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Legislation

Portugal

Reformulation of the pharmacy and therapeutics committees

Following the modifications to the PTC reformulation of the Regional Health Administrations, the creation of the National Commission of Pharmacy and Therapeutics (Comissão Nacional de Farmácia e Terapêutica - CFT) and the publication of the National Drug Formulary, it was determined, by order of the State Secretary for Health dated 17 March 2017, a new framework for CFTs of public sector hospital entities (local CFTs).

Local CFTs will be tasked with proposing, within their health facilities, therapeutic guidelines and more efficient use of medicinal products within the framework of the drug policy, based on a sound basis of clinical pharmacology and evidence of cost- effectiveness, monitoring the prescription of medicines, their use, guaranteeing all users fair access to therapy.

It should be noted that, according to the Regulation annexed to Order no. 2325/2017, local CFTs are created by resolution of the board of directors of the administrative entity, which may consist of six to ten members, with an equal number of doctors and pharmacists, according to the volume of use and prescription of medicines, appointed for three years. The local CFT is chaired by the clinical director of the hospital or specialist physician appointed by the latter for this purpose, with the remaining members being nominated by the Director of Pharmaceutical Services among the doctors and pharmacists attached to the institution.

The alterations carried out through the Ordinance in the CFT-ARS regime aim above all to reinforce the technical support role of each Regional Health Administration, to ensure coordination with the National Commission and to adapt the mission of these entities to reality, and in particular to ensure the implementation of the rules concerning the National Formulary List.

Approval of the nagoya protocol on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization

By Decree 7/2017 of 13 March, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits arising from their utilization (adopted on 29 October 2010) was adopted.

For the purposes of this Protocol, "use of genetic resources" means conducting research and development activities on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology (the latter being defined as any technological

application using Biological systems, living organisms or their derivatives for the creation or modification of products or processes for specific use).

The Nagoya Protocol broadens the general framework of the Convention on Biological Diversity with a view to achieving one of its three fundamental objectives, in particular by seeking to create conditions for Parties to promote the conservation and sustainable use of biological diversity and to strengthen the predictability of conditions for access to genetic resources, to increase the effective sharing of benefits between users and suppliers of genetic resources, and to ensure that only legally acquired genetic resources are used.

The Nagoya Protocol also stipulates additional obligations for Parties arising from the obligation to adopt legislative, administrative or political measures in order to ensure (i) the fair and equitable sharing of benefits between the country of origin or supplier and the purchaser of such benefits; (ii) that access to genetic resources and access to traditional knowledge associated with genetic resources is carried out with the prior informed consent of the Party providing the resources or with the approval and participation of indigenous and local communities when it is the case (iii) the existence of a national focal point for the provision of information to applicants on procedures for access to genetic resources and access to traditional knowledge associated with genetic resources; (iv) establishment of control posts to monitor and increase transparency in the use of genetic resources.

The Protocol also provides that an internationally recognized certificate of conformity shall be issued stating that access to genetic resources has been carried out in accordance with prior informed consent and that mutually agreed terms have been established regarding the access and benefit-sharing of the Party granting prior informed consent.

This regulation will come into force in our legal system on July 10, 2017.

New regulation on varieties of agricultural and vegetable species

Decree-Act No 42/2017 of 6 April regulates the production, control, certification and marketing of seeds of agricultural and horticultural species, transposing Implementing Directives (EU) No 2015/1168 , 2015/1955, 2016/11 and 2016/317, and also updates the regulations for registration in the National Catalogue of Varieties of Agricultural Species and Vegetable Species - CNV, in relation to test protocols resulting from Commission Implementing Directive (EU) No. 2015/1168 of 15 July 2015.

This law intends to clarify the current regulatory framework, which regulates the CNV of varieties of agricultural and horticultural species regardless of whether they are propagated by seeds or by vegetative route. It does not apply to varieties of fruit trees and vines, whose lists or catalogues of varieties are regulated under specific legal regimes.

Likewise, the registration of varieties of agricultural and horticultural species in the CNV and the system of production, control and certification of their seed, for multiplication and marketing, repealed the previous legislation on the production, control, certification and marketing of seeds of agricultural and horticultural species, with the exception of those used for ornamental purposes.

It is worth noting the elimination of the compulsory licensing of the farmer-multiplier activity without jeopardizing the fulfilment of European obligations regarding the production, certification and marketing of seeds, as well as the adoption of the above-mentioned Directives:

1. The changes made (i) in respect of the production, control, certification and marketing of seed of agricultural and horticultural species, in the light of changes in European law and (2) the conditions to which barley hybrids must comply.

2. The adaptation of the minimum level of varietal purity for hybrid seed and spring rape seed to the standards laid down by the OECD.

3. The imposition of the obligation to insert an official serial number in order to improve the security of official labels, allowing the control of the printing, distribution and use of those labels and reducing the possibility of fraudulent practices.

Creation of agricultural and animal research and experimentation networks

The creation of the National Network of Agricultural and Animal Research and Experimentation and, Rexia 2 (hereinafter referred to as "Rexia2"), as well as of two regional networks - Alentejo Agricultural Research and Extension Network (hereinafter referred to as " Alentejo AGROnet") and the Experimentation and Research Network of the Vine and Douro Wine, Riev2 (hereinafter referred to as "Riev2"), which will work closely with Rexia2 – were approved on 6 April. These entities are not endowed with independent legal personality.

Rexia2's mission is to promote the development of a network of experimental farms at the national level, together with research and experimental development activities based on practice and oriented towards the valorization of national agricultural products as well as business innovation.

Rexia2 comprises Polytechnic Institutes with agricultural education (Bragança, Castelo Branco, Coimbra, Portalegre, Santarém, Viana do Castelo and Viseu), INIAV, I.P. - National Institute of Agrarian and Veterinary Research, I.P. - and ICNF, I.P. - Institute of Nature and Forestry Conservation, I.P., as well as by the Regional Directorates of Agriculture and Fisheries of the North, Centre, Lisbon and Tagus Valley, Alentejo and Algarve.

The strategic action of Rexia2 targets seven main areas: (I) sustainable management of agroforestry systems; (II) development and sustainable management of agricultural and livestock systems; (III)

sustainability of irrigated agricultural production from an integrated production-to-processing perspective; (IV) quality, authenticity and traceability of high added value food products; (V) conservation and enhancement of national genetic heritage; (VI) planning production and sustainable management of forest areas, and (VII) study and monitoring of pests and diseases and strengthening of the National Agricultural Warning System.

Regional Alentejo AGROnet and Riev2 entities have the task of facilitating research and scientific and technological development, propose solutions and coordinate the network use, and stimulate actions for the production, dissemination and transfer of knowledge, in order to enhance regional sustainability of the sector.

It should also be mentioned that other public entities, as well as private entities in the agro-industrial sector, particularly in the form of a Collaborative Laboratory, within the scope of the mission of these entities may join the National Network or the regional networks.

New rules on the application of plant protection products

Tthe new rules on the application of plant protection products came into force on 23 May 2017, and the contravention regime associated with breaches of the established rules was also updated.

With regard to the application of plant protection products, we highlight the following changes:

1. Imposition of the display obligation in a prominent place in the area to be dealt with by new names, namely the identification of the responsible entity or entities, the expected date of treatment and the date from which the movement of people and animals to the site should be restored;

2. The re-entry interval is determined by spray drying (previously an interval of at least 24 hours was provided);

3. Repeal of the obligation of consultation of the Regional Directorate of Agriculture and Fisheries on the location of apiaries and consequent notification obligation of beekeepers when applying dangerous products to bees.

At the same time, a ban on the application of phytosanitary treatments with plant protection products was introduced in kindergartens, gardens and nearby urban parks, camping sites, hospitals and other health care facilities, in residential structures for the elderly and in educational establishments (except for those providing training in agrarian sciences), except in the following conditions:

1. Where alternative means and control techniques, including mechanical, biological, biotechnical or cultural control means, are not available; or

2. where it is necessary to deal with a plant health hazard which poses a risk to agriculture, forestry or natural environments, preference should be given to plant protection products which are permitted to be used in organic production, low-risk plant protection products or which present a low toxicological, ecotoxicological and environmental hazard and which do not require any particular risk reduction measures for man or the environment;

3. And, cumulatively, the application is authorized by the General Food and Veterinary Office (DGAV), with the power to delegate this competence to the Regional Directorate for Agriculture and Fisheries (DRAP)

Violation of this prohibition or its application in contravention of the legal regulations constitutes an infringement punishable with a fine of € 250.00 to € 3,740.00 in the case of a natural person and € 500.00 to € 22,500.00, in the case of a legal person.

European Union

Refusal to authorise a health claim made on foods and referring to the reduction of disease risk

As scientific evidence is insufficient to establish a cause and effect relationship between the consumption of Anxiofit-1 and the reduction of subthreshold and mild anxiety, Commission Regulation (EU) 2017/236 of 10 February 2017 refusing to authorise a health claim made on foods and referring to the reduction of disease risk refuses to include in the Union list of permitted claims the following claim: "Anxiofit-1 has been shown to ameliorate subthreshold and mild anxiety. Subthreshold and mild anxiety are risk factors in the development of anxiety disorders and depression".

Procedures for the notification of alerts as part of the EWRS established in relation to serious cross-border threats to health

The Early Warning and Response System ('EWRS'), as a permanent communication network between the Commission and the competent public health authorities in each Member State, for the prevention and control of certain categories of communicable diseases, was provided for by Decision No 2119/98/EC of the European Parliament and of the Council, Decision that was subsequently repealed and replaced by Decision No 1082/2013/EU of the European Parliament and of the Council, which, inter alia, laid down rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health.

It is in the above context that Commission Implementing Decision (EU) 2017/253 of 13 February 2017 laying down procedures for the notification of alerts as part of the early warning and response

system established in relation to serious cross-border threats to health and for the information exchange, consultation and coordination of responses to such threats pursuant to Decision No 1082/2013/EU of the European Parliament and of the Council has been adopted.

Amendment of the US-EC MRA Pharmaceutical Good Manufacturing Practices Annex

The Agreement on Mutual Recognition between the European Community and the United States of America (MRA), signed in 1998, contains a Sectoral Annex for Pharmaceutical Good Manufacturing Practices that has been amended by Decision No. 1/2017 of 1 March 2017 of the Joint Committee established under Article 14 of the Agreement on Mutual Recognition between the European Community and the United States of America, amending the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs) [2017/382].

As stated in Article 2, the purpose of this Annex is to facilitate the exchange of official GMPs documents between the parties and reliance on the factual findings in such documents, as well as to facilitate trade and benefit public health by allowing each party to leverage and to reallocate its inspection resources, including by avoiding duplication of inspections, so as to improve oversight of manufacturing facilities and better address quality risk and prevent adverse health consequences.

Release from the obligation of applying directives on the marketing of certain species or material

Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 1999/105/EC, 2002/54/EC, 2002/55/ EC and 2002/57/EC regulate the marketing of, respectively, fodder plant seed, cereal seed, material for the vegetative propagation of the vine, forest reproductive material, beet seed, vegetable seed and seed of oil and fibre plants. However, insofar that the seed of some species is not reproduced or marketed in all the Member States and there are States of the European Union where the propagation of vine and the marketing of propagation material are of minor economic importance, the aforementioned Directives also provide that, subject to certain conditions, Member States may be wholly or partially released from the obligation to apply those Directives in respect of certain species or material.

And that is what the Commission did in Decision 2010/680/EU, now repealed and replaced by Commission Implementing Decision (EU) 2017/478 of 16 March 2017, releasing certain Member States from the obligation to apply to certain species Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 1999/105/EC, 2002/54/EC, 2002/55/EC and 2002/57/EC.

Judgments and decisions

Portugal

Decision on the transfer of marketing authorization

Recently, the Lisbon Court of Appeal has been called upon to rule on the jurisdiction of the arbitral tribunals to determine the suspension of marketing authorizations (hereinafter "MAs") and to consider that a request for non-transfer of MAs to third parties is appropriate.

In its judgment (TRL 07-03-2017 (Peter Brighton) Proceeding No. 470/15.2YRLSB-1), the Court held that the arbitral tribunal had jurisdiction in so far as the request was in a dispute involving reference medicinal products and generic medicinal products, for which the arbitral tribunals are competent by virtue of the provisions of the Statute of Medicines (Article 15a of Decree-Act No 176/2006) and that, in this case, the arbitral tribunal had been duly constituted under that Statute.

The Court of Appeal also ruled on the decision of the arbitral tribunal that "the offer of the process [under the terms and for the purposes of Article 101 (2) of the Industrial Property Code - IPC"] involves a violation of the right conferred by the patent, irrespective of the application for a MA, a permission to use, which the offeror is not in a position to grant without infringing the patent".

Contrary to that decided by the Arbitral Tribunal, the Lisbon Court of Appeal considered that, in the light of the legislative procedure in this area, it cannot reasonably be considered that the granting of authorization to introduce a generic on the market is not in itself an infringement of the patent that protects the substance, manufacturing process or use involved in that medicine, and does not fall under any of the acts prohibited by article 101(2)of the IPC ("manufacture", "offer", "storage", "introduction", "use", "import" or "possession").

Decisions concerning the admission of arbitral jurisdiction in proceedings concerning the production of generic medicinal products

In two judgments of 25 May 2017, the Court of Appeal of Lisbon ruled on the admission of arbitral tribunals in proceedings relating to the production of generic medicinal products whose marketing (and similar acts) allegedly infringes industrial property rights attributed to the medicinal product, depending on whether the applicant has claimed infringement of the patented process.

The decision of the Court of Appeal was consistent in both cases. On the one hand, the Court considered the jurisdiction of the arbitral tribunal in a necessary arbitration to be unchanged, whether or not the complainant has claimed that the reference product is produced using the process and has the technical characteristics claimed in the European patent [TRL 25-05-2017 (Maria Teresa Albuquerque) Proc. No. 79 / 17.6YRLSB.L1-2].

On the other hand the Court also stated that the jurisdiction of the arbitral tribunal covers disputes relating to generic and reference medicinal products irrespective of whether or not the reference medicinal product is manufactured through the allegedly patented process (TRL 25-05-2017 (Jorge Leal) Proc. No. 410/17.4YRLSB.L1-2). In other words, the Court has held that what matters is the existence of protection of the holder's industrial property rights (through the patent) and its infringement by the generic medicinal product (regardless of whether or not the process protected by the patent has been used to manufacture the generic medicinal product).

Decision on the supplementary protection certificate

On 23 March 2017, the Lisbon Court of Appeal decided that the generic anti-inflammatory reference in the claims of the basic patent that underpins a Supplementary Protection Certificate (SPC) is not sufficient for granting of the latter. The Court of Appeal understands that in the basic patent, which supported the SPC application in question, the addition of active ingredients is only one embodiment of the invention. Moreover, the active ingredient in question, "nepafenac", is not expressly set forth in the claims of the basic patent, nor is it implicitly referred to therein, inasmuch as the generic patent reference is only made to anti-inflammatories. The Court of Appeal held that, in the wake of decisions previously issued by the National Institute of Industrial Property (INPI), at an administrative level, and by the Intellectual Property Court (IPC), on appeal, in the case under consideration the active ingredient was not covered either by a structural form or by a functional formula contained in the claims, in particular when interpreted in the light of the description of the invention, so as to be able to conclude that the claims implicitly but necessarily targeted the active ingredient in question in a specific manner.

Publication of arbitration awards

In the period from 1 March to 31 May 2017, the following arbitration awards were published in the Intellectual Property Journal:

1. Arbitration decision of 26 November 2016, relating to the dispute between Novartis Pharma AG and Novartis Farma - Produtos Farmacêuticos, S.A. Generis Farmacêutica S.A., for generic medicinal products containing the active substance "levodopa + carbidopa + entacapone": There being a dissenting vote of one of the arbitrators, the arbitral tribunal decided to find for the Respondent and order the Complainants to bear the full costs of the proceedings and to order the Respondent to bear half of the costs of one of the expert witness reports.

2. The proceedings initiated by (i) Merck Canada Inc. and Merck Sharp & Dohme, Ltd. Elpen, A.E., with regards to generic medicinal products containing the active substance "Etoricoxib", (ii) Merck Sharp & Dohme Corp. Vs. Pharmathen, S.A., for generic drugs containing the active substance "caspofungin", (iii) Merck Sharp & Dohme Corp. Vs. Teva B.V., for generic drugs

containing the active substances "Etinlestradiol" and "Etonogestrel", (iv) Pfizer, Ltd. and Warner-Lambert Company, LLC. Vs. Lupine (Europe), were settled by virtue of agreements reached by the parties.

European Union

Liability of the notified body appointed by a manufacturer to check on the conformity of medical devices

The judgment of the Court of Justice of the European Union (First Chamber) of 16 February 2017 in Case C-219/15, in response to a request for a preliminary ruling from the Bundesgerichtshof (Federal Court of Justice, Germany) in proceedings between Elisabeth Schmitt and TÜV Rheinland LGA Products GmbH, has interpreted Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003.

This judgment was given on referral of a number of questions raised in the course of proceedings concerning a female citizen who, having had breast implants manufactured in France and fitted in Germany, years later had them removed after the competent French authority established that the manufacturer in question had produced breast implants using industrial silicone which did not comply with quality standards.

The concerned party brought an action for damages against the notified body appointed to assess the manufacturer's quality system, arguing that an inspection of the delivery notes and invoices would have enabled this body to ascertain that the manufacturer had not used an approved form of silicone.

Having the action failed at first instance and on appeal, the German Supreme Court asked the CJEU whether it is the purpose and intention of Directive 93/42 that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance should act in order to protect all potential patients and may therefore, in the event of a culpable infringement of an obligation, have direct and unrestricted liability towards the patients concerned, if it is subject to a general obligation to examine devices, or at least to examine them where there is due cause, and if it is subject to a general obligation to examine the manufacturer's business records and/or to carry out unannounced inspections, or at least to do so where there is due cause.

According to the CJEU, the notified body is not under a general obligation to carry out unannounced inspections, to examine devices and/or to examine the manufacturer's business records. However, in the face of evidence indicating that a medical device may not comply with the requirements laid

down in Directive 93/42, as amended by Regulation (EC) No 1882/2003, the notified body must take all the steps necessary to ensure that it fulfils its obligations.

Moreover, it is also held in the judgment that in the procedure relating to the EC declaration of conformity, the purpose of the notified body's involvement is to protect the end users of medical devices. The conditions under which culpable failure by that body to fulfil its obligations under the directive in connection with that procedure may give rise to liability on its part vis-à-vis those end users are governed by national law, subject to the principles of equivalence and effectiveness.

Restrictions on advertising relating to the provisions of oral and dental care services and EU Law

1. The use of advertising by dentists is restricted by laws of nations for public interest reasons, such as the protection of public health. This is so to the extent that, in some countries, restrictions go as far as prohibiting any type of promotion of oral and dental care services. And this explains why the Court of Justice of the European Union ("CJEU") has recently been asked whether this type of prohibition is in conformity with EU law. The CJEU has ruled on the matter in its judgment of 4 May 2017 in Case C-339/15 (Openbaar Ministerie v Luc Vanderborght) on the occasion of Belgian legislation, under which the use of advertising by dentists is restricted and the advertising of dental services is prohibited.

2. The first question facing the CJEU concerns the compatibility of advertising restrictions with the Unfair Commercial Practices Directive ("Directive 2005/29"). In this regard, it is necessary first of all to determine whether the advertising constitutes a commercial practice within the meaning of Directive 2005/29 and is therefore subject to the rules laid down by the same. The CJEU concludes that the advertising of oral and dental care services such as that at issue, whether through publications in advertising periodicals or on the internet, or through the use of signs, constitutes a 'commercial practice', for the purposes of Directive 2005/29. However, notwithstanding the application of Directive 2005/29, Member States are free to adopt stricter rules than those laid down in Directive 2005/29 in relation to the practices of members of a regulated profession such as that of dentist.

3. The CJEU concludes that advertising relating to the provision of oral and dental care services by means of a website is commercial communication that falls within the scope of Directive 2000/31. The CJEU believes that Directive 2000/31 requires Member States to ensure that the use of commercial communications which are part of, or constitute, an information society service provided by a member of a regulated profession is permitted. Indeed, as provided by art. 8(1) of Directive 2000/31, said advertising may be subject to compliance with the professional rules regarding, in particular, the independence, dignity and honour of the profession, professional secrecy and fairness towards clients and other members of the profession. But such rules cannot include a general and absolute prohibition of that type of communication.

4. The CJEU has also analysed whether the prohibition of advertising can affect two fundamental freedoms of the Union: the freedom of establishment (art. 49 Treaty on the Functioning of the European Union (TFEU)) and the freedom to provide services (art. 56TFEU). The CJEU thus acknowledges that there is a restriction on the freedom of establishment because 'national legislation which imposes a general and absolute prohibition of any advertising for a certain activity is liable to restrict the possibility, for the persons carrying on that activity, of making themselves known to their potential clientele and of promoting the services which they offer to their clientele'. However, not all restrictions are contrary to the TFEU. In fact, it is settled case law of the CJEU that national measures which are liable to prohibit, impede or render less attractive the exercise of fundamental freedoms guaranteed by the Treaty may be allowed if they pursue an objective in the public interest, are appropriate for ensuring the attainment of that objective and do not go beyond what is necessary to attain the objective pursued. For instance, the judgment of 16 April 2013 in Case C-202/11 (Anton Las v PSA Antwerp NV) or the judgment of 12 September 2013 in Case C-475/11 (Kostas Konstantinides).

Although the CJEU understands that, in this case, the prohibition of advertising responds to a public interest objective (in so far as it seeks the protection of public health and the dignity of the profession of dentist), it is of the belief that the general and absolute prohibition of any advertising relating to the provision of oral and dental care services exceeds what is necessary to attain the objectives pursued by that legislation. This is because a radical prohibition also affects advertising messages that do not harm public health or the dignity of dentists.

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