Portugal

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A. DISTRIBUTION

1. PRECONDITIONS FOR DISTRIBUTION

1.1 What are the legal preconditions for a drug to be distributed within the jurisdiction? Does the drug need to be licensed (authorised) for distribution? Are there exceptions or different categories such as compassionate use?

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

A medicinal product, to be distributed in the national territory, pursuant to the Medicine Act, must hold a marketing authorisation (MA) obtained via: (i) the centralised procedure before the European Medicines Agency (EMA) or through ; (ii) the Decentralised Procedure (DCP); or (iii) the Mutual Recognition Procedure (MRP); or (iv) via a strictly national procedure (see EU laws section).

Medicines without an MA, including the so-called medicines for compassionate use, can, under special and exceptional circumstances, be allowed to be used to treat patients in Portugal, always under 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, I.P.) (INFARMED or MRA). The rules applicable to the authorisation of medicinal products for compassionate use are provided in INFARMED's Decision 105/CA/2007, of 1 March 2007.

1.2 Are any kinds of named patient and/or compassionate use programs in place? If so, what are the requirements for pre-launch access? (for EU countries only: has Article 5 (1) of Directive 2001/83/EC been transposed by your national legislator?)

There are several programs 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.

INFARMED can authorise the pre-launch access by patients to such medicines when one of the following conditions are met: (i) for reasons of

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

Article 5(1) of Directive 2001/83/EC has been enacted in Portugal and is reflected in Article 92 of the Medicine Act (partially reproduced in the previous paragraph) and in INFARMED'S Decision 105/CA/2007, of 1 March 2007.

1.3 What is the structure of the procedure regarding licensing a drug for distribution? Which national body (agency) is responsible for licensing?

INFARMED is the national licensing agency for medicinal products. The applicant's request for a MA must include the information and documentation listed and detailed in Chapter II of the Medicine Act.

INFARMED must adopt the final decision on a complete MA application within a period of 210 days, without prejudice to potential time suspensions (eg, requests for information to the applicant due to detected deficiencies in the submitted file). The MA is initially granted for a period of five years.

1.4 Is there a simplified license proceeding or are there relaxed licensing conditions for drugs which have already been licensed for distribution in another jurisdiction? What about parallel imports, is there a simplified procedure for these?

There are simplified licensing proceedings where INFARMED, in accordance with the Medicine Act, participates in the MRP and DCP procedures as a Reference Member State (RMS).

In terms of parallel imports, there is a legal presumption that a medicine subject to EU parallel trade has the same qualitative and quantitative composition, pharmaceutical form and indications, and that it does not represent a risk to public health. This presumption is applicable when the medicine to be imported has a common origin or 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 only has to declare, not demonstrate, that any differences in any inactive carrier substances (excipients) does 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 in which the request is submitted before INFARMED.

1.5 Is it possible to distribute drugs 'virtually' from your jurisdiction (ie, the physical products never enter the country but are distributed using the authorisation obtained in your country).

'Virtual' distribution does not appear to be possible under the rules of the Medicine Act, as in accordance with the applicable provisions the distribution

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

1.6 Is there a legal remedy (appeal) against licensing decisions?

Yes, the licensing decisions of INFARMED can be subject to judicial review before administrative courts. The appeal must be filed before the MRA within a period of three months from the day in which the decision is notified to the interested party.

1.7 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 INFARMED, the applicable base fees, among others, are the following: (i) MA requests under the national procedure (per dosage and pharmaceutical form): EUR 2,915.55; (ii) MA requests that Portugal be the RMS: EUR 7,672.50 (per dosage and pharmaceutical form); and (iii) authorisation request for the parallel import of a medicine: EUR 1,759.56 (per dosage and pharmaceutical form).

2. DISTRIBUTION TO CONSUMERS

2.1 What are the different categories of drugs for distribution?

Medicines for distribution, in terms of access by the public, are classified under one of the following main categories: (i) medicines subject to medical prescription (MSMP); or (ii) medicines not subject to medical prescription or over the counter medicines (OTC).

Medicines are classified as MSMP if they: (i) are likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision; or (ii) 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; or (iii) contain substances or preparations thereof, the activity and/or adverse reactions of which require further investigation; or (iv) are normally prescribed by a doctor.

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

MSMP can be further classified as: (a) medicines subject to a renewable medical prescription; (b) medicines subject to a special medical prescription; and (c) medicines restricted to a medical prescription, reserved for use in certain specialised areas.

Medicines subject to a renewable medical prescription are those that address specific diseases or prolonged treatments and may, in compliance with safety in their use, be acquired more than once, without needing 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 are those who meet one of the following criteria: (i) the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the applicable legislation; or (ii) 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 (iii) 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 subject to a restrictive medical prescription, reserved for use in certain specialised areas are those who meet one of the following conditions: (i) 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; (ii) 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 (iii) the medicinal product is intended for outpatients but its use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.

2.2 Who is entitled to distribute prescription drugs to consumers? What authorisation do they require?

According to Decree Law 307/2007, 31 August 2007, which governs the rules applicable to pharmacies, the sale of MSMP to consumers can only be made through pharmacies.

Pharmacies are subject to strict supervision and must be registered with INFARMED. Each pharmacy must have a pharmaceutical technical director and an additional pharmacist.

2.3 Who is entitled to distribute over-the-counter drugs to consumers?

OTC medicinal products can be distributed by: (i) pharmacies and (ii) OTC medicine retailers – the latter are also subject to registration with INFARMED.

OTC medicine retailers are subject to the rules of Decree Law 134/2005, 16 August 2005, as amended by Decree Law 238/2007, 19 June 2007.

2.4 Which drugs may be distributed by the attending physician, 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 his/her patients. Free-of charge supply may be made in strict and duly justified cases, notably in an emergency.

2.5 Who may 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*).

2.6 Is direct mailing/distance selling of drugs permitted? Under what conditions, by whom, and to whom? Might sales be made beyond the borders of your country?

Home delivery of medicines is allowed (see Order 1427/2007, 2 December 2007), specifically by pharmacies in relation to MSMP and by OTC retailers regarding OTC medicines.

Thus, the drugs can be sold at a pharmacy/OTC retailer or through the pharmacy/OTC retailer distance selling system. Delivery to a patient's residence or workplace can be arranged by telephone, fax, online or via e-mail.

The service of home delivery can only be provided in the geographic municipality of the pharmacy/OTC retailer and in the surrounding municipalities.

The current legal framework provided in Order 1427/2007 does not address the cross border supply of medicines and the applicable legal framework does not expressly allow such direct cross-border sales. Furthermore, the destination country rules must also be taken into account.

2.7 Which body (agency) is responsible for supervising distribution activities regarding consumers? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

INFARMED is the agency responsible for the supervision and enforcement of the provisions applicable to distribution activities. The MRA ensures that the legal requirements governing medicinal products are complied with, by means of inspections, if necessary unannounced to the facilities of pharmacies and OTC retailers, as well as through audit and reporting requirements, including of adverse reactions under pharmacovigilance rules. In the use of its supervision and enforcement powers, INFARMED can adopt decisions, including interim measures, leading to the suspension or revocation of licenses.

The decision of the MRA can be subject to judicial review through the competent court on misdemeanours.

2.8 What are the legal consequences in case of non-compliance?

Non-compliant distribution activities, without prejudice to potential criminal, tort and disciplinary liability, depending on the specificities of each case, are subject to the application by INFARMED of misdemeanour fines and accessory sanctions. The fine, per illicit conduct, is capped at EUR 44,891.81 in the case of legal persons and in the case of natural persons, also per infringement, at EUR 3,740.98.

3. WHOLESALE DISTRIBUTION

3.1 What is the legal regime regarding wholesale of drugs? Under what conditions, by whom, and to whom is wholesale of drugs permitted?

The Medicine Act encompasses the rules applicable to the wholesale distribution of medicinal products. Wholesale distribution of medicinal

products is subject to prior authorisation by INFARMED to permit the activity. In order to obtain a distribution authorisation, the applicants must fulfil the following minimum requirements: (i) they must have suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products; (ii) they must have staff, and in particular, a qualified technical director designated as responsible; and (iii) they must undertake to fulfil the following obligations:

a) they must make the premises, installations and equipment accessible at all times to the person responsible for inspecting them;
b) they must obtain their supplies of medicinal products only from persons who are themselves in possession of the distribution authorisation or who are exempt from obtaining such authorisation under the applicable derogation;
c) they must 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;
d) they must have an emergency plan which ensures effective implementation of any recall from the market ordered by INFARMED or carried out in cooperation with the manufacturer or MA holder for the medicinal product concerned;
e) they must 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: date, name of the medicinal product, quantity received or supplied, name and address of the supplier or consignee, as appropriate;
f) they must keep the records referred to under (e) available to INFARMED, for inspection purposes, for a period of five years;
g) they must comply with the principles and guidelines of Good Distribution Practice for medicinal products as laid down in Order No.348/98, 15 June 1998;
h) The wholesale supply of medicinal products can only be executed to persons who are themselves in possession of the distribution authorisation (other distributors) or who are authorised or entitled to supply medicinal products to the public, notably pharmacies, OTC retailers and healthcare centres authorised to acquire medicines directly from distribution wholesalers.

3.2 Which body (agency) is responsible for supervising wholesale distribution activities? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

INFARMED is the agency responsible for the supervision and enforcement of the provisions applicable to wholesale distribution activities. The MRA ensures that the legal requirements governing the wholesale distribution of medicinal products are complied with, by means of inspections, if necessary unannounced to the facilities of pharmacies and OTC retailers, as well as through audit and reporting requirements, including under the national guidelines of Good Distribution Practice for medicinal products as provided in

Order No.348/98, 15 June 1998. In the use of its supervision and enforcement powers, INFARMED can adopt decisions, including interim measures, leading to the suspension, withdrawal and revocation of authorisations.

The decision of the MRA can be subject to judicial review before administrative or criminal courts, depending on the matter addressed in the decision.

3.3 What are the legal consequences in case of non-compliance?

Non-compliant wholesaler distributorship activities – without prejudice to criminal, tort and disciplinary liability, depending on the specificities of each case – are subject to the application by INFARMED of criminal fines and accessory sanctions. The fine, per illicit conduct, is capped at EUR 44,891.81 in the case of legal persons.

B. MARKETING

4. PROMOTION (MARKETING)

4.1 What is the general legal regime regarding marketing of drugs (overview)? What are the general limits to marketing activities?

The general legal regime governing the marketing of medicines is provided in the Medicine Act, as well as the National Advertising Code (the latter to a lesser extent), established in Decree Law 330/90, 23 October 1990, as amended (Advertising Code).

The following are not considered advertising: (i) the labelling and the accompanying package leaflets; (ii) correspondence to answer a specific question about a particular medicinal product; (iii) factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims; and (iv) statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.

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

MSMP, as well as medicinal products which contain psychotropic or narcotic substances, and all medicines subject to reimbursement by the NHS cannot be marketed to the general public, but only to healthcare professionals (eg, doctors, pharmacists and nurses). OTC medicines can be marketed to the general public.

Advertising of any of the aforesaid categories of medicinal products must fulfil the following requirements:

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

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

- 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; and

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

The advertising of a medicinal product to the general public shall 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 – this prohibition shall 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, 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 thereof.

Advertising of a medicinal product to persons qualified to prescribe or supply such products shall include: (i) essential information compatible with the summary of product characteristics; (ii) the supply classification of the medicinal product; and (iii) the conditions for reimbursement by the NHS.

4.2 Besides the legal regime, are there other codes of conduct, eg, by professional or industry organisations? How are they implemented? What is the relationship between the industry code (if any) and the legal regime?

The Portuguese Association of the Pharmaceutical Industry (*Associação Portuguesa da Indústria Farmacêutica*, APIFARMA) has, since 1983, developed a Code of Conduct for Promotional Practices by the Pharmaceutical Industry with Healthcare Professionals (CODE). The current version of CODE, which entered into force on 1 January 2012, takes into account and is aligned with the rules of the Medicine Act, as well as the European Federation of

Pharmaceutical Industries and Associations Code (EFPIA) on promotion of prescription-only medicines to, and interactions with, healthcare professionals.

The implementation of the provisions of CODE is supervised by the Council of Ethics of APIFARMA. In the case of an alleged breach of CODE, the claim is sent to APIFARMA's Council of Ethics. In case of non-compliance with the provisions of CODE, the association requests the offender to immediately put an end to the irregular activity and to undertake, in writing not to repeat that practice.

The breach of CODE by a company is considered a disciplinary offence and the applicable sanctions are provided for in APIFARMA Statutes. Where a breach is found, the applied sanction, as well as the nature of the offence, is publicised by APIFARMA.

5. MARKETING TO CONSUMERS

5.1 What is the legal regime with respect to marketing to consumers (overview)? Which products might/might not be advertised to consumers?

Medicinal products which contain psychotropic or narcotic substances, MSMP and medicines subject to reimbursement by the NHS cannot be marketed to the general public, but only to healthcare professionals (eg, doctors, pharmacists and nurses).

OTC medicines can be marketed to the general public.

Please also see question 4.1 above.

5.2 What kinds of marketing activities are permitted with regard to consumers and the products which might be advertised to them?

OTC medicines can be subject to most common types of marketing activities (eg, television, radio, magazines and newspapers).

5.3 Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers eg, 'buy-one-get-one-free'?

Consumers cannot be provided with free samples of medicinal products. Samples can only be provided to healthcare professionals under very stringent situations. 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. Thus, such a special offer is not permitted under the Medicine Act.

Pharmacies can, however, grant discounts to consumers when acquiring medicinal products, as discounts are not subject to the advertising rules of the Medicine Act. Furthermore, Decree Law 112/2011, 29 November 2011, as amended, which establishes the price regime of MSMP and OTC medicines reimbursed by the NHS, specifically states that discounts are allowed in all the medicine circuit, 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 NHS are applicable only to the part of the price not subject to reimbursement.

5.4 Are there particular rules/codes of practice on the use of the Internet/Social Media in respect of drugs and their advertising?

Other than the rules identified above regarding advertising to consumers, there are no specific rules on the use of the internet or social media.

In relation to healthcare professionals, the APIFARMA CODE specifically states that the internet promotion of medicinal products targeting healthcare professionals should be based on technical, scientific and professional principles. In addition, it also provides that pharmaceutical companies should adopt measures to guarantee that the promotion is accessed only by healthcare professionals (and not by the general public).

5.5 Which body (agency) is responsible for supervising marketing activities to consumers? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

INFARMED is the agency responsible for the supervision and enforcement of the provisions applicable to consumer marketing activities. The MRA ensures that the legal requirements applicable to advertising rules are complied with. In case of suspicion of non-compliant promotional activities the MRA, *ex officio* or based on a complaint, can open an inquiry which can potentially lead to the application of fines as well as to the loss of licenses, authorisations or permits.

The decision of the MRA can be subject to judicial review in the competent court.

5.6 What are the legal consequences in case of non-compliance?

Non-compliant marketing activities, without prejudice to criminal, tort and disciplinary liability, which can vary depending on the specificities of each case, are subject to the application by INFARMED of misdemeanour fines and accessory sanctions, including a ban to advertise the medicine for a period of up to two years. The fine, per illicit conduct, is capped at EUR 44,891.81 in the case of legal persons, and in the case of natural persons, also per infringement, at EUR 3,740.98.

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

6. MARKETING TO PROFESSIONALS

6.1 What kinds of marketing activities are permitted with regard to professionals?

The Medicine Act allows, *inter alia*, the following types of marketing activities:

- advertisement in publications exclusively addressed to healthcare professionals (in the case of MSMP);
- visits by sales representatives to healthcare professionals (restrictions apply, see question 6.3 below),
- promotional events, including meetings, congresses, conferences, and symposia attended by persons qualified to prescribe or supply medicinal products;
- supply of samples (restrictions apply, see question 6.8 below);

- benefits in kind may be given or offered to professionals, but only if those benefits have a low cash value (no more than EUR 25 if one takes into account the APIFARMA CODE) and are relevant for the practice of medicine or pharmacy and/or involve a benefit for the patient.

The APIFARMA CODE also specifically allows the use of faxes, email, automatic call systems, text messages and other means of electronic communication to contact professionals with the previous authorisation or request of the health professional.

6.2 Are there particular types of marketing activities which are not permitted with respect to professionals (eg, provision of reprints, non-interventional studies, provision of and type of gifts/educational items)?

Yes. The Medicine Act states that the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind are strictly prohibited, except when their intrinsic value is minimal (no more than EUR 25 if one takes into account the APIFARMA CODE) and are relevant for the practice of medicine or pharmacy and/or involve a benefit for the patient.

6.3 Are there restrictions on how, when, where or how often professionals might be targeted by sales representatives?

Yes, but these restrictions only apply to sales representatives when targeting healthcare professionals active in establishments of the NHS. In the case of healthcare professionals who provide their services in establishments of the NHS, sales representatives must be registered with INFARMED and their contact with professionals are governed by strict rules, as provided in MRA's Dispatch 2837/2004, 8 January 2004.

In principle, pharmaceutical companies, in relation to institutions of the NHS, can only make six visits per year to each institution or service. Also in principle, and still in relation to the NHS, each sale representative should not visit more than ten healthcare professionals per day. Furthermore, the maximum number of daily visits permitted is, as a rule, two sales representatives per NHS hospital service. However, on such visits, each pharmaceutical company may only have, as a rule, one representative present.

The sales representative visits to the NHS shall take place in a location suitable for the aim of the meeting and cannot be held in: (i) emergency services, (ii) areas where patients are accommodated, or (iii) internment services held during allocated patient times. The visits should take place outside consultation hours, preferably after the end of such periods.

6.4 What are the restrictions on meetings with groups of professionals and the provision of hospitality?

The Medicine Act provides that 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 and support is strictly limited to the main purpose of the event. Hospitality, registration, travel and accommodation costs are considered to be acceptable expenses during an event.

Supported accommodation costs shall not exceed the period between the day prior to the beginning of the event and the day after the end of it and shall not 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 to the rules of the Medicine Act, the APIFARMA 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 MA or promoter of a medicinal product must take place in a suitable venue;
- the companies which are holders of a MA 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 scientific or educational events;
- the events should be held in Portugal, unless it is logistically more reasonable to hold the event in another country (i) taking into account the home countries of most of the guests; or (ii) taking into account the location of the resources or relevant knowledge which are the main topic of the event;
- when the events are held in another country (international events) the following rules should be complied with: (i) where MSMP 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, 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 shall apply, (ii) regarding 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 APIFARMA CODE also provides that sponsorship of any promotional, scientific or educational event should take into consideration the following principles:

- the sponsorship should be clearly announced prior to the event, during the event itself, and during the post-event phase;
- the payment of fees and the reimbursement of expenses, including travel, meals and accommodation for the speakers and moderators of the events are deemed to be suitable;
- any and all material or information that result from the event must be accurate and honestly reflect the talks and discussions;
- if the program is recognised for post-graduation vocational training purposes by a recognised medical organisation or any other recognised

healthcare professional's organisation, and if there is any support provided by the pharmaceutical industry, it should be disclosed.

6.5 What information is it legally required to include in advertising?

Any advertising of a medicinal product to persons qualified to prescribe or supply such products shall include:

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

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.

6.6 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 APIFARMA CODE provides that comparative advertising is only permitted among healthcare professionals and that comparisons among different medicinal products should be based on relevant and comparative aspects and should neither be deceitful nor 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 or on credible clinical data.

The Advertising Code also provides rules applicable to comparative advertising, stating that comparative advertising shall, as far as the comparison is concerned, be permitted when 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;
- for products with designation of origin, it relates in each case to products with the same designation;
- it does not take unfair advantage of the reputation of a trade mark, trade name or other distinguishing marks of a competitor or of the designation of origin of competing products; and
- it does not present goods or services as imitations or replicas of goods or services bearing a protected trade mark or trade name.

6.7 Are discounts permitted? If they are, under what conditions, by whom, and to whom?

Decree Law 112/2011 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 NHS are applicable only to the part of the price not subject to reimbursement. Thus, discounts can be granted by the manufacturer to the wholesale distributor and by the wholesale distributor to the retailer (pharmacy or OTC retailer).

6.8 Is it permitted to provide professionals with free samples?

Yes. Free samples can be provided on an exceptional basis and only to persons qualified to prescribe them on the following conditions:

- the number of samples for each medicinal product each year on prescription shall be limited;
- any supply of samples shall be in response to a written request, signed and dated, from the prescribing agent;
- those supplying samples shall maintain an adequate system of control and accountability;
- each sample shall be identical to the smallest presentation on the market;
- each sample shall be marked '*amostra gratuita*' (free sample) or '*venda proibida*' (not for sale) or marked with other wording having the same meaning;
- each sample shall 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 may be supplied;
- 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.

6.9 Is sponsoring of professionals allowed? Under what conditions, by whom, and to whom and for what purpose(s)?

The Medicine Act comprises strict rules in the sponsoring of healthcare professionals. The Act provides and allows the payment of fees to healthcare professionals for their active participation, notably through the presentation of scientific communication in events of that nature or in training and promotion sessions of medicinal products, as long as the payment is not directly or indirectly dependent upon the professional prescribing or dispensing of medicinal products.

In addition, the APIFARMA 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 are authorised if:

- 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 CODE further provides that no donations or subsidies should be granted to healthcare professionals individually.

6.10 Are other indirect incentives allowed? Under what conditions, by whom, and to whom?

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

6.11 Which body (agency) is responsible for supervising marketing activities regarding professionals? How is supervision implemented? Is there a legal remedy (appeal) against decisions?

Marketing activities are subject to the supervision of INFARMED and investigations are opened based on the results of audits, complaints by competitors or publicly available information.

INFARMED's decisions are subject to judicial review.

6.12 What are the legal consequences in case of non-compliance?

Non-compliant marketing activities, without prejudice to possible criminal, tort and disciplinary liability (which can vary depending on the specificities of each case), are subject to the application by INFARMED of misdemeanour fines and accessory sanctions, including an advertisement ban on the medicine for a period of up to two years.

The fine, per illegal conduct, is capped at EUR 44,891.81 in the case of legal persons and in the case of natural persons, at EUR 3,740.98 (both per infringement).

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

7. ENGAGEMENT WITH PATIENT ORGANISATIONS

7.1 What kinds of activities are permitted with respect to engagement with patient organisations?

The Medicine Act does not entail any express provisions regarding interactions with patient organisations, but the restrictions identified above in sections 5 and 6 apply.

The APIFARMA CODE states that companies should also comply with the provisions of APIFARMA's Code of Conduct for the relations between the Pharmaceutical Industry and Patient Organisations (PATIENTS CODE), based on the similar EFPIA code.

Under the PATIENTS CODE, companies that want to provide direct or indirect financial support and significant non-financial support to patients' organisations should put this in writing, by means of an agreement 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 of formal approval of the referred agreements.

In addition, companies and patients' organisations may agree contracts under which patients' organisations may provide services to companies with the purpose to support 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:

- specify the nature of services to be provided and the payment conditions;
- identify, in a clear way, the legitimate need for those services;
- the criteria to select the services should relate directly with the need identified in the previous subparagraph and the people in charge for its selection should have the suitable experience and knowledge to assess if the speakers, experts and/or consultants 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 contracts signed with patients' organisations cannot be an incentive for the recommendation of a particular medicinal product;
- the payment of the services provided should be reasonable and reflect the market practice in a fair manner;
- agreements 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 contract 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; and
- the benefits received, as far as significant non-financial support to which no monetary value can be ascribed are concerned.
- According to the PATIENTS CODE, companies should make sure the information on the sponsorship of patient's organisations is made available in a clear and transparent manner, upon request of any stakeholder or through the institutional website of the company, until 31 May each year.

7.2 What are the restrictions that are imposed on relationships with patient organisations?

The relationships with patient organisations are subject, under the Medicine Act, to the duties and restrictions identified above in sections 5 and 6.

In addition to this, pursuant to the PATIENTS CODE:

- no company can describe itself as being the exclusive sponsor of a patients' organisation or of its main programs;
- companies should not influence the content of materials produced by patients' organisations they sponsor, so as to favour their commercial interests;
- the independence of patient organisations regarding their political decisions, their policies and their activities must be guaranteed.