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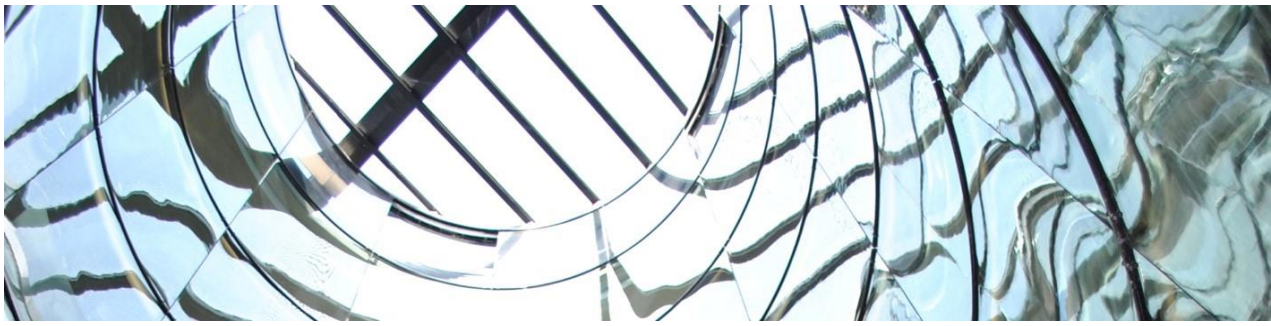

NEWSLETTER I HEALTH LAW

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HEALTH LAW NEWSLETTER I JANUARY, 2018

I NEW RULES FOR ORPHAN-DESIGNATED MEDICINES

Until now, for a medicinal product to be qualified as an orphan-designated medicine, the developer should submit the application for the designation of an orphan-designated medicine to the European Medicines Agency (EMA) at any stage of the product development. However, given the incentives that exist for the development and manufacture of these medicines, such as reductions in scientific advice rates and commercial exclusivity for a period of 10 years, the most common is that this process of designation of orphan medicinal products occurs in an initial stage of medicine development.

Since January 2018, a new stage in the marketing authorization application for orphan-designated medicines has been introduced which mainly consists in the revaluation of the orphan-designation. The European Medicines Agency (EMA) will be publishing a so-called orphan maintenance assessment report for every orphan-designated medicine which has been recommended for marketing authorization by the Agency. The Committee assesses whether a medicine fulfils the criteria for orphan designation at two points in time: early on in a medicine's development to provide access to incentives supporting the development activities, and again at the time of marketing authorization of the new treatment to reconfirm its eligibility for ten-year market exclusivity.

Please note that, to qualify for orphan designation, a medicine must target a disease that is life threatening or chronically debilitating that affects less than 5 in 10,000 patients in the EU. If there is already another treatment available for the targeted rare disease, the developer of the new medicine must show that there is a significant benefit to patients compared to the existing options, meaning the medicine provides a clinically relevant advantage or a major contribution to patients.

Lastly, these reports will be published for all positive and negative Committee opinions, as well as withdrawals. They will describe the orphan condition and its seriousness, the spread of the condition at the time of maintenance of the designation, and, if applicable, the significant benefit over already authorized medicines.

II NATIONAL LEGISLATION

National Health Service

Order 283/2018 - D.R. 4/2018, Series II of 2018-01-05

Determines the organization of the network for the provision of hospital health care in the National Health Service (SNS), in the context of human immunodeficiency virus and viral hepatitis infection, for the prison population

Ordinance 15/2018 - D.R 8/2018, Series I of 2018-01-11

Proceeding to the first amendment of Administrative Rule 35/2016, of March 1 [Establishes the State reimbursement regime in the maximum price of reagents (test strips) for determination of blood glucose, ketonemia and ketonuria and of needles, syringes, lancets and other medical devices for the purpose of self-monitoring of persons with diabetes, to beneficiaries of the National Health Service and revokes Ordinance 222/2014, of November 4]

Order 860/2018 - D.R. 15/2018, Series II of 2018-01-22

Provides that NHS services and establishments may only acquire medical devices coded by INFARMED, National Authority for Medicines and Health Products, I.P., and which appear in the respective database, and establishes provisions

Reimbursement

Ordinance 35/2018 - D.R. 9/2018, Series II of 2018-01-12

Amends the annex to Administrative Rule 158/2014 of 13 February, published in the Portuguese Official Gazette, 2nd series, no. 37, of February 21 (revises the special reimbursement regime for medicines for hepatitis C disease)

Statement of Rectification 2/2018 - D.R. 13/2018, Series I of 2018-01-18

Rectifies Administrative Rule 15/2018, dated January 11, of Health, which proceeds to the first amendment of Administrative Rule 35/2016, of March 1 [Establishes the State reimbursement regime in the maximum reagent price (test strips) for the determination of blood glucose, ketonemia and ketonuria and of needles, syringes, lancets and other medical devices for the purpose of self-monitoring of persons with diabetes, to beneficiaries of the National Health Service and revokes Administrative Rule 222/2014, of 4 of November], published in the Portuguese Official Gazette, 1st series, no. 8, of January 11, 2018

Ordinance 36/2018 - D.R. 19/2018, Series I of 2018-01-26

Determines that measures for the treatment of patients with ichthyosis benefit from an exceptional reimbursement scheme

Shared Services of the Ministry of Health

Order 688/2018 - D.R. 11/2018, Series II of 2018-01-16

Defines the price list to be practiced by the Shared Services of the Ministry of Health, E. P. E. (SPMS, E. P. E), for the provision of services to entities not integrated in the National Health Service and in the Ministry of Health

INFARMED

Statement of Rectification 57/2018 - D.R. 15/2018, Series II of 2018-01-22

Corrects Order 10857/2017, published on December 12, which creates a Working Group which is responsible for evaluating the alternative scenarios for the implementation of the relocation of INFARMED - National Authority for Medicines and Health Products, I. P.

Regional Health Administration of Lisbon and Vale do Tejo, I. P

Order 895/2018 - D.R. 16/2018, Series II of 2018-01-23

Subdelegation of competencies in the Board of Directors of the Regional Health Administration of Lisbon and Vale do Tejo, I. P., for the practice of procedures in the scope of subcontracting of services by the Managing Entities of the Cascais and Loures Hospitals

Order 1058/2018 - D.R. 20/2018, Series II of 2018-01-29

Sub-delegates to the Board of Directors of the Regional Health Administration of Lisbon and Vale do Tejo, IP, the competence to practice various acts, regarding requests to change studies and projects of hospital buildings, under the Management Contracts of the Hospital de Cascais, the Hospital of Loures and the Hospital of Vila Franca de Xira

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