NEWSLETTER_LIFE SCIENCES N. 30/2015

Life Sciences Department

I. NATIONAL LEGISLATION / REGULATION ("*DIÁRIO DA REPÚBLICA*")

Human tissues and cells

Law 1/2015 – Diário da República 5/2015, Series I of 2015-01-08 – Parliament - First amendment to Law 12/2009, of 26 March, establishing the legal framework of standards for the quality and safety of donation, procurement, testing, processing, preservation, storage, distribution and application of cells and tissue of human origin, transposing Commission Directive 2012/39/UE, of 26 November 2012, which amended the Commission Directive 2006/17/CE, regarding certain technical requirements for the testing of human tissues and cells.

Guarantee of quality and safety of human organs intended for transplantation

Law 2/2015 – Diário da República 5/2015, Series I of 2015-01-08 – Parliament - Amendment to Law 36/2013, of 12 June, approving the framework for the quality and safety of human organs intended for transplantation on the human body, so as to ensure the protection of public health, Directive 2012/25/UE, of 9 October, laying down information procedures for the exchange between Member States.

Transplantation

Order 2055/2015 - Diário da República 40/2015, Series II of 2015-02-26 – Ministry of Health – Cabinet of the Assistant Secretary of State of the Ministry of Health – Established the condition in which compensation may be granted, in accordance with Article 4(2) of Law 36/2013, of 12 of June, which approved the framework for the guarantee of quality and safety of human organs intended for transplantation on the human body.

HTA – New System for the Health Technology Assessment (*SiNATS*)

The Council of Ministers approved the creation of the National System for the Evaluation of Health Technologies ("*Sistema Nacional de Avaliação de Tecnologias de Saúde* – SiNATS"), integrating all private and public entities within the health sector. SiNATS has as its aim a shift of the paradigm in the manner of use and acquisition of health technologies, including medicinal products and medical devices, contributing to the achievement of health gains and its harmonization with other European systems aimed at achieving the same goal. This system will allow health technologies to be the subject of evaluation and re-evaluation within an integrated context and with preferential recourse for the establishment of objectives through contracts with authorized MA holders. As mentioned by the statement issued by the Council of Ministers, SiNATS is in line with European best practices and is an important step towards improving the functioning of the national health system.

Decree-Law 97/2015 - Diário da República 105/2015, Series I of 2015-06-01 – Ministry of Health – Proceeds with the creation of the National System for the Evaluation of Health Technologies, and the first amendment to Decree-Law 46/2012, of 24 February, which approves the structure for INFARMED — National Authority on Medicinal and Health Products, entering into force on 1 July 2015.

SINATS is comprised of the number of entities and resourced which undertake the evaluation of health technologies and respective use, of which the management is entrusted to INFARMED.

Its application is dependent to regulation through the following Ministerial Orders:

Ministerial Order 195-A/2015 - Diário da República 125/2015, 1st Supplement, Series I of 2015-06-30 – Ministry of Health – Approved the common procedure for reimbursements and prior evaluation of medicinal products.

Ministerial Order 195-B/2015 - Diário da República 125/2015, 1st Supplement, Series I of 2015-06-30 - Ministry of Health – Regulates the determination of homogeneous groups for the purpose of reimbursements as relates to the price reference system.

Ministerial Order 195-C/2015 - Diário da República 125/2015, 1st Supplement, Series I of 2015-06-30 - Ministry of Health – Establishing the rules and procedures for the formation, amendment and revision of the price of reimbursable medicinal products subject to medical prescription and medicinal products not subject to medical prescription, as well as the respective trade margins.

Ministerial Order 195-D/2015 - Diário da República 125/2015, 1st Supplement, Series I of 2015-06-30 - Ministry of Health – Establishing the pharmacotherapeutic groups and sub-groups of medicinal products which may be subject to reimbursement and the respective levels of reimbursement.

Prescription medicinal products

Ministerial Order 223/2015 - Diário da República 144/2015, Series I of 2015-07-27 – Regulates the procedure for reimbursement payments by the State as relates to the retail sales price of medicinal products supplied to beneficiaries of the National Health System (NHS). This Ministerial Order entered into force on the first day of the month following publication.

Ministerial Order 224/2015 - Diário da República 144/2015, Series I of 2015-07-27 - Established the legal framework regarding the rules for prescription and supply of medicinal and health products and defines the obligations to provide information to patients. This Ministerial Order entered into force on the first day of the month following publication.

Exceptional marketing authorisations

Deliberation 1546/2015 - Diário da República 152/2015, Series II of 2015-08-06 – Ministry of Health - INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I. P. – Approval of the new regulation regarding exceptional marketing authorizations ("AUE") and the marketing authorisation for those medicinal products for which there is a pending application for a medicinal product authorised in another Member State for which there is no authorisation or registration in Portugal ("SAR"), and the exemption from inclusion in the labeling and package leaflet of some mandatory indications, as well as the wording of the labeling and package leaflet in the Portuguese language, for certain medicinal products intended to be administered to the patient by a health professional, or in cases where there are serious availability issues of the medicinal product.

Also, for more information, also see INFARMED Deliberation 76/CD/2015, of 18 June **which approved the new regulation for exceptional marketing authorizations.**

Child and youth healthcare

Parliament Resolution 116/2015 - Diário da República 154/2015, Series I of 2015-08-10 - Strengthens primary child healthcare and in the provision of care to children and youth.

Access to infertility treatments

Parliament Resolution 117/2015 - Diário da República 154/2015, Series I of 2015-08-10 - Guarantee of access to infertility treatments.

Framework for the protection of living organ donors

Decree-Law 168/2015 - Diário da República 163/2015, Series I of 2015-08-21 - Ministry of Health - Establishes the system of protection of living organ donors as relates to possible complications within the donation and procurement process.

Law on tabacco

Law 109/2015 - Diário da República 166/2015, Series I of 2015-08-26 - Parliament – First amendment to Law 37/2007, of 14 August, transposing Directive 2014/40/EU of the European Parliament and of the Council, of 3 April 2014, on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC and Commission Delegated Directive 2014/109/EU of, 10 October 2014, amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products.

Case Law

Judgment 216/2015 - Diário da República 94/2015, Series II of 2015-05-15 – Constitutional Court - Does not rule unconstitutional the rule extracted from the combination of Articles 25(1) (2), and 179(1)(2) of the Medicines Statute (Decree-Law 176/2006, 30 August) and Article 8(3)(4) and Article 9(1) of Law 62/2011, of 12 December as regards the powers attributed to INFARMED as related to Marketing Authroization proceedings and retail sales price.

Judgment 123/2015 - Diário da República 130/2015, Series II of 2015-07-07 – Constitutional Court - Does not rule unconstitutional the resulting normative dimension of Article 2 of Law 62/2011, of 12 December, according to which the holder of industrial property rights can only resort to mandatory arbitration, precluding direct use of the judicial court system as regards injunctions.
Rules unconstitutional the resulting normative dimension of Article 3(1), in conjunction with Article 2 of Law 62/2011, of 12 December, according to which the holder of industrial property rights cannot take legal action against the Marketing

Authrotization holder or petitioner beyond the period of 30 days from the date of publication by INFARMED as referred to in Article 9(3) of the same Law.

II. INFARMED - AUTORIDADE NACIONAL DO MEDICAMENTO E PRODUTOS DE SAÚDE, I.P. (*"NATIONAL AUTHORITY ON MEDICINAL AND HEALTH PRODUCTS"*)

New Good Distribution Practices regulation

Informative Notice 113/CD/8.1.7. – The Deliberation 47/CD/2015, of 19 March, was published by INFARMED, approving the regulation regarding Good Distribution Practices for medicinal products for human use, in accordance with Article 59(10) of Decree-Law 176/2006, of 30 August. The Good Distribution Practices now approved replace those established by Ministerial Order 348/98, of 15 June. This regulation entered into force on 1 July 2015.

Amendment of the classification of medicinal products

Deliberation 80/CD/2015 of 10 July – Amendment to the classification of the supply to the public as relates to the change of medicinal products to medicinal products not subject to a medical prescription.

Exceptional marketing authorisations

Deliberation 76/CD/2015, of 18 June – Approval by INFARMED of the new regulation regarding exceptional marketing authorizations ("*AUE*") and the marketing authorisation for those medicinal products for which there is a pending application for a medicinal product authorised in another Member State for which there is no authorisation or registration in Portugal ("*SAR*").

Sudmission of translations (proceedings for Marketing Authorisations, Renewals and Amendments)

Informative Notice 143/CD/100.20.200 – In order to simplify the evaluation process of the translations of the summaries of medicinal product characteristics (SPC), package leaflet (PL) and labeling in accordance with the market authorization (MA) requests, amendments to the terms of MA's and renewal by mutual recognition and decentralized procedures, Infarmed adopted certain measures with regard to: (i) assessment of translations based on risk criteria, (ii) finalization of MA requests, amendments and renewals without approval of the national information version and (iii) MA requests, amendment to the terms of MA's and renewals awaiting decision by Infarmed .

Submission of Prior Evaluation Requests – Form for the definition of maximum acquisition prices of medicinal products for hospital use

Informative Notice 154/CD/100.20.200 - Medicinal products subject to medical prescription that are to be acquired by entities supervised by the Government body responsible for healthcare are subject to prior evaluation, in accordance with Article 25 of Decree-Law 97/2015, of 1 June.

As indicated in accessibility management application to medicine products (GAM), the request for prior evaluation of medicinal products is accompanied by, among other mandatory documents, the "Structure of price cost formation."

In order to assist the submission mentioned herein, the specific form for this purpose is available at: http://www.infarmed.pt.

The maximum purchase price of non-generic drugs for hospital use is determined according to the rules defined in Article 20 of Ministerial Order 195-C/2015, of 30 June.

As regards generic medicinal products for hospital use, the calculation of the maximum purchase price for the reference medicinal product should be made initially, in accordance with the rules for non-generic medicinal products. Subsequently, during the economic evaluation, the maximum purchase price, adjusted by Infarmed, is reduced by at least 30%, as stipulated in Article 25(9) of Decree-Law 97/2015, of 1 June.

Price Reference System – Amendment to the new homogeneous groups

Informative Notice 148/CD/100.20.200 - The list of Homogeneous Groups and unit reference prices, in force within the 3rd quarter of 2015, is to be updated with the inclusion of 11 new homogeneous groups, for which the respective reference price has been approved: (GH1049, GH1050, GH1051, GH1052, GH1053, GH1054, GH1055, GH1056, GH1057, GH1058 and GH1059). The new homogeneous groups took effect on 1 September 2015.

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