SINGAPORE, 06 FEBRUARY 2007
HEALTH SCIENCES AUTHORITY

PUBLIC CONSULTATION ON THE CONTROL OF MEDICAL DEVICES AND DRAFT OF THE HEALTH PRODUCTS (MEDICAL DEVICES) REGULATIONS

Introduction

The Health Sciences Authority (HSA) invites feedback from the medical device industry and healthcare professionals as well as consumers and the general public on the proposed control of medical devices and the draft of the Health Products (Medical Devices) Regulations. Copies of the draft Regulations and the Health Products Bill (which is the parent legislation under which the Regulations will be made) are available on the HSA website at www.hsa.gov.sg. All feedback should be emailed to hsa_feedback@hsa.gov.sg by 3 April 2007.

Background

2 The nature of medical devices, and the way in which they are used, distinguish them from common consumer appliances. With the higher degree of risk and potential problems that may be associated with medical devices when used inappropriately, there is a need for some degree of regulatory control over devices used in, or as part of, the medical treatment of human beings. Moreover, with technological advancements, many medical devices are increasingly being designed for use by laypersons, instead of just healthcare professionals. Therefore, regulatory control on the presentation and advertisement of medical devices has also become increasingly important.

3 There is currently no formal control on medical devices in Singapore to regulate the manufacture, import, supply and use of these products. . To address this, an interim voluntary product registration scheme (VPRS) has been put in place by HSA since 2002 for manufacturers and/or importers to register their products. HSA, working in collaboration over the last few years with the medical device industry and healthcare professionals, has also been laying the ground for the establishment of a formal regulatory framework for medical devices. With the recent introduction of the new Health Products Bill in Parliament, it will be possible to implement such a framework under a written law.

4 HSA has drawn up a proposed regulatory framework and a draft version of the Health Products (Medical Devices) Regulations, and now seeks further input and views from the industry and healthcare professionals as well as consumers and the

general public, to further improve and refine the framework before it is formalised and written into the law.

Developing A Regulatory Framework Aligned To International Best Practices

5 In drawing up its regulatory framework for medical devices, HSA has adopted a measured approach to safeguard public health but without unduly restricting consumer choice and their access to new technologies. This is also aimed at promoting technological innovation and facilitating international trade without imposing excessive regulatory costs to the industry. HSA has also consulted widely with overseas regulatory counterparts, experts and key local industry groups.

6 HSA studied the medical device regulatory systems in developed country counterparts which have more than a decade of regulatory experience for medical devices, including the US Food and Drug Administration (FDA), European Union, Canada's Medical Devices Bureau (MDB), Japan's Ministry of Health Labour and Welfare and Australia's Therapeutic Goods Administration (TGA).

7 The proposed regulatory framework will be based on the principles endorsed by the Global Harmonisation Task Force (GHTF)[1] with modification to suit the Singapore context. This applies the concept of risk management to ensure that the level of regulation is proportional to the degree of risk involved and the benefits offered in using a medical device. Examples of the key requirements for the safety, quality and performance of medical devices include the classification of medical devices according to the level of risk to patients and users, a set of essential principles for the design, manufacture and clinical performance of medical devices, and a system of post-market monitoring, surveillance and adverse incident reporting.

8 HSA's proposed regulatory framework incorporates the following elements from the regulatory model recommended by the GHTF :

- Definition of medical devices[2].
- Risk-based classification system and rules[3].
- Essential principles of medical devices for ensuring the safety and performance[4].
- Risk-based assessment and risk management

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1 GHTF is an international forum of medical device regulators and representatives from the medical industry. Conceived in 1992, with the EU, USA, Japan, Australia and Canada as the founding member countries, the purpose of the GHTF is to encourage convergence in regulatory practices relating to medical devices. The GHTF's role is similar to the International Conference on Harmonisation's (ICH) contribution to the regulatory guidances for pharmaceuticals in that it is the key international driver for harmonizing the way in which medical devices are regulated.

2 Please refer to the First Schedule of the Health Products Bill.

3 Please refer to the First Schedule of the draft Health Products (Medical Devices) Regulations.

4 Please refer to the Second Schedule of the draft Health Products (Medical Devices) Regulations.

Control of Dealers Manufacturing, Importing and Supplying Medical Devices

9 The proposed framework comprises the following key elements :

a) Licensing of establishments dealing with medical devices

These licensing controls are aimed at regulating the supply chain and ensuring that only *bona fide* persons are engaged in dealing with medical devices. The main control is on the supply chain in the ordinary course of business-to-business activity, namely: import, local sales, export, authorized representatives (i.e. registrants) who place devices on the local market, and local manufacture of medical devices.

b) Conditions and obligations on licensees

Certain conditions and obligations will be imposed on the licensees. These include compliance with standards (e.g. good manufacturing practice, good distribution practice), the mandatory requirement for distribution records, and the establishment of procedures for handling product recalls and adverse events involving their products. These measures are essential to ensure that products can be traced and swift corrective actions can be taken even after a product has entered the Singapore market. They also reflect the continuing responsibility of all licensees to ensure that the products they market remain safe and of good quality.

c) Restriction on access to certain types of devices

There will be controls restricting access to certain types of medical devices that are more complicated and potentially harmful when used wrongly or inappropriately, so that such devices are only supplied to and used by qualified persons (e.g. doctors).

Control on Safety, Quality and Performance of Medical Devices

10 The proposed framework imposes pre-market controls and controls on labelling, advertising and promoting medical devices.

a) Pre-market controls

Pre-market controls will require that only devices which meet requirements of safety, quality and performance are allowed to be sold in Singapore. All medical devices must bear proper product labels which reflect the permitted claims on the intended use of the device, as well as instructions for use. All devices would need to be registered with HSA prior to entering the Singapore market.

b) Controls on advertisement and sales promotion

HSA will set out the circumstances under which advertising and marketing are permitted, to curb any false or misleading advertisement claims inconsistent with the safety, quality and intended uses of the product as

registered, and promoting the appropriate and safe use of the product. An advertiser promoting a medical device with false or misleading claims may be penalised by requiring him to publish a corrective advertisement, in addition to the usual penalties imposed by the Court.

c) Singapore Medical Device Register

Consumers and healthcare purchasers of medical devices can consult an online register containing a list of medical devices registered with HSA and legally available for sale in Singapore. This register will also contain information on the brand-owner, local authorised representative, distributor and intended use of a device.

Special Allowances and Exemptions Under Certain Circumstances

11 The proposed framework also envisages exemptions from product registration and licensing requirements, and special access to unregistered medical devices, which will be provided under certain circumstances, for example, in the case of investigational devices for clinical trials and custom-made devices 'manufactured' solely for use by a particular patient.

Feedback Sought

12 The regulatory framework that HSA is proposing at this point are embodied in the provisions in the draft Health Products (Medical Devices) Regulations as well as in the Health Products Bill itself. However, the proposed framework remains a 'work-in-progress', and HSA welcomes any input or feedback from all stakeholders – i.e. industry, healthcare professionals and consumers.

13 The draft Health Products (Medical Devices) Regulations are subject to changes depending on the outcome of this public consultation. The draft Regulations are, of course, also subject to further changes depending on whether the Health Products Bill is amended by Parliament and subsequently enacted as the Health Products Act.

Health Sciences Authority
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