THE PROPOSED MEDICAL DEVICE REGULATORY SYSTEM IN MALAYSIA

1. Aims

The proposed medical devices regulation is aimed at protecting public health and safety. At the same time it is aimed at facilitating trading activities in order to ensure timely availability of beneficial new technologies to medical community and the public.

2. Objective of the proposed regulation

The objective of the proposed regulation is to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of medical devices.

3. Guiding principles

The primary goal of the regulatory system is to protect public health and safety. The level of control should be proportional to the degree of risk, taking into account of the benefits offered by the use of the device. The regulatory system should expedite timely availability of and access to safe and beneficial medical devices while preventing sub-standard, unsafe and ineffective medical devices from entering the market.

1) Assuring medical device safety requires oversight of the use of medical devices rather than just the functioning of the device. All elements of control from design through disposal are required to be put in place to ensure continued safety and quality as well as ongoing regulatory compliance after market clearance has been obtained.
2) The regulatory system will be in-line with global harmonization effort with some modifications to suit local circumstances. Harmonization with international system is important to minimize regulatory barriers, facilitate international trade and improve access to new technologies as well as to

reduce the cost of implementing regulation for the government and the industry.

4. Definition of medical device

4.1 The term medical device refers to medical technology, supplies and equipment. It encompasses the very broad range of healthcare products used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or handicap but exclude drugs. In contrast with medicinal product the intended primary mode of medical device action to human body is not metabolic, immunological or pharmacological.

4.2 GHTF defines medical device as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of;

i) diagnosis, prevention, monitoring, treatment or alleviation of diseases;

ii) diagnosis, monitoring, treatment, alleviation of or compensation for injury;

iii) investigation, replacement, modification, or support of the anatomy or of a physiological process;

iv) supporting or sustaining life;

v) control of conception;

vi) disinfection of medical devices;

vii) providing information for medical purposes by means of in vitro examination of specimens derived from the human body;

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means ([1]).

4.3 Medical devices range from simple contact lenses to precise robotic arm and sophisticated CT machines, radiation-emitting equipment, lasers, implanted hip joints and heart valves and they can be categorized into 12 categories according to the Global Medical Devices Nomenclature (GMDN) system ([2]).

5. Classification of medical devices

5.1 Regulatory controls should be proportional to the level of risk associated with a medical device. Based on the level of risks, medical devices consist of four risk classes, which are sufficient to accommodate all medical devices and allows an efficient and graduated system of conformity assessment controls.

5.2 The determination of class is based on a set of 16 rules derived from those features of devices that create risk. In general, low-risk are external to the body, and if applied correctly, involve minimum risk to the patients. The higher risk devices penetrate the human body, involve a high- energy source, or used to sustain life.

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[1] GHTF Working Draft: Information Document Concerning the Definition of the Term "Medical Device" SG1/N029R11, 25 February 2002

[2] GMDN is a classification system developed to allow for the classification of all medical devices put onto the market. It is developed by the European Standards body CEN and sponsored by the European Commission, with full participation and parallel acceptance by the ISO. It is the only nomenclature system in use within the European Economic Area and is being endorsed by many legislators. It is also endorsed by the GHTF as the global nomenclature to be used by regulators for the classification and registration of medical devices.

6. Scope of the proposed regulation

6.1 The phases of the life span of a medical device extend from design and development, manufacture through its disposal as illustrated in Figure 2. These phases can be divided into three common stages, namely pre-market, placement on-market and post market. Each of the phases of the life span of a medical device may affect its safety and performance. It is therefore important that the scope of the regulatory control encompasses all the phases of the medical device life span. Some of the elements that may affect safety and performance of a medical device are described in the following paragraphs.

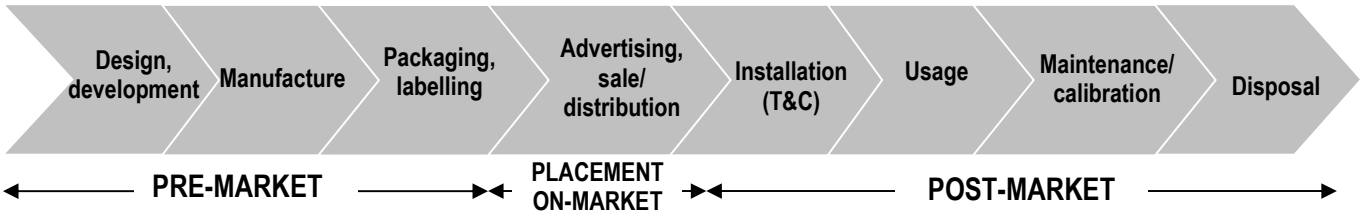

Figure 2: The phases and corresponding stages in the life span of a medical device

6.1.1 Design and development

The scientific principles upon which a device is based are fundamental to its safety and performance. The concept, design, construction and testing (including verification, validation and clinical trials) require the scrutiny of scientific experts to ensure that design parameters and performance characteristics do not impose unwarranted risks.

6.1.2 Manufacture

Good, functional medical devices are produced when the manufacturing process is adequately managed. Poor manufacturing management can produce inconsistency in the quality of products, such that non-conforming devices can filter through the production line to the market, even when the original prototype has been well designed.

6.1.3 Packaging and labeling

Well-designed packaging systems is important especially in delivering clean, sterile and protected medical devices to the point of use. Subtle damage can result during transportation and handling unless the total packaging system is designed robustly and can withstand various stresses. Labeling, hazard warnings or cautions and clear instructions are very crucial in identifying a medical device and specifying instructions for its proper use. Mislabeling of medical devices can result in serious consequences for the user.

6.1.4 Advertising and sale/distribution

Advertisement has the potential to create expectations and influence the belief in the capabilities of a medical device. Misleading or fraudulent advertising of medical devices may deprive the patient of more appropriate treatment and could lead to patient or user injury. The sale of medical devices by the vendor is a critical stage that leads to the device being put into actual use. There is a higher risk of exposing the public to low quality or ineffective devices if the vendors are not subject to regulation.

6.1.5 Usage (including installation and maintenance/calibration)

Unfamiliarity with a certain technology or operating procedure, and the use of products for clinical indications outside the scope of those specified in the labeling can cause device failure even in the absence of any inherent design or manufacturing defects. The re-use of disposable devices contrary to the manufacturers instructions, and without proper control or precautions for minimizing associated risks, can be dangerous. Some devices require proper installation (including testing and commissioning) prior to usage and proper maintenance/ calibration to ensure the devices continue to function properly. The lack of, or inappropriate, testing and maintenance/calibration of such devices may jeopardize their safety and performance.

6.1.7 Disposal

Disposal of certain types of devices should follow specific safety rules. For example, devices that are contaminated after use (e.g. syringes) or devices that contain toxic chemicals can present hazards to people or the environment and must be disposed of properly.

7. Activities of the proposed medical devices regulation

7.1 The regulatory control should encompass the entire life span of a medical device and it should cover the manufacturing process, the product itself, the representation of the product, the vendor and the user (including those involve in maintaining/calibrating the device). Activities of the regulatory system include;

i) Pre-market control;

ii) Placement on market control;

iii) Post-market control;

iv) Operation and usage control;

v) Quality system requirement; and

vi) Use of standards.

7.1 Pre-market control

7.1.1 Pre-market review on a medical device is performed to ensure that a device satisfies safety and performance as well as quality system requirements before market clearance is given. In addition, labeling requirement should also be satisfied to provide identification of a medical device, its manufacturer, local representative or importer and instructions for the safe use of the device. The degree of scrutiny depends on the potential risks of the device according to the risk-based classification system. Pre-market control may be achieved by;

a) registration/licensing for high-risk devices; and

b) notification for low-risk devices

7.1.2 Registration/licensing for high-risk devices – all medical devices except those that fall into low-risk (Class A) devices must be registered to obtain market clearance. Manufacturers are responsible to fulfill the requirements for product registration. If the manufacturer does not have a business establishment in Malaysia, local representative should be appointed. Three options may be adopted in assessing the compliance of devices to registration requirements;

Submission of evidence of prior regulatory clearance/approval from recognized authorities to prove that safety, effectiveness and quality of the product are up to international standards. Certification/relevant documents from:

i) authorities such as US Food and Drug Administration, European Union, Australian Therapeutic Goods Administration, Canadian Therapeutic Products Directorate and Japanese Ministry of Health and Welfare can be used as evidence of regulatory clearance/approval. This is the easiest and fastest assessment option and it will avoid delay in introducing new and effective medical devices.

ii) Submission of certificate issued by a conformity assessment body (CAB) after a product has complied with applicable standards and requirements. The advantage of making use of CAB is the flexibility of drawing expertise for assessment.

iii) Submission of technical documentation and clinical evaluation/trial data for assessment. This option requires more resources and feasible only if qualified staff are available to perform assessment in relevant areas.

7.1.3 Notification of low-risk devices – Low-risk (Class A) devices require the least stringent control. Even though pre-market assessment is exempted,

the manufacturer is still required to follow essential principles of safety and performance in design, manufacturing and labeling requirements. The manufacturer is required to notify the regulatory authority and maintain the list of Class A products they have placed into the market. This is important to facilitate recall of devices whenever necessary.

7.2 Placement on-market control

7.2.1 A medical device that has satisfied the pre-market control may be put into the market. Manufacturers/vendors who introduced medical devices into the market will be regulated to identify the parties seeking market clearance and the devices to be marketed. This control is crucial to track the manufacturers/vendors in the event when difficulty arises, especially in emergency situations, once the product is in use. It also enables the government to carry out inspections and audits to ensure ongoing compliance.

7.2.2 All local manufacturers who manufacture, alter or re-package devices to be sold in Malaysia and local representatives (of imported Class B and above devices) will be registered/licensed. Local representatives for imported medical devices can be any private company appointed to act on behalf of the manufacturer. The representative should maintain linkage with the manufacturer and should be able to obtain support if required. In addition, the manufacturers/vendors are also required to perform post-market obligations such as post-market surveillance and other duties as one of the registration/licensing requirements.

7.2.3 Advertisement control is performed to ensure correct product representation and to prevent misleading/fraudulent advertisements or claims that may lead the user or public to purchase an inappropriate medical device.

7.3 Post-market control

7.3.1 Post-market control is required to ensure continued safety and quality as well as ongoing regulatory compliance of medical devices after market clearance. No amount of rigor in pre-market review can predict all devices failures or incidents arising from the use of a device. Monitoring of performance of the devices and reporting problems associated with the use of medical devices are important components of regulatory control. Two major activities are required to be performed by the manufacturers, namely post-market surveillance study and adverse event reporting.

7.3.2 In post-market surveillance study, the manufacturers are required to establish system to collect post-market surveillance data of high-risk medical devices. This is required as a condition for product approval and to re-affirm product safety. Precautionary measures should be taken to minimize any potential health hazards associated with their use. Post-market surveillance should include after-sale obligations for implant registration and distribution record.

7.3.3 Adverse event reporting is important to carry out timely intervention for any adverse incident and it provides an opportunity for product identification and carry out remedial action such as modification or product recall. It also allows timely dissemination of information that is necessary to prevent recurrence of similar incident.

7.3.4 Adverse incident reporting requires manufacturers/representatives to report adverse incidents that reasonably suggest that death or serious injury of a patient has been caused/contributed by the use of a medical device. The manufacturers/ representatives are required to investigate and carry out follow-up actions, such as product recall, and report the results to the authority. Healthcare professionals are encouraged to notify manufacturers/ representatives of adverse incidents. Injuries arising from the use of medical devices by non-health professionals should also be reported.

7.4 Operation and usage control

7.4.1 Some sophisticated medical devices require specialized and trained personnel to ensure their safe operation and proper maintenance and calibration to ensure their continued safety and performance.

7.4.2 The objective of operation and usage control is to prevent unnecessary harms or complications arising from the improper use of medical devices. Operation and usage control addresses the issues of proper usage as well as maintenance and calibration of such devices.

7.4.3 Owners of these devices are required to apply to the authority to possess and use such devices and to undertake to comply with a set of requirements which include requirements for qualification and training, safety precautions and maintenance/calibration.

7.5 Quality system requirement

7.5.1 A quality system is required to identify the organizational structure, responsibilities, procedures, processes and resources required to implement quality management. Quality system requirement impose strict quality assurance on every aspect of the production of medical devices. It reduces the likelihood of non-conforming products, ensures consistency in the quality of a device and provides the basis for greater reliability in its safety and performance.

7.5.2 The quality system is subject to periodic audits by the government or third party agencies, management review and corrective and preventive measures that will maintain product quality.

7.6 The use of standards

7.6.1 The use of national or international standards in conformity assessment has become essential in establishing medical devices regulation as it helps in improving productivity, market competitiveness and export capability which are very important for manufacturing and international

trade. The use of standards can reduce cost, simplify regulatory process and promote international harmonization.

7.6.2 Standards are used to demonstrate conformance to essential principles of safety and performance of medical devices. This includes conformity to product standards, conformity to process standards and conformity to management standards. Accreditation of competent third party is required to carry out specific conformity assessment task.