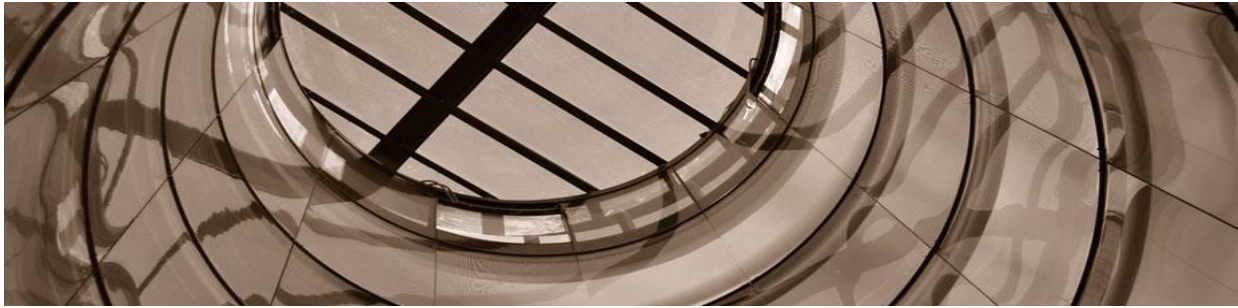


# CUATRECASAS, GONÇALVES PEREIRA



## NEWSLETTER | HEALTH LAW

HEALTH LAW NEWSLETTER | October - December, 2015

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## HEALTH LAW NEWSLETTER

### I LEGAL REGIME ON HEALTH ADVERTISING PRACTICES (DECREE-LAW 238/2015, 14TH OCTOBER)

With the new legal regime on health advertising practices approved by Decree-Law No. 238/2015 of 14<sup>th</sup> of October ("DL 238/2015"), which entered into force on the 1<sup>st</sup> of November of 2015, publicity on this domain is now subject to specific regulation. Until this moment, except for some special regimes like the one for medicines, advertising practices on the health sector were regulated under the Publicity Code's general regime.

In order to tackle the issues related to health advertising practices, DL 238/2015 has a broad scope of application. Firstly, it excludes all matters regulated under special legislation, namely medicines, health products and State's institutional publicity.

The new diploma is engaged in the health advertising practices, which are defined on article 2, paragraph b). Therefore, the scope of this new legislation is mostly defined depending on the advertising message's content, regardless (i) of the quality of the person who conveys it (i.e. being, or not, a health care provider), (ii) of the formal classification of the publicity object as product or health service, and (iii) of the way in which the message is conveyed, covering any commercial communication, including the one who is widespread under the appearance of editorial information.

Therefore, any commercial communication, including market placement not only of goods and healthcare products, as of those which, although not classified as such, are presented as having curative, preventive or diagnostic effects of human diseases, and also to the dissemination of principles, ideas and initiatives for the protection of health, became regulated by specific legislation.

Unconventional therapeutics, complementary means of diagnose, any treatments or therapies, including those with cells, are also included in the new legislation.

The main principle is that each and any advertising practice in health issues shall be oriented by patients' interests, should the parties abstain of any conducts that involve the divulgation of publicity messages that are not true, misleading or create false consumption necessities. The principles that should guide health-advertising practices are also principles of transparency, reliability and lawfulness of health advertising. Irrespectively of having to be objective, health advertising practices also have to comply the principle of scientific rigor, i.e., the claims that address to scientific and technical accepted by the scientific and technical community.

The legal statute prohibits all advertising claims and practices that include false or untrue information, or information that is misleading confusing or unclear, or that, encourages the acquisition of health services or products without considering necessity requirements, real proprieties of the acts and services at stake or without considering the need for a

previous evaluation or diagnose. Advertising practices that induce health needs on an artificial manner are also forbidden.

DL 238/2015 also prohibits practices that describe the product as being “free”, “free of charge”, or “with discount” or “promotion”, if and when the patient has to pay more than the inevitable cost to acquire the product or service at stake.

The infringement of the previously described constitutes an administrative offense punishable with a fine that can go up to forty five thousand euros. Apprehension of the advertising materials, objects or property used, temporary prohibition from exercising professional or advertising activity and deprivation of right and benefit granted by regulatory authorities or public services are also applicable as accessory penalties.

The competent authority designated to supervise these practices and to conduct proceedings is now the Portuguese Health Regulator.

## II LEGISLATION

### **PUBLICITY**

#### **DECREE-LAW No. 238/2015 - DIÁRIO DA REPÚBLICA No. 201/2015, SERIES I OF 2015-10-14**

Establishes the legal regime on health advertising practices

### **HEALTH PROFESSIONALS**

#### **DECREE-LAW No. 223/2015 - DIÁRIO DA REPÚBLICA No. 197/2015, SERIES I OF 2015-10-08**

Creates an incentive to be granted, upon the enhancement of the list of users, to medical specialists in general and familiar medicine which work in family health units of model A and in personalized healthcare units, both in geographical areas qualified as poor.

#### **ORDER No. 390/2015 - DIÁRIO DA REPÚBLICA No. 214/2015, SERIES I OF 2015-11-02**

Defines the information to quit smoking, namely cellphone numbers and websites aimed to inform consumers about the available incentive programs to quit smoking that shall be included in the combined health warnings and general health warning

### **HEALTH MINISTRY**

#### **ORDER No. 406/2015 - DIÁRIO DA REPÚBLICA No. 229/2015, SERIES I OF 2015-11-23**

First amendment to Ordinance No. 55/2013, of 7<sup>th</sup> of February, that defines the categories of goods and services specific to the health area whose public supply contracts and procurement procedures are signed and conducted by the Shared Services of the Ministry of Health

### **NATIONAL HEALTHCARE SYSTEM**

#### **DECREE-LAW No. 239/2015 - DIÁRIO DA REPÚBLICA No. 201/2015, SERIES I OF 2015-10-14**

Sixth amendment to the Decree-law no. 28/2008, of 22<sup>nd</sup> of February, that establishes the regime of creation, structuration and operation of the groups of health centers of the National Healthcare System

**ORDER No. 417/2015 – DIÁRIO DA REPÚBLICA No. 238/2015, SERIES I OF 2015-12-04**

First amendment to Ordinance no. 223/2015, of 27<sup>th</sup> of July, that regulates the payment procedure for medicines reimbursement in the selling price to the public and dismissed to the beneficiaries of the National Healthcare System and to Ordinance no. 224/2015, of 27<sup>th</sup> of July, that establishes the legal regime currently met by the prescription and dismissal of medicines and health products and defines the information requirements to be provided to patients

**SINATS**

**ORDER No. 12682-A/2015, 10TH OF NOVEMBER**

Establishes France, Spain and Slovakia as reference countries to consider in 2016 for the authorization procedure on prices of new medicines, as well as for purposes of annual revision of medicines prices on both hospital and clinic markets

**USER FEES**

**ORDER No. 324-A/2015 - DIÁRIO DA REPÚBLICA No. 192/2015, 2nd SUPPLEMENT, SERIES I OF 2015-10-01**

Sets the values for user fees regarding the voluntary interruption of pregnancy

**ORDER No. 408/2015 – DIÁRIO DA REPÚBLICA No. 231/2015, SERIES I OF 2015-11-25**

First amendment to Ordinance no. 306-A/2011, of 20<sup>th</sup> of December, that approves the values of the user fees foreseen on article 2 of Decree-law no. 113/2011, of 29<sup>th</sup> of November, as well as the respective rules of calculation and collection

**NATIONAL HOSPICE CARE NETWORK**

**ORDER No. 340/2015 - DIÁRIO DA REPÚBLICA No. 197/2015, SERIES I OF 2015-10-08**

Regulates, within the National Hospice Care Network, the characterization of the services and the admission of local teams and the conditions and requirements of construction and safety of the facilities

**OTHERS**

**ORDER No. 343/2015 - DIÁRIO DA REPÚBLICA No. 199/2015, SERIES I OF 2015-10-12**

Defines the conditions of installation and operation that regulate level 1 inpatient units of pediatric integrated care (UCIP level 1) and pediatric clinic, as well as the working conditions to be met by the high management teams and integrated continuous care teams designed to pediatric care of the National Network of Integrated Continuous Care (RNCCI)

**ORDER No. 353/2015 - DIÁRIO DA REPÚBLICA No. 200/2015, SERIES I OF 2015-10-13**

Creates a consortium between Hospital and Academic Center of Coimbra, E. P. and the University of Coimbra

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