applicable to advertising rules are complied with. If the INFARMED has suspicions of non-compliant promotional activities, the INFARMED can open an inquiry (on its own initiative or based on a complaint). Such an inquiry can potentially lead to the application of significant misdemeanour fines, per illicit conduct, and/or the loss of licences, authorisations or permits.

Supervision

See above, *Regulatory authority*.

Rights of appeal

A decision of the INFARMED relating to marketing activities can be subject to judicial review before the competent national court.

26. What are the legal consequences of non-compliance with consumer marketing laws?

The legal consequences for non-compliant marketing activities vary depending on the specificities of each case. The activities will be subject to investigation from the Portuguese Medicine Regulatory Authority (INFARMED), which may order misdemeanour fines and accessory sanctions for the activities, including a ban on advertising the medicine for a period of up to two years (the non-compliant entity may also be subject to criminal, contractual, tort or disciplinary liability). The fine, per illicit conduct, can reach 15% of the infringing company's annual turnover or EUR180,000 (whichever is the lower).

In addition, in the case of a medicine subject to reimbursement by the National Health Service, the breach of the relevant advertising provisions can also lead to the medicine being excluded from the applicable public reimbursement regime.

Marketing to professionals

27. What kinds of marketing activities are permitted in relation to professionals?

The Medicine Act allows for the following types of marketing activities:

- Advertisements in publications exclusively addressed to healthcare professionals (in the case of prescription drugs).
- Visits by sales representatives to healthcare professionals (however, restrictions apply, see *Question 28*).
- Promotional events, including meetings, congresses, conferences, and symposia attended by persons qualified to prescribe or supply medicinal products.
- Supply of samples (however, restrictions apply, see *Question 31*).
- Benefits-in-kind can be given or offered to professionals, but only if those benefits have a low cash value (no more than EUR60 (*Ministry of Health Dispatch 12284/2014, 6 October 2014*)) and are relevant for the practice of medicine or pharmacy and/or involve a benefit for the patient.

In addition, the Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interactions with Healthcare Professionals and Institutions, Organisations or Associations comprising Healthcare Professionals (API Code) specifically allows the use of fax, e-mail, automatic call systems, text messaging and other means of electronic communication to contact professionals with the previous authorisation or request of the healthcare professional.

28. Are there any restrictions on marketing to professionals?

Marketing activities

The Medicine Act states that the provision of inducements to prescribe or supply medicinal products by gift, offer or promise of any benefit or bonus, whether in money or in kind, are strictly prohibited. However, an exception may apply if the intrinsic value of the offer is minimal and cumulatively it is relevant for the medical practice. For example, where the value:

- Does not exceed EUR60 (*Ministry of Health Dispatch 12284/2014, 6 October 2014*).
- Is no more than EUR25, if one takes into account the Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interactions with Healthcare Professionals and Institutions, Organisations or Associations comprising Healthcare Professionals (API Code), and cumulatively the offer to the healthcare professional is relevant for the practice of medicine or pharmacy and/or involves a benefit for the patient.

There are also limits on interactions by sales representatives when addressing healthcare professionals active in establishments of the National Health Service (NHS). In the case of healthcare professionals who provide their services in establishments of the NHS, sales representatives must be registered with the Portuguese Medicine Regulatory Authority (INFARMED) and their contact with

the professionals are governed by strict rules (*INFARMED Dispatch 8213-B/2013, 24 June 2013*).

Frequency

Pharmaceutical companies, in relation to institutions of the NHS, can only make six visits per year to each institution or service (though in specific circumstances, eight visits may be allowed). Also, as a rule, and in relation to the NHS, each sales representative should not visit more than eight healthcare professionals per day.

Furthermore, the maximum number of daily visits permitted is:

- Two sales representatives per NHS hospital service.
- Three sales representatives in the case of other NHS services.

On such visits, each pharmaceutical company can only have one sale representative present. The sales representative's visits to the NHS must take place in a location suitable for the purpose of the meeting and cannot be held in:

- Emergency services.
- Areas where patients are accommodated.
- Internment services.

Visits to healthcare professionals must also take place outside of consultation hours.

Non-compliance with the applicable rules can lead the sales representative and respective pharmaceutical company being banned from performing visits to healthcare professionals at NHS institutions for up to three years.

Provision of hospitality

Under the Medicine Act, only educational, informative, scientific or promotional events can be addressed to healthcare professionals. The entities which promote or organise the event can only support the hospitality costs of healthcare professionals which are participants (support is strictly limited to the main purpose of the event).

Under the Medicine Act, hospitality, registration, travel and accommodation costs are considered to be acceptable expenses during an event. However, the supported accommodation costs must not:

- Exceed the period between the day prior to the beginning of the event and the day after the end of it.
- Include any social events that may impede participation in the sessions of the event.

The location of the event is subject to strict criteria from both a professional and a logistical standpoint, most notably in terms of hospitality and financial costs.

In addition, the API Code further states that:

- Any meeting, congress, conference, symposium or other event of a promotional, scientific or professional nature, organised or sponsored by a company which is the holder of a marketing authorisation or promoter of a medicinal product must take place in a suitable venue.
- The companies which are holders of a marketing authorisation or the promoters of a medicinal product should not choose places and/or tourist complexes which are known for their leisure, entertainment or sport facilities to hold a scientific or an educational event.
- The event should be held in Portugal, unless it is logistically more reasonable to hold the event in another country, taking into account:
  - the home countries of most of the guests; or
  - the location of the resources or relevant knowledge which are the main topic of the event.
- When the event is held in another country (international event) the following rules must be complied with:
  - where a prescription drug is promoted within the scope of the event, the rules of the Code of Ethics in force in the country where the promotion takes place are applicable, except if the rules of the Code of Ethics of the country of the home country of the company which organises or sponsors the event are more stringent, in which case the latter will apply; and
  - in relation to interactions with healthcare professionals within the scope of the event, the rules of the Code of Ethics in force in the country where the healthcare professional works.

The API Code also provides that the sponsorship of any promotional, scientific or educational event should take into consideration the following principles:

- The sponsorship should be preceded by a written request of the beneficiary entity, dated and signed, addressed to the company which grants the sponsorship.
- The sponsorship should be clearly announced prior to the event and during its duration.
- The payment of fees and the reimbursement of expenses (including travel, meals and accommodation for the speakers and moderators of the events) should be deemed suitable.
- Any and all material or information resulting from the event must be accurate and honestly reflect the talks and discussions.

29. What information is it legally required to include in advertising to professionals?

Under the Medicines Act, any advertising of a medicinal product to persons qualified to prescribe or supply such products must include:

- The medicine's name.
- Supply classification of the medicinal product.
- The conditions for reimbursement by the National Health Service.
- Essential information compatible with the summary of product characteristics.

When the advertising is a mere reminder of the medicinal products' international non-proprietary name, where this exists, or the trade mark, the conditions provided above may not be applicable.

Portuguese Medicine Regulatory Authority (INFARMED) Decision 44/CD/2008, 7 February 2008 further states that advertising elements addressed to healthcare professionals must also include information on the following:

- The pharmaceutical form.
- The quantitative and qualitative composition.
- The therapeutic indications.
- The dosage and mode of application.
- The contra-indications (that is, the situations in which the medicine should not be used because it may be harmful to the patient).
- The side effects.

In accordance with INFARMED Decision 44/CD/2008, the following elements must also be included, if deemed relevant from a clinical point of view:

- Warnings and special precautions for use.
- Information on interactions with other medicinal products and other forms of interaction.

30. Are there rules on comparisons with other products that are particularly applicable to drugs?

The Medicine Act does not allow comparative advertising of medicines before the general public.

The Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interactions with Healthcare Professionals and Institutions, Organisations or Associations comprising Healthcare Professionals provides that:

- Comparative advertising is only permitted among healthcare professionals.
- Comparisons among different medicinal products should be based on relevant and comparative aspects and should not be deceitful or defamatory.

Furthermore, comparisons among different medicinal products can only be made based on the elements included in the respective summary of the medicinal products' characteristics, respective instructions for use and technical documentation or on credible clinical data.

The Advertising Code also provides rules applicable to comparative advertising. Under these rules, comparative advertising is generally permitted when all of the following conditions are met:

- It is not misleading.
- It compares goods or services meeting the same needs or intended for the same purpose.
- It objectively compares one or more material, relevant, verifiable and representative features of those goods and services, which may include price.
- It does not create confusion in the market place between the advertiser and a competitor or between the advertiser's trade marks, trade names, other distinguishing marks, goods or services and those of a competitor.
- It does not discredit or denigrate the trade marks, trade names, other distinguishing marks, goods, services, activities, or circumstances of a competitor.
- It does not take unfair advantage of the reputation of a trade mark, trade name or other distinguishing mark of a competitor or of the designation of origin of competing products.
- It does not present goods or services as imitations or replicas of goods or services bearing a protected trade mark or trade name.

31. What other items, funding or services are permitted to be provided to professionals?

Discounts

Decree Law 97/2015, 1 June 2015, specifically states that discounts are allowed at all stages of the distribution chain, from the manufacturer to the retailer. This Decree Law further states that discounts applied by pharmacies to the price of medicines partially reimbursed by the National Health Service are applicable only to the part of the price not subject to reimbursement. Therefore, discounts can be granted by the manufacturer to the wholesale distributor and by the wholesale distributor to the retailer (pharmacy or over-the-counter retailer).

Free samples

Free samples can be provided on an exceptional basis and only to healthcare professionals qualified to prescribe them on the following conditions:

- The number of samples for each medicinal product must be limited to 12 units per year.
- Any supply of samples must be in response to a written request, signed and dated, from the prescribing agent.
- Those supplying samples must maintain an adequate system of control and accountability.
- Each sample must be identical to the smallest presentation on the market;
- Each sample must be marked "*amostra gratuita*" (free sample) or "*venda proibida*" (not for sale) or marked with other wording having the same meaning.
- Each sample must be accompanied by a copy of the summary of product characteristics.
- No samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions can be supplied.
- In the case of medicines subject to a medical prescription, the samples can only be provided in the first two years from the effective date of the respective placement of the medicinal product on the market for commercialisation.

Sponsorship of professionals

The Medicine Act provides strict rules in relation to the sponsorship of healthcare professionals.

The Medicine Act provides and allows the payment of fees to healthcare professionals for their active participation through, for example:

- The presentation of scientific communication in events related to healthcare.
- Training and promotion sessions of medicinal products.

However, the payment for the participation must not be directly or indirectly dependent upon the professional prescribing or dispensing medicinal products.

In addition, the Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interactions with Healthcare Professionals and Institutions, Organisations or Associations comprising Healthcare Professionals (API Code) states that donations and subsidies and benefits in kind granted to institutions, organisations or associations of healthcare professionals and/or professionals providing healthcare or engaged in research will be authorised if all of the following apply:

- They are made for the purpose of supporting health care provision or research.
- They are documented and recorded by the donor.
- They do not constitute an incentive to the recommendation, prescription, purchase, supply, sale or administration of certain medicinal products.

The API Code further provides that no donations or subsidies should be granted to healthcare professionals individually.

Other items, funding or services

The Medicine Act does not allow indirect incentives to healthcare professionals.

32. What regulatory authority is responsible for supervising marketing activities regarding professionals?

Regulatory authority

Medicines marketing activities are subject to the supervision of the Portuguese Medicine Regulatory Authority (INFARMED). Under its supervising competences, the INFARMED can open investigations based on the results of audits, complaints by competitors or publicly available information on potential non-compliant marketing activities.

Supervision

See above, *Regulatory authority*.

Rights of appeal

The INFARMED's decisions regarding alleged non-compliant actions in the setting of marketing activities can be subject to judicial review.

33. What are the legal consequences in case of non-compliance with professional marketing laws?

Non-compliance with consumer distribution laws may cause the product owner to be subject to misdemeanour fines and accessory sanctions (including an advertisement ban on the medicine for a period of up to two years) by the Portuguese Medicine Regulatory Authority (INFARMED) (the product owner may also be subject to criminal, contractual, tort or disciplinary liability).

The INFARMED's fines can reach 15% of the infringing company's annual turnover or EUR180,000 (whichever is the lower) per each piece of illicit conduct.

In addition, in the case of a medicine subject to reimbursement by the National Health Service, the breach of the relevant marketing provisions can also lead to the medicine being excluded from the applicable public reimbursement regime.

ENGAGEMENT WITH PATIENT ORGANISATIONS

34. What kinds of activities are permitted in relation to engagement with patient organisations? What are the restrictions that are imposed on relationship with patient organisations?

The Medicine Act does not entail any provisions applicable exclusively to interactions with patient organisations (however, the restrictions identified in *Questions 21* to *26* apply).

Subsidies, sponsorships, subventions or any other amount, product or right determinable in cash, granted to patients organisations must be reported to the Portuguese Medicine Regulatory Authority (INFARMED) by the grantor and the beneficiary within a 30-day period from the date the benefit was granted (*Medicine Act*). All benefits with a value above EUR60 are subject to such communication to the INFARMED (*Ministry of Health Dispatch 12284/2014, 6 October 2014*).

The Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interactions with Healthcare Professionals and Institutions, Organisations or Associations comprising Healthcare Professionals (API Code) provides that member companies must also comply with the provisions of API's Code of Conduct for the relations between the Pharmaceutical Industry and Patient Organisations (Patients Code), based on the (similar) European Federation of Pharmaceutical Industries and Associations Code.

Under the Patients Code, companies that aim to provide direct or indirect financial support and significant non-financial support to patients' organisations should draft it in writing, by means of an agreement duly signed by both parties. The agreement should mention the express amount of the financing, as well as its purpose or a description of the significant non-financial support as the case may be. Each company should also establish internal proceedings to formally approve the agreements.

In addition, companies and patients' organisations can agree contracts under which patients' organisations can provide services to companies for the purpose of supporting health and/or research.

Companies are also allowed to contract patients' organisations to be speakers, experts and/or consultants during meetings held by them. In this context, the following criteria should be complied with:

- The parties must specify the nature of services to be provided and the payment conditions.
- The parties must identify, in a clear way, the legitimate need for such service.
- The criteria to select the service should relate directly to the need identified above and the person responsible for its selection should have the suitable experience and knowledge to assess if the speaker, expert and/or consultant meet those criteria.
- The extent of the service provided cannot exceed what is reasonably necessary to meet the identified needs.
- The contracting company should keep the records regarding the services provided and use that information in a suitable way.
- The agreements signed with patients' organisations cannot be an incentive for the recommendation of a particular medicinal product.
- The payment of the service provided should be reasonable and reflect the market practice in a fair manner.
- The agreement should include the obligation for patients' organisations to declare that they provide paid services to a company every time they write or speak in public on subjects covered by the agreement or matters related to the company.

Furthermore, the list of patients' organisations sponsored by each company within the scope of the agreements above should be disclosed each year, in the manner identified below, and should mention:

- The nature of the provided support.
- The monetary value of the provided support.
- The benefits received, as far as significant non-financial support which no monetary value can be ascribed are concerned.

Companies should ensure the information on the sponsorship of patient's organisations is presented in a clear and transparent manner, and is available on request of any stakeholder or through the institutional website of the company, until 31 March each year (Patients Code).

REFORM

35. Are there any plans to reform the law on the distribution and promotion of drugs in your jurisdiction?

Between 2011 and 2014, Portugal was under an EU/IMF Financial Assistance Programme (FAP) which involved an extensive set of initiatives including structural measures relating to public finances, financial stability and competitiveness. In relation to the health sector, the FAP involved:

- 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 National Health Service (NHS), (including pharmaceutical companies).
- Improvements to the billing and collection of revenues from NHS moderating fees (*taxas moderadoras*), insurance companies and fees for the treatment of cross-border/foreign patients.
- Improvements to 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.
- Removal of administrative and legal hurdles to enhance the use of generic medicines.
- Regulation of medicines cross-border sales by pharmacies to the general public.

Although FAP was concluded in 2014, part of the referred measures will continue to be adjusted and monitored during the coming years by national public authorities.

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