Update

Momentum

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GOOD DISTRIBUTION PRACTICE OF MEDICAL DEVICES

(NEW ORDINANCE PUBLISHED)

An Ordinance governing the good wholesale distribution practice of medical devices — *Portaria* nr. 256/2016 — has recently been published and will enter into force on October 28th, 2016.

The approval of such a diploma was already foreseen in Article 37 of *Decreto-Lei* nr. 145/2009 (the "Medical Devices Act") that established a one year period for said purpose. Seven years elapsed, though. The approval of this *Portaria* comes thus with a significant delay, despite the fact that the mentioned statute also stated that the rules on the distribution of medicinal products for human use should apply in the meantime.

Therefore, *Portaria* nr. 348/98 of June 15th has been applied *mutatis mutandis* to the distribution of medical devices since the end of the nineties and until 2015; with the exception of the provision requiring the management representative to be a pharmacist (art. 37(4) of the Medical Devices Act). Such requirement would in fact be contrary to EU law and, arguably, the Constitution of the Portuguese Republic. Also, the 1998 administrative regulation made reference to the principles and rules provided under the first guidelines on good distribution practice of medicinal products issued by the European Commission (OJ C 63 of 1.3.1994, p. 4), already superseded.

Most recently, following the publication in the EU Official Journal of the revised guidelines on good distribution practice of medicinal products for human use (2013/C 343/01), adopted by the European Commission on November 5th 2013, INFARMED, I.P. approved the *Regulation on the good distribution practice (of medicinal products)* — Resolution nr. 047/CD/2015. Furthermore, *Portaria* nr. 181/2015 of June 19th revoked the *Portaria* in force since 1998.

Oddly enough, the preamble of the Portaria published mentions that *«the rules and principles of wholesale distribution of medical devices are laid down in EU guidelines nr. 94/C63/03 regarding the good distribution practice, published in the Official Journal of the EU n. C63, of March 1st 1994»*. On the one hand, these guidelines govern the good practice of medicinal products and, on the other hand, they have been subject to several amendments in order to take into account advances in practices for appropriate storage and distribution of medicinal products in the European Union, as well as new requirements introduced in the Community code relating to medicinal products for human use.

Similarly to the rules applicable to medicinal products, the diploma which has now been published governs several requirements relating, namely, to personnel, premises and equipment, all types of procedures, documentation, records as well as transportation.

Even though the distribution of medical devices is usually carried out by operators who also distribute medicinal products, this ordinance lays down specific rules for the distribution of these products that may require different distribution procedures from those adopted for the distribution of medicinal products. In particular, the fact that medical devices may be yielded without transfer of ownership (number 5.3), namely by means of loan, consignment or even provision of services; this option requires the compliance with specific procedures and records (namely, for traceability and safety reasons), which do not apply to the distribution of medicinal products.

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