Medical Devices and Regulatory Framework

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Introduction

The world of medical devices is a very large and diverse universe covering extremely heterogeneous products ranging from bandages, wheelchairs, surgical instruments, syringes and insulin pump to high-tech products such as implantable medical devices (defibrillators, pacemakers, etc...). They can be custom made (orthopedic shoes, abdominal support belts).
This is an area of strong innovation benefiting to patients and public health. Medical devices are diagnostic, prevention and improving healthcare practices tools.

This fast innovation is particularly due to the development of industrial technologies (microelectronics and information technologies) and rapid progress in drugs' industry (medical device associated with a drug can be classified as medical device).
Deployment of medical technologies, especially implantable devices, both in terms of their development (innovation) and their use are largely "operators' dependent" (practitioners, surgeons). The performance of DM may depend on the medical team related practices and individual learning and the technical platform (knowledge and experience), writes the National Authority for Health (HAS) in its practical guide, "Parcours du dispositif médical", released in 2009.
In 2009, the global medical device market is worth the third of the drugs' one (189 billion €). By combining hip prostheses, stents, pacemakers, defibrillators, it is estimated that 20% of the population in developed countries would be carrying an implanted medical device[1].
The pace of ongoing innovation must go hand in hand with a better understanding of these health products, constraints on innovation, evaluation and reimbursement.
But many countries do not have access to high quality medical devices adapted to their epidemiological needs. This is particularly true in developing countries where the majority of the products are imported, technology assessment is rare and where regulation is almost absent giving way to unscrupulous market influences and endangering patients' lives by importing products that do not always comply with safety standards.

The medical device is described[2] as "any instrument, apparatus, equipment, material, product, except for the products of human origin, or other article used alone or in combination, including accessories or software for its functioning, intended by the manufacturer to be used in humans for medical purposes and whose principal intended action is not obtained by pharmacological, immunological or metabolic means, but whose function may be assisted by such means.

Medical devices that are designed to be implanted in whole or in part in the human body or placed into a natural orifice, and that depend for their operation on a source of electrical energy or any source of power other than that that is directly generated by the human body or gravity, are called active implantable medical devices".
In other words, any object used "for medical purposes" which is neither a drug nor biological product is a medical device.

Medical devices are organized, according to their compliance with EU minimal requirements, around five main categories[3]:

1. Active implantable medical devices (AIMD): Source of power other than that produced by the human body ex. pacemaker ...
2. In Vitro Diagnostic Medical devices.
3. Medical device custom made.
4. Medical device for disability compensation: hearing aid.
5. All other medical devices:
   a. Non-active implants, prosthesis, intraocular lens, heart valves ...
   b. Facilities: MRI Scanner, fans,
   c. Consumables: surgical instruments, bandages, contact lenses,
   d. Medical device accessories: contact lens solution

Recent years have witnessed the spread of "combined medical devices", that usually incorporate a drug (ex. Drug eluting coronary stent)

Medical Devices Regulation

The growth of medical device sector in the most advanced countries in this area (United States, European Union, Australia, Canada and Japan) is submissive to regulatory frameworks.
In an effort to standardize regulatory systems, "Global Harmonization Task Force" was created in 1993 by the above-mentioned countries to reduce regulatory barriers, facilitate trade and improve access to new technologies that have demonstrated their safety and efficiency, the aim being to encourage convergence of standards and regulatory practices relating to the safety, performance and quality of medical devices. The group is composed of representatives of regulatory authorities and industry of the founding countries.

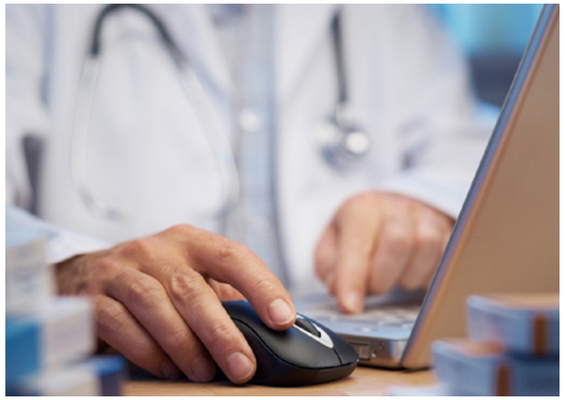
The fulfillment of these efforts is illustrated by the publication and dissemination of harmonized guidance documents "new approach" that defines the minimum requirements for the marketing of MD.

After several accidents (the most recent one involving breast implants PIP), debates intensify around strengthening the clinical dimension in assessing particular implantable medical devices (IMD), a strengthening of regulation is also needed for post-marketing surveillance.
Challenges rose by the globalization of production of medical devices and the emergence of new technologies have led to the creation of the International Medical Devices Regulators Forum in October 2011. This forum aims to address the risks that threaten the convergence of international regulations and to promote an effective regulatory model for medical devices.
Any medical device carries some risk and can cause problems in specific conditions.
The current approach to the MD safety is based on the evaluation of its potential to create a hazard which can cause serious problems and be harmful.
At the international level, the regulatory systems of the countries members of the GHTF classify medical devices based on the concept of risk assessment: Class I, II (IIa, IIb), and III. These classification systems are similar in defining the level of risk, the highest level corresponding to the Class III which represents the highest potential risk to patients.
At European level, unlike drugs whose marketing requires an authorization, the MD certification of compliance with the EU requirements is initiated by the manufacturer: the CE marking; the certificate issued by a "notified body" allows the marketing of the product.

Medical Devices Market

The medical device industry is a relatively young and highly diverse sector. The weight of its workforce is important and this workforce comes from different backgrounds. The landscape consists of medical devices (80%) of small and medium enterprises (around 10,000 worldwide).
In France, the number of products sold is estimated at between 800,000 and 2 million. The sector structure reflects this heterogeneity: the very small businesses working along with multinationals positioned on market segments using electronics. According to the French Ministry of Industry, 5300 French companies were listed in 2008 as related to the medical device which 95% are SMEs[4].

In the region of the Gulf Cooperation Council, health expenditure reached 27.7 trillion which represents 3% of gross domestic product; forecasts for 2013 are around 47 trillion.
This growth is driven by "demand push" factors including the population growth, a demographic shift towards a diagram showing an aging population and increasing incidence of lifestyle-related diseases (urbanization, imbalanced nutrition, sedentary lifestyle, etc. ...) aggravating the prevalence of cardiovascular diseases.
Concerning the medical devices, the golf market is estimated at $1.7 trillion (equivalent to $45 per capita) in 2009. This represents an average of 6.1% of total health expenditure. Saudi Arabia and the United Arab Emirates are the two biggest markets with more than 80% of the golf market. The growth in these markets is estimated at around 5% per year to more than $ 2 trillion in 2013[5].
Until very recent years, and like most countries in the region, the GCC has suffered from a lack of regulation for medical devices; there were no laws that directly address medical devices. The regulatory framework in this regard is currently changing.



The Lebanese Regulatory System for Medical Devices

The Lebanese market can hardly be distinguished from neighboring markets in the field of medical devices and demonstrates the same trend.
Local production is limited to basic items such as syringes, furniture, medical supplies and other devices being in the lowest position of the technological scale. Low local production capacity of medical devices has left the country in total dependence on the import of these products in the near future. The weak regulatory environment leaves seep products from countries with low production costs (countries Southwest Asia) which are not always complying with the minimum security requirements; evaluating products that are not approved by the competent authorities (FDA, CE, and others) appears here of great importance.
The Ministerial Decision No. 139/1 dated 02.02.1995 as amended by Decision 9/1 dated 6/1/1999 prohibits the importation into the Lebanese market of refurbished medical devices; Exception are made for doctors importing medical devices that was used in their personal clinics or through donations to institutions of public interest that has healthcare facilities.
The Lebanese Institute (LIBNOR) has, in the last few years, adopted national standards for medical devices based on International and European standards and is working to make them mandatory by decrees.

The available data doesn't allow estimating the volume of the market related to medical devices.
The Ministry of Health, being aware of its role in promoting patient safety and the potential for quality improvement that may represent the monitoring of implantable medical devices, has launched a program to establish a regulatory system for the importation and use of MD; this program is conducted in cooperation with the French agency for drugs and medical products safety (Agence nationale de la sécurité du medicament et des produits de santé) and the Ecole Supérieure des Affaires de Beyrouth (ESA).

Based on the achievements of this cooperation, the Ministry of Public Health issued a ministerial decree 455/1 dated 16 April 2013; this decree obliges the supplier to register their imported implantable products that shall be compliant to the international requirements at the Ministry of Public Health.

References

[1] *Le dispositif médical. Antoine Audry & Jean-Claude Ghislain. Que sais-je. 2009*

[2] *as per article L.5211-1 of the French Code of Public Health,*

[3] *Le dispositif médical. Antoine Audry & Jean-Claude Ghislain. Que sais-je. 2009*

[4] *Evolution et maitrise de la dépense des dispositifs médicaux. Rapport tome I. Inspection Générale des affaires Sociales. Novembre 2010.*

[5] *Medical devices market GCC. Osec Business Network Switzerland. Osec.ch. March 2010*