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Safe innovation: On medical device legislation in Europe and Africa

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KEYWORDS

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Abstract

Objectives: The principal motivation for regulating medical devices is to protect patients and users. Complying with regulations may result in an increase in development, manufacturing and service costs for medical companies and ultimately for healthcare providers and patients, limiting the access to adequate medical equipment. On the other hand, poor regulatory control has resulted in the use of substandard devices. This study aims at comparing the certification route that manufacturers have to respect for marketing a medical device in some African Countries and in European Union.

Methods: We examined and compared the current and future regulations on medical devices in the European Union and in some countries in Africa. Contextually we proposed future approaches to open design strategies supported by emerging technologies as a means to enhance economically sustainable healthcare system driven by innovation.

Results: African medical device regulations have an affinity to European directives, despite the fact that the latter are particularly strict. Several states have also implemented or harmonized directives to medical device regulation, or have expressed interest in establishing them in their legislation. Open Source Medical Devices hold a great promise to reduce costs but do need a high level of supervision, to control their quality and to guarantee their respect for safety standards.

Conclusion: Harmonization across the two continents could be leveraged to optimize the costs

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of device manufacture and sale. Regulated open design strategies can enhance economically sustainable innovation.

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Introduction

A medical device can be described as any means of improving or monitoring patient health that acts on the body in a non-metabolic fashion. This wide definition includes electromedical equipment, implantable mechanical devices, diagnostic devices, and even everyday life objects such as band-aids and glasses [1].

Across the world, countries regulate the placement of such devices on the market through legislation that sets the responsibilities of the manufacturers by referring to technical requirements. Technical requirements are usually made available to the manufacturers as documented technical standards or norms. Those documents provide specifications, guidelines or characteristics, including testing methods and acceptance criteria, for the design and manufacturing of medical devices.

Medical device regulations vary greatly across the world, ranging from comprehensive to poor. Moreover, over the past two decades, the number, range, and complexity of medical devices has increased resulting in the proliferation of regulatory documents and procedures to encompass these changes. Coupled with this, the differences in regulations between countries oblige manufacturers to prepare a different dossier for each country, which constitutes a lengthy and costly process, leading to a disincentive to medical device companies to sell in some countries. They are also a deterrent to innovation and the development of new products. It has been estimated that developing a medical device from the idea to the market has a cost of around \$31 million for a low-to moderate-risk device, and around \$94 million for high-risk products [2].

The worldwide market for medical devices is increasing, but access to them varies according to the socio-economic and political status of each country [3]: around one million patients die every year due to the lack of adequate medical equipment [4,5]. Redressing this imbalance is a complex problem, which many African nations are trying to solve [6]. Promoting international standards and streamlining the regulatory process could reduce the legislative burden, lower costs and remove unnecessary delays to new products reaching patients in Africa.

In 1992, the European Union (EU), the United States of America (USA), Canada and Japan conceived the idea of an international partnership between medical device authorities and regulated industry. In 1993, the Global Harmonization Task Force (GHTF) was born with the goal of standardizing medical device regulations worldwide. The GHTF was disbanded in 2011 and the International Medical Device Regulators Forum (IMDRF) was conceived "as a forum to discuss future directions in medical device regulatory harmonization". The IMDRF, which includes medical device regulatory authorities of Australia, Brazil, Canada, China,

EU, Japan, Russia, Singapore, South Korea, and USA, with the World Health Organization (WHO) as official observer, is currently developing internationally agreed upon documents related to a wide variety of topics affecting medical devices [7].

The path to harmonization is still far from completion; nevertheless, several African countries have oriented their regulatory processes for medical devices on the EU system. In this paper, after outlining the EU regulatory framework, we will analyse the regulatory landscape in a number of African countries in which at least a representative of the African Biomedical Engineering Consortium (ABEC, <http://abec-africa.org>) is present. The consortium was founded in 2012 with the mission of pursuing capacity building in Biomedical Engineering for sustaining local healthcare systems. To date ABEC is composed of 16 member institutions from 8 countries. Among these countries, we selected five from different geographical regions, for better describing differences and similarities with EU legislation.

Finally, we will suggest possible solutions for reducing the costs of developing safe, effective and quality medical devices for guaranteeing affordable and equitable healthcare for African citizens.

European regulation for medical devices

In order to place a medical device on the EU market, specific European Directives have to be met. The regulatory processes of medical devices are based on the Medical Device Directive (MDD), which consists of three core directives for safety regulations and marketing of medical devices: the Active Implantable Medical Device Directive (AIMDD 90/385/EEC), the Medical Device Directive (MDD 93/42/EEC) and the In Vitro Diagnostic Medical Device Directive (IVDMDD 98/79/EC) [8].

The new European Regulation was recently published [9]: this new Regulation (EU 2017/745) will substitute the current Directives after a 3 to 5 year transition period.

As proof of compliance to the strict safety requirements of the Directives, manufacturers have to apply a CE mark on their medical devices. The CE mark can be seen as a declaration of the manufacturer that the product is compliant to the relevant legislations including those related to safety. The CE marking consists of several processes that start from the manufacturer's choice of the conformity assessment route, which itself depends on the classification of the medical device [10]. It also addresses the evaluation of intrinsic risk and expected benefit. According to the intended use, length of time used, interaction with the human body and other technical characteristics, the device is considered more or less risky for the patient and therefore classified. By applying the classification rules of Annex IX of the MDD 93/42/EEC all medical devices are individually

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