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PHARMACEUTICAL LAW

RULES AND GOOD PRACTICES FOR THE DISTRIBUTION OF MEDICAL DEVICES

The aim of this newly published legislation is to establish the regulations for distribution of these devices, and this activity is of the greatest importance throughout the integrated circuit of supply of medical devices. In this respect, it is important to note that these regulations apply at every stage of the medical devices distribution circuit.

Ministerial Order no 256/2016 was published in *Diário da República*, the official Portuguese Gazette, on 28 September 2016. It establishes the principles and rules of good practices to be observed in the distribution of medical devices by companies that engage in the wholesale distribution of these devices and are licensed for this purpose under Decree-Law no. 145/2009 of 17 June, as amended by Law no. 21/2014 of 16 April, and by Law no. 51/2014 of 25 August.

The rules on the manufacture, distribution and sale of medical devices were already addressed in Decree-Law no. 145/2009 of 17 June, amended by Law no. 21/2014 of 16 April and by Law no. 51/2014 of 25 August. However, article 37(3) of that Decree-Law provided that the rules on good practices for wholesale distribution of these devices would be established by ministerial order.

In this context, a ministerial order has now been published that establishes a system of good practices for distribution of medical devices. In fact, the nature and function of these devices makes exhaustive regulations necessary, to guarantee not only their quality, but also that they are traceable when introduced into the supply chain.

Under the legislation referred to above, a "medical device" is defined as *"any instrument, appliance, equipment, software, material or article used in isolation or in combination, including the software intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes, which is necessary for the correct functioning of the medical device, whose principal intended effect on the human body is not achieved by pharmacological, immunological or metabolic means"*.

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The rules and principles applicable to the wholesale distribution of medical devices are already established in EU Directive no. 94/C63/03 on good distribution practices. However, with the publication of this ministerial order, the rules to which wholesale distribution of these devices are now subject are now enshrined in national legislation, which makes the rules in question easier to apply.

The aim of this newly published legislation is to establish the regulations for distribution of these devices, and this activity is of the greatest importance throughout the integrated circuit of supply of medical devices. In this respect, it is important to note that these regulations apply at every stage of the medical devices distribution circuit. This ensures there can be no deterioration during the distribution and sale process. It also guarantees that all transactions are registered and, therefore, that all medical devices placed on the market are traceable.

The rules and procedures on quality control, monitoring, traceability, dispatch, storage, security and recall from the market are set out in specific terms, and this demonstrates the scope of operations involved in this area.

The rules on good distribution practices now published fundamentally address the requirements that apply to distributors, their staff, their premises and equipment, the organisational procedures to be adopted, the documentation and registration relating to their operation that must be kept permanently available at their premises, complaints in respect of counterfeit devices, receipt and dispatch of devices, storage, transport, returns, and procedures for recalling devices from the market and for rejected products.

The ministerial order applies to the activity of wholesale distribution of medical devices in Portugal, including cases in which the distribution activity is carried on from another Member State by companies that have premises in Portugal.

In order to comply with the newly published provisions, licensed wholesale distributors must adopt the guiding principles and rules, and each distributor's technical manager will be responsible for implementing and monitoring their application. On this point, it is important to note that these rules apply to all of the distributor's staff.

Finally, as is the case with the award of licences to distribute and sell these types of devices, the authority responsible for supervision of the implementation and compliance with the good practices now published is INFARMED – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (INFARMED is the Portuguese authority for medicines and healthcare products).

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