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HEALTH SCIENCES AUTHORITY
PRESS RELEASE
6 FEBRUARY 2006

HSA SEEKS VIEWS ON PROPOSED

HEALTH PRODUCTS (MEDICAL DEVICES) REGULATIONS

The Health Sciences Authority (HSA) invites feedback from the public and stakeholders from the device industry as well as healthcare professionals on the proposed Health Products (Medical Devices) Regulations 2007. The draft Regulation is 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, it is appropriate for formalised regulatory controls to be introduced. With technological advancements, many medical devices are increasingly being designed for use by laypersons. As such, regulatory control on the presentation and advertisements of medical devices has also become increasingly important.

3 At present, there is no formal regulatory control on medical devices in Singapore to regulate the manufacture, import, supply and use of these products. However, an interim voluntary product registration scheme (VPRS) implemented by HSA has been in effect since 2002 for manufacturers and/or importers to register their products.

4 HSA, working in collaboration over the last few years with the medical device industry and healthcare professionals, has 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.

A REGULATORY FRAMEWORK ALIGNED TO INTERNATIONAL BEST STANDARDS

5 In mapping 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. HSA has also studied the medical device

regulatory systems in developed country counterparts, 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).

6 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.

7 Some key elements of the proposed framework comprises licensing of establishments dealing with medical devices, restricting access for medical devices that are more complicated and harmful if used inappropriately, product registration and labelling, and controls on advertisement and sales promotion.

8 Through this public consultation, HSA seeks the inputs and views of all stakeholders, which will help to refine the proposed regulatory framework for medical devices before it is formalised for implementation.

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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 guidelines for pharmaceuticals in that it is the key international driver for harmonising the way in which medical devices are regulated.