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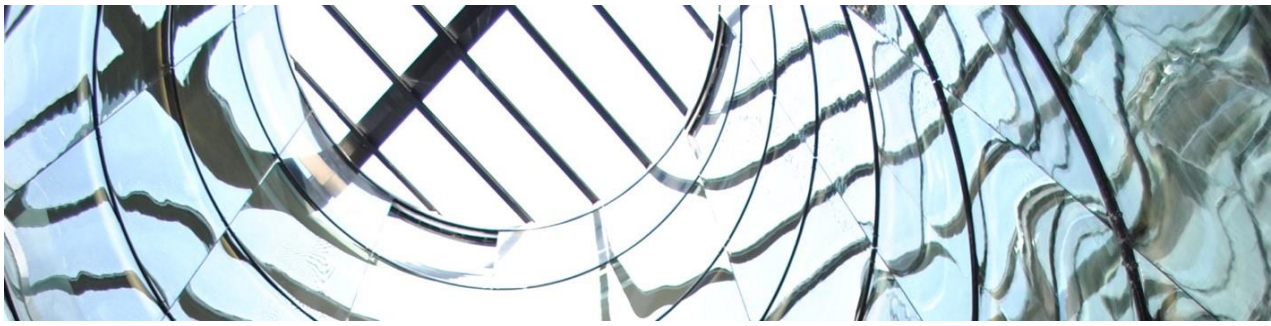

NEWSLETTER I HEALTH LAW

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I SINATS: ENTRY INTO FORCE OF NEW LAWS

Following the entry into force of Decree-Law 115/201 of 7 September, which conducted the first amendment to the National Health Technology Assessment System ("SINATS"), two relevant ordinances were published in Portuguese Official Gazette:

- Ordinance 270/2017, which proceeds to the first amendment to the Ordinance 195-A/2015
- Ordinance 271/2017, which proceeds to the first amendment to the Ordinance 195-B/2015

The great novelty established by Decree-Law 115/2017 was to determine that, since the date of granting the marketing authorization ("MA") and during the legal period established for the prior evaluation procedure, the provision of medicinal products subject to the Exceptional Use Authorization ("EUA") should be made simultaneously under an Early Access Program ("EAP") and therefore free of charge.

Term of the legal period established for the prior evaluation procedure

Ordinance 270/2017 defines the new deadlines for the decision on co-participation and evaluation as follows:

- 30 calendar days for generic and similar biological medicines;

- 75 calendar days for non-generic medicines whose international non-proprietary name or therapeutic indication has already been co-participated or authorized for use in the institutions and services supervised by the member of the Government responsible for health, upon prior evaluation;

- 180 calendar days for medicines whose international non-proprietary name or therapeutic indication is not yet co-participated or authorized for use in the institutions and services supervised by the member of the Government responsible for the health area, upon prior evaluation.

Thus, the aforementioned amendment intendeds to fix the legal deadlines for prior evaluation and co-participation with targets that are closer to the European reality and to promote compliance with legal deadlines.

New scheme of functioning of the "Reference Price System" within the scope of the reimbursement

Given the market evolution and with the intention of contributing to the sustainability of the National Health Service, it was necessary to review the criteria for determining the reference price of the Homogeneous Groups.

In this respect, whereas the previous regime only stated that the reference price for each homogeneous group should correspond to the average of the five lowest PVPs (retail selling price) on the market - taking into account the medicinal products included in that group, the new Ordinance 271/2017, adopting exactly the same criterion, adds a requirement: if the average of the five PVPs exceeds the price of the most expensive generic medicinal product that belongs to the homogeneous group, this should be the reference price for the purposes of the reimbursement decision.

II NATIONAL LEGISLATION

National System for the Evaluation of Health Technologies

Dispatch no. 7925/2017 - D.R. 175/2017, Series II of 2017-09-11

Appoints the members of the Health Technology Assessment Commission (CATS) in addition to the appointees through Decree 5847/2016, 7069/2016, 7062/2016, 1646/2017 and 1878/2017, published in the Portuguese Official Gazette.

Reimbursement of Medicinal Products

Ordinance 281/2017 - D.R. 183/2017, Series I of 2017-09-21

States that medicinal products intended for the treatment of patients with rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis and spondyloarthritis may benefit from an exceptional 100% reimbursement scheme.

Ordinance 282/2017 - D.R. 185/2017, Series I of 2017-09-25

Proceeding to the second amendment of Administrative Rule 48/2016, dated March 22, amended by Administrative Rule No. 198/2016 of July 20 (Determines that drugs intended for the treatment of patients with rheumatoid arthritis, ankylosing spondylitis, arthritis psoriatic arthritis, polyarticular juvenile idiopathic arthritis and plaque psoriasis benefit from an exceptional reimbursement regimen).

Oncology

Order 8254/2017 - D.R. 183/2017, Series II of 2017-09-21

Establishes the technical criteria for population-based oncology screenings performed at the National Health Service (NHS), in particular as regards recruitment and selection methods.

Vaccines

Dispatch 8320/2017 - D.R. 184/2017, Series II of 2017-09-22

Determines that vaccines of the National Vaccination Program and other vaccines and tuberculins for the protection of public health and groups at risk are to be centralized in the category of goods, according to strategies defined by the Directorate-General for Health.

Portuguese Health Ministry

O*rder 8355/2017 - D.R. 185/2017, Series II of 2017-09-25*

Appoints the Monitoring Committee to execute the agreements signed between the Ministry of Finance, the Ministry of Health, the National Association of Pharmacies and the Association of Pharmacies of Portugal and determines that it is the responsibility of the Commission to evaluate and monitor the application of the provisions of Administrative Rule 262/2016 of 7 October.

D*ispatch 8977/2017 - D.R. 196/2017, Series II of 2017-10-11*

It forms the National Trauma Commission and appoints its members.

Cybersecurity

Dispatch 8877/2017 - D.R. 194/2017, Series II of 2017-10-09

Establishes the governance model for the implementation of the health cyber security policy.

National Health Service

Dispatch 8379/2017 - D.R. 185/2017, Series II of 2017-09-25

Determines that the implementation of the HIV computer system should be completed by December 31, 2017 in all NHS hospitals that follow people living with HIV.

Decree-Law no. 131/2017 - D.R. 195/2017, Series I of 2017-10-10108280429

Extends the list of health care dispensed from the payment of fees to the National Health Service.

III INFARMED

Licensing Portal +

In the context of the implementation of the Simplex + program, which aims at a modernization that is transversal to several areas and an more direct relationship between individuals and businesses with the Portuguese Government, it was completed and implemented on 28 September 2017, the 2nd Phase of the Licensing Portal +, which, in addition to submitting applications for licensing pharmacies and entities in the circuit of the manufacture of medical devices, distribution of medicinal products for human use and medical devices and direct acquisition, now allows the communication of pharmacy operating hours and requests for home care and/or Internet sales, consolidating all available information regarding those entities on a single platform.

In addition, new information was also available for public consultation on pharmacies, namely regarding the Technical Directorate and the provision of home care and internet sales of medicines, being in the implementation phase, the availability to the public of the opening hours of pharmacies and webservice for information to the entities of the Ministry of Health.

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