Update

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ADVERTISING OF MEDICINES AND MEDICAL DEVICES: NEW LEGAL ACT PUBLISHED

On the 6th of January a Decree-law was published altering significantly the rules on advertising of medicinal products for human use ("medicines") and medical devices. *Decreto-Lei* n. 5/2017 will enter into force on the 5th of February and establishes the general principles on advertising to medicines and medical devices and the rules regarding scientific events occurring in institutions of the Portuguese National Health System ("SNS").

Besides the principle of transparency, already mentioned in the Medicines Statute (*Decreto-Lei* n. 176/2006), and in the Medical Devices Statute (*Decreto-Lei* n. 145/2009), the new legal act introduces a set of principles intended to govern the legal scheme applicable to advertising of these health products: integrity (article 3), respect (article 4), responsibility (article 5), moderation (article 6), and collaboration (article 7). The concrete impact of these new principles in the conformation and application of the specific provisions of the statutory scheme altered is yet to be known.

Other changes of more immediate relevance to companies merit a more detailed reference.

First: the prohibition on institutions and offices of the SNS and bodies of the Ministry of Health to promote the solicitation or to directly or indirectly receive benefits, whether pecuniary or in kind, from suppliers of goods and services, in the sectors of medicines, medical devices and other health technologies, equipments and services in the area of information technologies or related. This prohibition, however, only applies if such conduct is found to affect or be susceptible to affect the exemption and impartiality of the said institution (article 9 (1)). Whether the exception is always dependent on authorization by the Minister of Health or not remains unclear (article 9(2). We do not believe this to be the case.

Second: the obligation to communicate any benefit related to the sponsorship of scientific or dissemination events (n. 12) imposed not only on natural and legal persons, agencies and offices of the SNS, but also on private associations or companies or even scientific or clinical studies medical societies! The notification must now be made only by the "donor" (article 10(5) and article 11, for medical

devices). The present reality of dual register of benefits is thus eliminated, and replaced by a mechanism of electronic communication from and to INFARMED, I.P. ((7) and (8)). No such obligation exists when the "benefit" is in reality the remuneration paid in the ambit of an employment or economic dependency relationship.

In any case, the different structure of article 9 on the one hand and article 10 and 11 on the other should be mentioned. The former are inexcusably prohibited, the latter are tolerated and may be legitimate but are subject to prior notification duties (*inter alia*).

The new law introduces further changes in this realm. While the current wording of the Medicines Statute mentions «*sponsorship, by any entity subject to the present Decrew-Law, of congresses, symposia or any scientific actions or events or of direct or indirect promotion of medicines*» (159(1) unaltered, free translation) regarding «any subsidy, sponsorship, subvention or any other value or cash-evaluable asset or right», *Decreto-Lei* n. 5/2017 introduces *ex novum* and for the purposes of this same article 159 a concept of "benefit" (article 159 (12): «*advantage, value, cash-evaluable asset or right, regardless of the form of attribution, whether as a prize, sponsorship, subsidy, subvention or other*»), which is naturally different – either in its conception, either eventually, in the scheme applicable – from the one resulting from article 9 of *Decreto-Lei* n. 5/2017.

Their scope is material and objectively different. In article 9 (general provision and extensible to other health products or even related information technologies) reference is only made to «*pecuniary or in kind benefits*» that may affect the independence and impartiality of the beneficiary. One might say that services («activities provided for remuneration»: article 57 of the Treaty on the Functioning of the European Union) and other types of advantages resulting from a contractual relationship established in accordance with general principles, including public procurement principles.

It should be further noted that *Decreto-Lei* n. 5/2017 enlarges unequivocally the communication obligations regarding sponsorships, in the case of medical devices. Transparency obligations contained in article 52(1) and that have only existed for medical devices mentioned in article 45(2) of *Decreto-Lei* n. 145/2009, of June 17, are now applicable to all medical devices.

Third: the prohibition of scientific actions or others of promotional nature or the sponsorship by companies of the pharmaceutical and medical device industry in institutions /offices of the SNS. With the sole exception of activities and access to said establishments by medical sales representatives.

Fourth: the limit of samples allowed each year to be given to health professionals is reduced from 12 to 4.

This new legal act requires and will certainly imply an increased attention by the companies but also by their regulatory officers and lawyers or consultants, whether external or in-house. Yet, certainly, its

enforcement shall give rise to difficulties, encumbrances and costs, as well as an assessment of liabilities and of the compatibility of the act with the law of the European Union and the fundamental rights enshrined in the Portuguese Constitution.

Miguel Gorjão-Henriques
mgh@servulo.com

Inês Avelar Santos
ias@servulo.com

Rua Garrett, n.º 64 1200-204 Lisboa - Portugal Tel: (+351) 21 093 30 00 Fax: (+351) 21 093 30 01/02
geral@servulo.com www.servulo.com