A Regulatory and Safety Perspective on Medical Devices

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Carla Pires
https://orcid.org/0000-0003-4526-0271
CBIOS, Universidade Lusófona, Portugal

Dinah Duarte
CBIOS, Universidade Lusófona, Portugal

INTRODUCTION

In Europe, medical devices market account for sales of EUR 100 billion, with the medical devices industry employing 575,000 people in the European Union (EU). This industry is one of the most representative employers in this economic area (European Commission, 2018). In 2015, the United States medical device market was evaluated at more than $140 billion, which represented nearly 45% of the global market (International Trade Administration, 2016). By 2021, the market of medical devices is expected to globally attain $342.9 billion, mainly due to the ageing of population (Lucintel, 2016). The main commercial trends in medical devices are, as follows: surgical and infection control, general medical devices, cardiovascular, and home healthcare. It is expected that in the future medical devices will tend to be smaller, portable, and including software (Lucintel, 2016).

The design and marketing of medical devices is strictly legislated. In accordance with World Health Organization (WHO) and Global Harmonization Task Force a medical device is defined as:

"an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means" (WHO, 2018; Global Harmonization Task Force, 2012).

Additionally, the Food and Drug Administration (FDA) through the 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act defines a device as:

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes" (FDA, 2018a, 2018b).

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Particularly, medical devices are regulated in accordance to Council Directive 93/42/EEC in the EU. According this Directive, all *medical devices must be designed and manufactured in such a way, that, when used under the conditions and for the purposed intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety*. In addition, each member state of the EU has a National Competent Authority (NCA), which oversees specific designated Notified Bodies (NBs), i.e. the private entities, which are responsible for the certification of medical devices and for compliance of medical devices to EU Directives (Kramer et al., 2013; World Bank income group, 2016). NBs are responsible for evaluating the risk analysis and risk management strategy of the manufacturer (article 26 of Decree- Law No. 145/2016). In Portugal, the NCA - INFARMED, I.P. - is responsible for designating and supervising the national NBs (article 22º and 25º of Decree- Law No. 145/2016,) or for supervising the marketed medical devices (article 60º of Decree- Law No. 145/2016).

All incidents regarding medical devices (e.g. malfunction, deterioration, or performance issues) are recorded and centrally evaluated by the competent authorities of each member state (article 10 of Council Directive 93/42/EEC); if the alerts on MDs are considered relevant (e.g. potential adverse events related to medical devices), they are circulated between member states in the form of a National Competent Authority Report (NCAR) (EU statistics, 2017). Among others competences, NCAs are responsible for communicating adverse events with medical devices to the European Databank on Medical Devices (EUDAMED) (Kramer et al., 2013). EUDAMED aims at the collection of information, the exchanging of information, and conduction of marketing surveillance on medical devices in all member states (European Commission, 2001). Similarly, FDA is the authority responsible for regulating manufacturing and marketing of medical devices, since 1976. A premarket approval is usually required for higher-risk devices. The applications of these devices usually comprise clinical data and must include data to prove safety and efficacy (FDA, 2018a; Jarow & Baxley JH, 2015; Peña, et al, 2007).

Despite these strict regulations, every year safety issues involving medical devices arise. For instance, in a cohort study (2005-2010) specifically enrolling cardiovascular, orthopedic, and neurologic devices first approved in the EU, safety issues and reporting of trial outcomes were quantified in comparison with the outcomes of the approved medical devices in the United States (US). This study concluded that devices first approved in the EU were associated with an increased risk of post-marketing safety alerts: 27% (62/232) vs. 14% (11/77), respectively, for safety alerts and recalls for devices approved first in EU vs. US (unadjusted rate); 2.9 (95% confidence interval 1.4 to 6.2) for the adjusted hazard ratio (Hwang et al., 2016). Contrary to this conclusion, another study identified a small difference between absolute occurrences of serious medical device recalls between the US and EU. Considering that EU approves a higher number of medical devices than US, the proportional number of serious occurrences with these products may be even lower in the EU (Davis et al., 2011). An in-depth analysis of clinical safety and effectiveness used in health technology assessments of high-risk medical devices was conducted in Europe through the evaluation of reports published between 2010 and 2015. It concluded that the quality of scientific evidence (e.g. scientific data) is low, thus recommending the application of higher quality standards such as the obligatory implementation of methodologically robust trials (associated with other evidence sources) (Olberg, B., Fuchs, S., Panteli, D., Perleth, M., Busse, R., 2017).