ROYAUME DU MAROC
Ministère de la Santé

Direction du Médicament et de la Pharmacie

المملكة المغربية
وزارة الصحة

مديرية الأدوية والصيدلة

Bill about registration and marketing Medical Devices

Medical devices are an integral part of any health system. Their use is widespread in the operating room, ambulatory care or at home. They contribute to the management of diseases and improving quality of life for patients.

The impact of medical devices on human health has prompted the health regulatory authorities, worldwide, to develop appropriate legal frameworks and systems of quality control and vigilance.

In Morocco and before 1997, medical devices were not subject to scrutiny prior to their placing on the market. Aware of the potential risks of these products to public health in the absence of any control and to ensure the safe use of medical devices and limit the movement of non-compliant products, the Ministry of Health, and pending the enactment of specific legislation, has established a registration system through the Ministerial Circular No. 7 of February 19, 1997.

This registration system transient marked a qualitative leap from the past indisputable and established the first rules of quality control.

However, this system had several shortcomings and limitations on the obligation to registries and punish. Recognizing the need to establish a legal framework for the whole environment of medical devices (product, activity and operators) and to guard against counterfeit devices and to manage the health risk, the Ministry of Health has prepared a bill that aligns with international standards and WHO recommendations on quality control, traceability, manufacturing standards, the alert system and vigilance.

The outline of this project address:

- The principle of the declaration, before the beginning of the activity, for establishments of manufacturing, importation, distribution and export of medical devices;

- The obligation for these institutions to develop standards of good manufacturing practice, essential elements of quality assurance;

- The principle of registration, prior to any marketing, based on clinical investigation or evaluation of clinical data in order to:

    - assess the performance of medical devices in normal use;

- assess the acceptability of the relationship between benefits and risks and determine their adverse effects; confirm compliance with essential requirements;

- The principle of transparency and consultation by submitting applications for registration to the notice of a multidisciplinary advisory panel whose members are bound by professional secrecy and the obligation to disclose conflicts of interest;

- The principle of the alert and vigilant in advocating a national system for monitoring equipment monitoring of medical devices on the market;

- Inspection for establishments of manufacturing, importation, distribution and export of medical devices;

- Measures to protect public health, emergency, giving the administration a decision-making power allowing him to conduct an immediate withdrawal of the medical devices market is concerned;

- Guidance on advertising, to avoid excesses and false advertising by introducing the principles of prior approval to any advertising to the public and advance deposits where the advertising is intended for health professionals;

The project pays special attention to medical devices used, which may be an alternative to expensive medical equipment and an important economic issue, and setting the conditions for placing on the market so that the use of such devices do not compromise the clinical condition and safety of patients or health and safety of users.