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HEALTH SCIENCES AUTHORITY
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HSA ENABLES FASTER AND EXPEDITED ACCESS FOR LOWER RISK MEDICAL DEVICES THROUGH ENHANCEMENTS TO ITS REGULATORY FRAMEWORK

The Health Sciences Authority (HSA) announced today that its regulatory framework will be enhanced for lower risk Class A and B medical devices, to facilitate expedited access and lower regulatory fees for these products. Class A and B devices account for about 70% of all medical device applications received by HSA. Further enhancements are also being planned for the higher risk Class C and D devices. The enhanced regulatory framework seeks to better address the concerns of the medical device industry while ensuring patient safety. HSA will continue to risk stratify the regulation of medical devices based on international best practice, while allowing greater customisation and flexibility in each class through judicious referencing of key overseas agencies and history of safety.

Faster and Expedited Access for Lower Risk Devices

2 HSA will be exempting all Class A devices from registration except for sterile devices from 1 May 2012. This will cover an estimated 80% (approx 4,700) of Class A product types, and importers/manufacturers will only be required to list the medical devices with HSA to facilitate post-market surveillance and monitoring. There will be no registration fee for exempted Class A devices.

3 For Class B medical devices, HSA will be implementing the following new routes on 1 September 2012:

(i) Immediate Registration Route

Immediate access for Class B medical devices that have already been approved by two of HSA's independent regulatory reference agencies[1], and marketed without any safety concern for at least three years in these jurisdictions.

(ii) Expedited Registration Route

Devices qualifying for this route are:

a. Class B devices which have already been approved by two of HSA's independent regulatory reference agencies; or

[1] US FDA, EU Notified Bodies/Australian Therapeutic Goods Administration, Health Canada & Japan Ministry of Health, Labour and Welfare

b. Class B devices which have already been approved by at least one of HSA's independent regulatory agencies and marketed in this jurisdiction or Singapore without any safety concerns for the past three years.

The medical devices that qualify for the Expedited Registration Route will see approval time being reduced from 100 to 60 working days.

4 For the Immediate and Expedited Registration routes, the regulatory fees will be reduced from $2,300 to $1,400 as the time and manpower needed to evaluate these products are correspondingly lower. An estimated 3,650 Class B applications will be eligible for these routes and represent 85% of Class B applications.

Further Initiatives

5 In addition, HSA is looking into a lower tiered fee structure for its Special Authorisation Route to take into consideration both existing and innovative, low cost and low volume medical devices to meet the continued medical needs of patients. This will be implemented on 1 August 2012 after reviewing the key products of concern with dealers and healthcare professionals.

6 Further enhancements are also being planned using the agency referencing approach for the higher risk Class C & D devices.

7 "Given the pervasive use and rapid technological advances of medical devices at all levels of health care delivery, patient safety remains the top priority for HSA. These changes reflect a flexible and responsive regulator that is willing to listen to the teething issues faced by the industry with the introduction of medical device regulation in Singapore, without compromising patients' well being. I am confident that these enhancements, in particular, for lower risk devices, will address the concerns of industry and that HSA will continue to enhance the framework to facilitate access to safe medical devices," said Dr Amy Khor, Minister of State (Health).

Greater Emphasis on Post-Market Measures

8 "We appreciate the feedback received on issues faced by the industry and healthcare professionals. HSA has therefore made enhancements to its risk-based framework to better address these concerns through more judicious referencing of key regulatory agencies. This will facilitate faster access to new low risk medical devices, without compromising patient safety. We will manage risk by putting more emphasis on post-market vigilance, compliance, audit and enforcement," said Associate Professor John Lim, CEO of HSA.

Cooperation with SMa

9 To address the issues faced by industry, HSA is in discussion with the Singapore Manufacturers' Federation (SMa) to pilot a project to provide training to companies on dossier submission, as well as a "concierge service" to help screen the completeness and appropriate risk classification of dossier applications to HSA.

10 The HSA-SMaRT Dossier Submission E-Guide will also be launched today on HSA's website. The E-Guide will provide industry with clearer step by step advice on dossier submission.

11 These initiatives will potentially help minimise delays due to incomplete submissions and documentation.

Extensive Consultation with Industry

12 The above changes and initiatives are the result of extensive engagement and consultation with the industry and healthcare professionals. HSA has had more than 60 communication sessions and workshops to help guide and explain the MD regulations to stakeholders over the past 4 years. In anticipation of issues that might arise in the final phase of implementing mandatory medical device regulation on 1 Jan 2012, HSA also initiated intensified engagement through 9 focus groups and dialogue sessions with doctors, dentists, medical device industry associations and hospitals' purchasing departments.

13 The feedback received has allowed HSA to understand key issues faced by stakeholders and craft the enhancements announced today. HSA will continue to engage its stakeholders to further enhance the medical device regulatory framework.

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About the Health Sciences Authority (HSA)
The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. It operates the national blood bank, Bloodbank@HSA, securing the nation's blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit http://www.hsa.gov.sg/

- **About HSA's Health Products Regulation Group**

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards.

ANNEX

Background on Medical Device Regulation in Singapore

Mandatory regulatory requirements for medical devices were introduced by the Health Sciences Authority (HSA) to ensure that our patients have access to safe, good quality and efficacious devices, and to facilitate prompt recalls when defects are detected. The regulations were implemented in phases since 2002 to allow stakeholders adequate time to transit to a full regulatory framework.

2. Medical devices are divided into 4 classes – more complex devices (Class D), such as sophisticated diagnostic imaging equipment or cardiac stents, are subject to tighter regulation and scrutiny than simpler devices (Class A) such as bandages. Devices that are of very low risk like tongue depressors are exempted from pre-market approval and hence no fees are involved.

3. The fees implemented are based on a cost-recovery basis. To assist in lowering regulatory costs, HSA allows for groupings of multiple devices to be submitted in one application, and product extensions of the same device do not require a new application for product registration. HSA had also implemented other initiatives such as lower incentive registration fees for early submissions from 2008-2010, progressive payment scheme and exemption of most Class A devices, to help the industry manage regulatory costs.

4. HSA takes into consideration the approval by key overseas regulators including the US Food & Drug Administration during our evaluation stage. These products go through a shorter evaluation process at a lower fee. Approximately 98% of applications undergo this route.

5. With feedback received since the start of the medical device regulation in 2007, HSA has been reviewing its framework and introduced measures to facilitate ongoing access to medical devices:

i. A Transition List was established in 2009 to allow devices to continue to be supplied while awaiting HSA's approval;
ii. Special Authorisation Routes (SAR) for unregistered devices where distributors can bring in devices for patient use deemed essential by doctors who take responsibility for such usage. Since Jan 2011, more than 1200 devices have been brought in via SAR;
iii. Exemptions from registration of more than 2,000 very low risk devices including bandages and walking aids.