GÓMEZ-ACEBO & POMBO

Newsletter Life Sciences

Portugal | N.º 1 | 2017

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Design and layout: José Ángel Rodríguez León • Translation and adaptation: John Woodger

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Legislation

Portugal

Advertising of pharmaceutical products and medical devices

The Decree-Law adopting the general principles of advertising for medicinal products and medical devices was adopted on January 6, 2017, based on guidelines from the European Commission, in particular the document "List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector", and involved changes to the Medicinal Products Statute and the legal regime for medical devices.

The performance of companies that produce, distribute or sell medicines and medical devices must therefore be governed by the principles of integrity, respect, responsibility, moderation, transparency and collaboration with their interlocutors and competent authorities.

A general prohibition on the National Health Service (SNS) agencies and organisations, regardless of their legal nature, and the Ministry of Health's agencies and bodies, is also introduced with regards to the soliciting or receiving, directly or indirectly, of a pecuniary or in kind benefit from companies that supply goods and services in the areas of medicinal products, medical devices and other healthcare technologies, which may affect impartiality, except when analysed and duly authorized for this purpose by the Minister of Health.

This law also introduced into the Portuguese legal system a prohibition on promoting scientific or other actions of a promotional nature in the SNS's agencies and organisations and the Ministry of Health's agencies and bodies; these may not be sponsored by companies producing, distributing or selling medicinal products and medical devices.

Notwithstanding the same, this rule will not adversely affect visits by and access arrangements for medical delegates and commercial representatives of medical devices, among others.

Lastly, it should be noted that the maximum number of free samples that can be distributed of each drug has been reduced from 12 to 4 units per healthcare professional.

It should be noted that the role of INFARMED, I.P. as a regulatory entity is strengthened by this legislative amendment, insofar as it now receives, in addition to the notices of grant and receipt of benefits (understood as any advantage, value, property or right assessable in cash, regardless of the method of delivery) from any entity to a regulated entity (and vice-versa), the validation of those benefits and the explanation supporting any non-validation, as well as information on the ultimate beneficiary of the benefit in the case of a healthcare professional. On the other hand, and insofar as INFARMED can now request a copy of each ad promoting a medical device produced by a regulated entity, an extension of the scope of INFARMED IP's inspection action can be expected. This faculty is similar to that provided for the advertising of medicinal products (in which case the referral to INFARMED is always mandatory).

Creation of the Instituto de Proteção e Assistência na Doença, I.P.

The *Instituto de Proteção e Assistência na Doença, I. P.* (Health Protection and Assistance Institute) replaces ADSE (the public administration's health subsystem). It is separate from the direct public administration and has the status of a special public institute integrated in the indirect public administration, with administrative and financial autonomy and its own assets.

ADSE, I.P. is supervised by the Health Ministry, thus consolidating the administrative relationship developed after the transfer of supervision and guidance powers to said Ministry by virtue of Decree-Act 152/2015.

This entity is thus, since January 1st 2017, a legal person in its own right and legal actions may be filed against it.

Governance of the National Health Service

Regulatory provisions approving the legal regime and articles of association of the National Health Service (NHS) healthcare facilities acting as public corporate entities were approved on February 10th. This regulation is aimed at increasing the NHS's efficiency by (i) strengthening its capacity, allocating human, technical and financial resources, (ii) perfecting the current procurement model, (iii) enhancing the autonomy and responsibility of managers at the NHS and its service providers; and (iv) clarifying duties within the NHS.

Decree-Act 18/2017, of 10 February, provides a unified regime applicable to all the NHS's healthcare facilities, in order not to have to interpret a variety of now revoked laws. It concentrates into one law the guiding principles for the provision of healthcare services, characteristics that the NHS's healthcare facilities may assume and the provisions and articles of association applicable to (i) Hospitals, Hospital Centres and Portuguese Oncology Institutes, E.P.E., (ii) Local healthcare facilities, E.P.E. and (iii) Administrative Public Sector Hospitals.

Ratification of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin

The Additional Protocol to the Convention on Human Rights and Biomedicine on Transplantation of Organs and Tissues of Human Origin (the "Additional Protocol") was ratified on February 16th and will enter into force on September 1st 2017.

Pursuant to the Additional Protocol, Portugal undertakes to comply with the principles of dignity and identity in the field of transplantation of organs and tissues of human origin for therapeutic purposes, including cells (e.g. hematopoietic stem cells) and excluding organ transplantation and reproductive tissues, embryonic or foetal organs and tissues, and blood and blood products.

Some particular obligations arising from these principles include compliance with professional standards and health and safety measures, provision of prior information to the recipient regarding the purpose, nature, implementation, consequences, risks and alternatives to the intervention, as well as the confidentiality of the whole transplant process.

The harvesting of organs from a living person is a last resort and can only be performed (i) for the therapeutic interest of the recipient; (ii) when no suitable organ or tissue is available from a deceased person and (iii) when there is no other alternative therapeutic method of comparable effectiveness. The free, informed and specific consent of the donor is required and may be withdrawn at any time. In addition, the donation may not be carried out if it represents a serious risk to the life or health of the donor.

The harvesting of organs from a deceased person requires (i) the prior verification of death in accordance with the law by physicians who will not participate in the harvesting of organs or tissues of the deceased person or subsequent procedures, (ii) the consent or authorization required by law; (iii) may not be carried out if the deceased person had objected; and (iv) the human body must be treated with respect.

Finally, it is worth pointing out that the Additional Protocol establishes an absolute prohibition on organ and tissue trafficking and on obtaining financial gain or comparable advantage from the human body or its parts as well as any advertising of the need for, or availability of, organs or tissues, with a view to offering or seeking financial gain or comparable advantage. The following are not covered by this prohibition: (i) the compensation of living donors for loss of income and justifiable expenses as a result of harvesting or related medical examinations, (ii) payment of justified fees for legitimate medical services or related technical services provided in transplantation and (iii) compensation in the event of justified damage arising from the harvesting of organs or tissues from living persons.

Ratification of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research

The Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (the "Additional Protocol") was ratified on February 20th and will enter into force on September 1st 2017.

The Additional Protocol covers the full range of research activities (clinical or other) in the health field involving interventions on human beings, excluding research on embryos in vitro and including foetuses and embryos in vivo. It sets out the principles that the investigation must respect, in particular the principles of the primacy of the human being (which shall prevail over the sole interest of society or science), freedom of research, absence of alternatives (research on human beings may only be undertaken if there is no alternative of comparable effectiveness), proportionality, scientific quality and confidentiality of all personal data.

It also sets forth that all research projects must be submitted, examined and approved by an Ethics Committee. The persons being asked to participate in a research project must be given adequate information in a comprehensible form, in order to be able to give their informed, free, express, specific and documented consent.

Bearing in mind that not all persons being asked to participate in a research project are in the same situation, the Additional Protocol also provides standards of protection for specific groups, in particular persons not able to consent to research, women who are pregnant or breast-feeding, persons in emergency clinical situations and persons deprived of their liberty.

Finally, it should be noted that sponsors or researchers within the jurisdiction of a Party to the Additional Protocol that plan to undertake or direct a research project in a State not party to this Protocol shall ensure that, without prejudice to the provisions applicable in that State, the research project complies with the principles on which the provisions of this Protocol are based. It should be noted that the Additional Protocol is currently in force in the following States: Bosnia and Herzegovina, Bulgaria, Slovakia, Slovenia, Georgia, Hungary, Moldova, Montenegro, Norway and Turkey, and has not yet been signed or ratified by any of the observer States (Australia, Canada, Holy See, Japan and the United States of America).

Animal use in scientific research

Following the approval of the amendments made to the Civil Code, giving domestic animals a legal status separate from other things, on February 23rd, Parliament passed Resolution no. 33/2017, by way of which it advises the government to:

(i) promote investment in the development of alternatives to the use of animals for experimental and other scientific purposes, thus complying with an effective implementation of the 3R policy (Reduction, Replacement and Refinement, which serve as a framework for humane animal research for scientific purposes);

(ii) promote the disclosure of information and the appropriate liaison between the different entities connected to animal research, in particular between the National Commission and the bodies responsible for animal well-being (ORBEA), advocating that institutions where such bodies are not yet established put them into place as soon as possible in order to ensure that the authorised and financed protocols are being duly executed, thus maximising the well-being of animals and,

(iii) evaluate and inform Parliament on the application of the recommendations contained in Parliamentary Resolution no. 96/2010, of 11 August (concerning the creation of a national network of vivariums to provide animals for scientific research and to promote the implementation of the 3R principles) and plan the implementation of the any measures that have not yet been implemented.

European Union

Maximum residue limits in foodstuffs of animal origin: Implementing Regulation (EU) 2016/885

In accordance with Council Regulation (EC) 470/2009, the maximum residue limit of pharmacologically active substances intended for use in the Union for veterinary medicinal products for food-producing animals or for biocidal products used in livestock farming should be laid down in a Regulation. Regulation (EU) 37/2010 lists pharmacologically active substances and their classification with regard to maximum residue limits in food products of animal origin. Among them is *"eprinomectin"*, which is listed as an authorized substance in cattle, sheep and goats as regards muscle, adipose tissue, liver, kidney and milk. Commission Implementing Regulation (EU) 2016/885 of 3 June, 2016, amending Regulation (EU) No. 37/2010 as regards the substance *"eprinomectin"* (Official Journal of the European Union No. L 148 of 4 June 2016) has made certain changes in this respect.

New chapter in the European Medicines Agency 's guidelines on good pharmacovigilance practices

The European Medicines Agency (EMA) has introduced a new chapter in its guidelines on good pharmacovigilance practices under the heading "Product- or population-specific considerations II: Biological medicinal products", which provides guidance on how to monitor and manage drug safety in order to optimize the safe and effective use of these products in Europe. This Chapter has been in force since August 16th, 2016 and can be consulted at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/08/WC500211728.pdf.

Plastic materials and articles intended to come into contact with food

Commission Regulation (EU) no. 2016/1416 of 24 August, amending and correcting Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food (published in the Official Journal of the European Union No. 230 of 25 August 2016), updates such regulation in light of the latest reports published by the European Food Safety Authority (EFSA)on particular substances that may be used in food contact materials as well as on the permitted use of substances that have been authorised previously. Errors and ambiguities in the text are also corrected.

Changes to the list of herbal substances, preparations or combinations thereof for use in traditional herbal medicinal products

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, establishing a Community Code relating to medicinal products for human use, provides for

the establishment of a list of herbal substances, preparations and associations thereof, for use in traditional herbal medicinal products. The list shall contain, with regard to each herbal substance, the indication, the specified strength and the posology, the route of administration and any other information necessary for the safe use of the herbal substance as a traditional medicinal product. The list was established by Commission Decision 2008/911/EC, which provided list of herbal substances, preparations and associations thereof, for use in traditional herbal medicinal products.

This list has been modified by the following provisions:

a) Implementing Decision (EU) 2016/1659, of 13 September 2016, amending Decision 2008/911/EC establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products.

b) Implementing Decision (EU) 2016/1658, of 13 September 2016, amending Decision 2008/911/EC establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products.

Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants

Published in Official Journal L 317, 23/11/2016 (available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R2031&from=EN), this Regulation establishes rules to determine the phytosanitary risks posed by any species, strain or biotype of pathogenic agents, animals or parasitic plants injurious to plants or plant products ('pests') and measures to reduce those risks to an acceptable level.

Judgments and decisions

Portugal

Arbitral award in the matter of the medicinal product "Inegy" and the active ingredient "ezetimibe+simvastatin"

The Arbitration Court's award of 29 November 2016 concerning the protection of industrial property rights (European patent and supplementary protection certificate) over the active ingredient "*Ezetimibe+Simvastatin*" (the reference medicinal product is "*Inegy*"), has been published.

This award orders the defendant to refrain from importing, manufacturing, storing, placing on the market, marketing or offering any generic medicinal product containing "ezetimibe" as an active ingredient in Portugal or in view of marketing in Portugal.

At the same time, the defendant was ordered to refrain from importing, manufacturing, storing, placing on the market, marketing or offering any generic medicinal product containing the combination of active ingredients "*Ezetimibe*" and "*Simvastatin*" in Portugal or in view of marketing in Portugal.

Such prohibitions shall be upheld as long as the referred industrial property rights remain in force.

Arbitral award in the matter of the medicinal product "Tracleer" and the active ingredient "bosentan"

The Arbitration Court's award of 5 January 2017 concerning the protection of industrial property rights (European patent and supplementary protection certificate) over the active ingredient "*Bosentan*" (the reference medicinal product is "*Tracleer*"), has been published.

This ruling orders the defendant to refrain from importing, manufacturing, storing, placing on the market, marketing or offering any generic medicinal product containing "*Bosentan*" as an active ingredient, in Portugal or in view of marketing in Portugal, as long as the referred industrial property rights remain in force.

Arbitral award in the matter of the active ingredient "ezetimibe"

The Arbitration Court's ruling of 15 December 2016, which approved the parties' agreement regarding generic medicinal products containing "*ezetimibe*" as an active ingredient, has been published.

As per this agreement, the defendant agrees, directly or indirectly through its affiliates or third parties, not to store, offer, place on the market or market in Portugal any medicinal product containing "*ezetimibe*" as the sole active ingredient or in association with one or more active ingredients (the "Products").

At the same time, the defendant undertakes not to grant or transfer to any third party (i) any right to place the Products on the market in Portugal, (ii) the requested marketing authorisation or any other marketing authorisations which may be requested and/or acquired and/or transferred by the defendant and/or its affiliates for the Products in Portugal.

Finally, the defendant undertakes not to execute any acts in Portugal which may be deemed as an infringement of the supplementary protection certificate pursuant to Portuguese law.

The terms of this agreement shall apply for as long as the referred industrial property rights remain in force.

Arbitral ruling on the medicinal product "arcoxia" and the active ingredient "etoricoxib"

The Arbitration Court's rulings of 19 and 28 October 2016 concerning the protection of industrial property rights (European patent) over the active ingredient "*etoricoxib*" (the reference medicinal product was "*Arcoxia*") have been published.

These rulings order the defendants to refrain from importing, manufacturing, storing, placing on the market, marketing or offering any generic medicinal product containing "*Etoricoxib*" as an active ingredient, in Portugal or in view of the marketing in said territory, as long as the referred industrial property rights remain in force.

These rulings acquitted the defendants from the claims filed to not transfer to any third parties the market authorisations and acquitted them from the claim for the payment of periodic penalties.

European Union

Price of medicines and "open house" model

In Germany, a "participation procedure" was established to conclude rebate agreements regarding medicines containing the active ingredient "*mesalazine*", which provided for the authorisation of all interested undertakings meeting the authorisation criteria and for the conclusion with each of those undertakings of identical contracts whose terms were fixed and non-negotiable. Furthermore, any other undertaking fulfilling those criteria also had the opportunity of acceding on the same terms to the rebate contract scheme during the contract period.

Thus, the CJUE (Fifth Chamber) of 2 June 2016, in proceeding C-410/14, *Dr. Falk Pharma GmbH* and *DAK-Gesund-heit*, with the intervention of *Kohlpharma GmbH*, ruled that this procedure is not subject to public procurement law since article 1(2)(a) of Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts must be interpreted as meaning that a contract scheme, such as that in the main proceedings, through which a public entity intends to acquire goods on the market by contracting throughout the period of validity of that scheme with any economic operator who undertakes to provide the goods concerned in accordance with predetermined conditions, without choosing between the interested operators and, allows them to accede to

that scheme throughout its validity, does not constitute a public contract within the meaning of that directive.

Insofar as the subject matter of an authorisation procedure, such as that at issue in the main proceedings, is of certain cross-border interest, that procedure must be conceived and organised in accordance with the fundamental rules of the FEU Treaty, in particular, the principles of non-discrimination and equal treatment between economic operators and the consequent obligation of transparency.

The contractual obligation to pay for the use of technology after the patent protecting it has been revoked is not a concerted practice

The Court of Justice of the European Union, in its ruling of 7 July 2016, Case C-567/14, *Genentech Inc. and Hoechst GmbH*, *Sanofi-Aventis Deutschland GmbH*, states that article 101 of the TFEU must be interpreted as not precluding the imposition on the licensee, under a licence agreement such as that at issue in the main proceedings, of a requirement to pay a royalty for the use of patented technology for the entire period in which that agreement was in effect, in the event of the revocation or non-infringement of a licenced patent, provided that the licensee was able freely to terminate that agreement by giving reasonable notice.

Repackaging of medicinal products by a parallel importer

The judgment of the Court of Justice of the European Union (CJEU) of 10 November 2016 in Case C-297/15, in response to a request for a preliminary ruling from the *Sø- og Handelsretten* (Maritime and Commercial Court, Denmark) in proceedings between *Ferring Lægemidler A/S* (acting on behalf of *Ferring BV*) and *Orifarm A/S*, addresses a recurrent theme in the pharmaceutical industry, namely the conditions under which a parallel importer may repackage medicinal products.

According to the CJEU, a trade mark proprietor may object to the continued marketing of a medicinal product by a parallel importer, where that importer has repackaged that medicinal product in a new, outer packaging and reaffixed the trade mark, where, first, the medicinal product at issue can be marketed in the importing State party to the Agreement on the European Economic Area (EEA Agreement) in the same packaging as that in which it is marketed in the exporting State party to the EEA Agreement and, second, the importer has not demonstrated that the imported product can only be marketed in a limited part of the importing State's market, and those are matters which it is for the referring Court to determine.

Foods and food ingredients which have not hitherto been used for human consumption

The judgment of the CJEU of 9 November 2016 in Case C-448/14, in response to a request for a preliminary ruling from the *Bayerischer Verwaltungsgerichtshof* (Higher Administrative Court of Bavaria, Germany) in proceedings between *Davitas GmbH* and *Stadt Aschaffenburg*, has interpreted Article 1(2)(c) of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, as amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009.

Regulation (EC) No 258/97, which concerns the placing on the market within the European Union (EU) of novel foods or novel food ingredients, applies, according to Article 1(2), to the placing on the market within the Union of foods and food ingredients which have not hitherto been used to a significant degree for human consumption to a significant degree within the EU.

Upon consideration of the questions referred, the CJEU concludes that Article 1(2)(c) of Regulation (EC) No 258/97 must be interpreted as meaning that the expression 'new primary molecular structure' relates to foods or food ingredients which were not used for human consumption in the territory of the EU before May 15th 1997.

Transitional measure in the Regulation on nutrition and health claims made on foods

1. Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, as amended by Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008, contains a transitional rule (Article 28(2)) that reads as follows: "Products bearing trade marks or brand names existing before 1 January 2005 which do not comply with this Regulation may continue to be marketed until January 19th, 2022 after which time the provisions of this Regulation shall apply".

2. The above provision has been interpreted by the judgment of the CJEU of 23 November 2016 in Case C-177/15, in response to a request for a preliminary ruling from the *Bundesgerichtshof* (Federal Court of Justice, Germany) in proceedings between Nelsons GmbH, on the one side, and Ayonnax Nutripharm GmbH and Bachblütentreff Ltd, on the other.

According to the CJEU, Article 28(2), first sentence, of Regulation (EC) No 1924/2006 must be interpreted as meaning that said provision applies in the situation in which a foodstuff bearing a trade mark or brand name was, before January 1st, 2005, marketed as a medicinal product and then after that date, although having the same physical characteristics and bearing the same trade mark or brand name, as a foodstuff.

Medicinal product for human use prepared industrially or manufactured by a method involving an industrial process

The judgment of the CJEU of 26 October 2016 in Case C-276/15, in response to a request for a preliminary ruling from the *Bundesgerichtshof* in proceedings between *Hecht-Pharma GmbH* and *Hohenzollern Apotheke*, states that "Article 2(1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011, must be interpreted as meaning that a medicinal product for human use, such as that at issue in the main proceedings, which, under national legislation, does not require a marketing authorisation by reason of the proven frequency with which it is the subject of medical and dental prescriptions, the essential manufacturing steps for such products are carried out in a pharmacy as part of the normal pharmacy business producing in the course of one day up to 100 packages ready for dispensation and intended for supply under the existing pharmacy operating licence, cannot be regarded as having been prepared industrially or manufactured by a method involving an industrial process, within the meaning of that provision, and consequently does not come within the scope of that directive, subject to the findings of fact which it is for the referring court to make".

The CJEU adds, however, that "should those findings lead the referring court to take the view that the medicinal product at issue in the main proceedings has been prepared industrially or manufactured by a method involving an industrial process, the answer must also be that point 2 of Article 3 of Directive 2001/83, as amended by Directive 2011/62, must be interpreted as meaning that it does not preclude provisions such as those laid down in Paragraph 21(2), point 1, of the Law on the marketing of medicinal products, read in conjunction with Paragraph 6(1) of the Regulation on the operation of pharmacies, in so far as those provisions, in essence, require pharmacists to comply with the pharmacopoeia when manufacturing officinal formulae. It is, however, for the referring court to determine whether, on the facts of the case before it, the medicinal product at issue in the main proceedings has been prepared in accordance with the prescriptions of a pharmacopoeia".

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