

LEGAL ALERT

GENERAL PRINCIPLES OF PUBLICITY OF MEDICINES AND MEDICAL DEVICES

REINFORCEMENT OF THE TRANSPARENCY RULES

Decree Law no. 5/2017 of 6th January that enters into force next 6th of February, **approves the general principles underlying the publicity activity of medicines and medical devices and reinforces the transparency principle in publicity matters.**

Article 9 of this diploma, prohibits the solicitation and the direct or indirect receipt by National Health Service (“NHS”) establishments and services and by Ministry of Health services and bodies of pecuniary or in kind benefits from supplying companies in the areas of medicines and medical devices and of other health technologies, equipment and services in the area of the information technologies, or other related, that affect or may affect the exemption and impartiality, except if the receipt of benefits does not demonstrably affects such exemption and impartiality and is authorized by the member of the Government responsible for the health area.

Actions of scientific nature or others to be executed, in accordance with the applicable law, in NHS establishments and services and Ministry of Health services and bodies cannot have a promotional nature nor be sponsored by manufacturers, producers, distributors or retailers of medicines and medical devices, as foreseen by the quoted article 9.

This diploma also amends article **159.º of the Portuguese Medicine Act** (approved by Decree Law no. 176/2006 of 30th of August). One of the amendments to be highlighted is that the granting of benefits to NHS institutions, services, employees and healthcare professionals and to the Ministry of Health services and bodies is now expressly covered by the report obligation to INFARMED I.P.

Regarding medical devices the new version of **article 52 of Decree Law no. 145/2009 of 17th June**, as amended by this Decree Law, expressly foresees the report obligation to INFARMED, I.P., of the granting of sponsorships and benefits in similar terms as the required for medicines by the above mentioned article 159.

It is also to be noted that by the amendments inserted in both articles 159 and 52, the recipients of the benefits/sponsorships are no longer required to report to INFARMED, I.P., the receipt of such benefits, but instead to validate or non-validate its receipt after being notified by e-mail by INFARMED, I.P.

Finally, the diploma amends **no. 2 of article 162 of the Portuguese Medicine Act** by setting in 4 the maximum annual number of samples to be provided to healthcare

professionals. In what concerns medical devices, a new no. 4 was added to **article 56 of Decree Law no. 145/2009**, which determines that the manufacturer or the company responsible for the information and promotion of the medical device are required to provide to INFARMED, I.P., when requested, in a 10 days term one specimen of the respective publicity piece..

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