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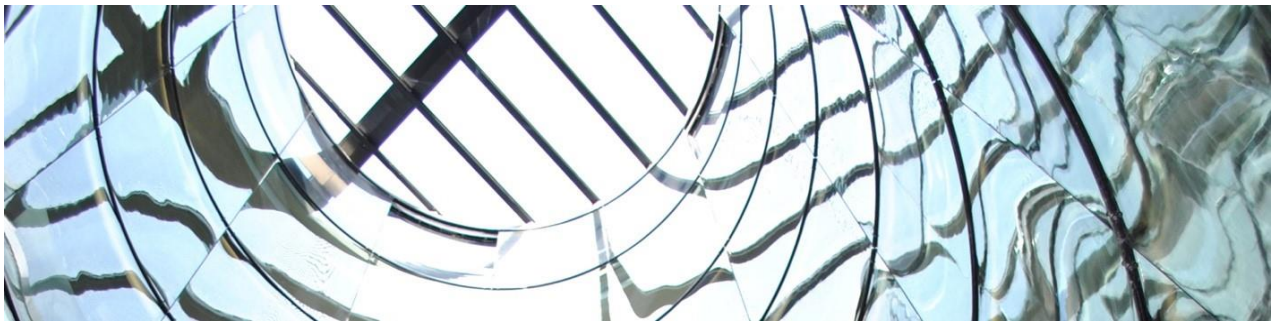

NEWSLETTER I HEALTH LAW

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I THE TRANSPOSITION OF THE MEDTECH EUROPE CODE OF ETHICAL BUSINESS PRACTICE

The new European Code of Ethical Business Practice, promoted by MedTech Europe, came into force on 1 January 2018.

The purpose of this initiative was to reinforce the commitment with the ethical principles of business practice, promoting a greater transparency and ensuring the independence between companies of the medical devices sector, healthcare professionals and healthcare organizations.

Under the new code, companies operating in the European market will no longer be able to finance directly the participation of healthcare professionals to third party organized educational events.

Accordingly, the companies that decide to sponsor third party organized educational events, will do so indirectly, through a health organization, which in turn will select who healthcare professionals will participate and benefit from this sponsorship.

Moreover, companies that are members of MedTech Europe, such as the Portuguese Association of Medical Devices Companies (APORMED) and the Portuguese Association of Pharmaceutical Industry (APIFARMA), were forced to review their respective codes, in order to transpose the new European Code of Ethical Business Practice into the Portuguese order.

APORMED approved a new Code of Ethical Business Practice for the medical devices sector, which will enter into force on the first day of July, 2018 - date from which all Portuguese and / or non-members companies of MedTech Europe will be obliged to comply with the rules foreseen in this Code.

The main innovations introduced by this Code are as following:

- Prohibition of direct sponsorship to health professionals at events organized by third parties

- New general criteria for the organization of events, applicable to events organized by the associated companies or by third parties

- New transparency obligations, envisaged in Decree-Law 5/2017, which regulates the transparency and publicity for medical devices in Portugal

Following the entry into force of new MedTech Europe Code of Ethical Business Practice, of which APIFARMA is a member and under the obligation to transpose the new Code, APIFARMA approved, on 18 December 2017, the revision of its Code of Ethics.

The main amendment to APIFARMA Code of Ethics is to enshrine the prohibition of member companies marketing in vitro diagnostic medical devices to directly support the participation of Healthcare Professionals in third party organized educational events.

II NATIONAL LEGISLATION

National Vaccination Program

Resolution of the Council of Ministers 184/2017 - D.R. 232/2017, Series I of 2017-12-04

Authorizes the acquisition of vaccines under the National Vaccination Program for 2018.

Health Service of the Autonomous Region of Madeira

Resolution of the Legislative Assembly of the Autonomous Region of Madeira 26/2017 / M - D.R. 238/2017, Series I of 2017-12-13

Appoints a parliamentary commission of inquiry to the services provided by SESARAM - Health Service of the Autonomous Region of Madeira, E. P. E.

Needle Exchange Program

Ordinance 466/2017 - D.R. 238/2017, Series II of 2017-12-13

Authorizes the Directorate-General for Health to assume a multiannual charge up to the amount of EUR 2,080,000.00 plus VAT at the legal rate in force, regarding the operationalization of the management of the Needle Exchange Program «Say no to a second-hand needle »

Hospital of East Lisbon

Resolution of the Council of Ministers 191-A / 2017 - D.R. 239/2017, 2nd Supplement, Series I of 2017-12-14

Determines the net present global value, by reference to December 2019, of the tender procedure for the Hospital of East Lisbon

Health Units

Resolution of the Assembly of the Republic 270/2017 - D.R. 243/2017, Series I of 2017-12-20

Recommends that the Government reject the concentration of health units in the region between Entre Douro and Vouga and valorize the Hospital Dr. Francisco Zagalo in Ovar

Price Revision

Statement of Rectification 45/2017 - D.R. 245/2017, Series I of 2017-12-22

Rectifies the Order 359/2017, of November 20, which defines the reference countries to be considered in 2018 for the authorization of prices of new medicines and for the purpose of annual review of the prices of medicines for the hospital and outpatient market, and maintains, for the same year, the exceptional criterion to be applied in the price revision regime, published in Portuguese Official Gazette, Series I, no. 223 of November 20, 2017

National Health Service

Order 11347/2017 - D.R. 247/2017, Series II of 2017-12-27

Establishes provisions on the organization and functioning model of Clinical Psychology and Health in the National Health Service (SNS).

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