



FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE
21 December 2012

HSA ENABLES FASTER AND EXPEDITED ACCESS FOR CLASS C & D MEDICAL DEVICES

The Health Sciences Authority (HSA) announced today that its medical device regulatory framework will be further enhanced to facilitate faster access and lower regulatory fees for Class C and D medical devices with effect from 01 January 2013. These changes were made following the enhancements to Class A and B medical devices made on 20 April 2012. Class C and D devices account for approximately 40% of all the total medical device applications received.

2 The introduction of the new expedited route for Class C and D devices is intended to facilitate faster access to medical devices, through judicious referencing of HSA's medical device independent reference regulatory agencies¹ and safe history of use of these products. The referencing of overseas agencies' evaluation also helps to reduce the time required for the review of each application, thereby translating to shorter turn-around times and lower regulatory fees.

3 To safeguard the health of our patients and in accordance to the risk-based approach to the medical device regulations, some of the long-term implantable devices, devices incorporating a registrable drug, and high risk diagnostic test kits with significant impact on public health will be excluded from the expedited registration routes for Class C and D devices (See **Annex A** for the full list of such devices). These devices will have to be registered via the full or abridged evaluation routes currently available.

Faster and Expedited Access for Class C and D Devices

4 HSA will be implementing the following new routes from 01 January 2013 (See **Annex B** for the summary):

i. Expedited Class C Registration Evaluation Route

Devices qualifying for this route are Class C medical devices that have obtained approval from at least two of HSA's independent reference agencies¹, or at least one of HSA's independent reference regulatory agencies and marketed in this jurisdiction without any safety issues for at least three years.

The turn-around time will reduce from 160 to 120 working days with an estimated cost saving of \$500 per application. About 75% of the current existing Class C applications will be eligible for this route.

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

ii. Expedited Class D Registration Evaluation Route

Devices qualifying for this route are Class D medical devices with approvals from at least two of HSA's independent reference regulatory agencies. The turn-around time will reduce from 220 to 180 working days, with a reduction of regulatory fee by \$300 per application. About 50% of the current existing Class D applications will be eligible for this route.

In view of the higher risk profile of these two categories of devices, HSA will not be introducing immediate access routes for Class C and D devices, unlike the earlier enhancements for Class B devices.

Reduced Regulatory Requirement for Class A Device Dealer Licensing

5 Importers and wholesalers of medical devices in Singapore are required to meet GDPMDS (Good Distribution Practice for Medical Devices in Singapore) requirements, the objective of which is to ensure the quality and integrity of medical devices throughout the distribution process. The GDPMDS certificate is issued by third party certification bodies accredited by the Singapore Accreditation Council, and is valid for three years with an annual site audit, in accordance with international ISO practice.

6 From 01 January 2013, HSA will be introducing a tiered quality management system (QMS) requirement for dealers (importers and wholesalers) who solely deal with low risk Class A medical devices. In place of the GDPMDS certification, companies will be required to satisfy HSA's reduced regulatory requirements by submitting HSA's QMS assessment form, with an annual declaration on the companies' compliance to the tiered QMS requirements. This translates to approximately 30% less documentation than the current GDPMDS requirements for the higher risk Class B - D devices. These dealers will be subject to post-market surveillance, including selective on-site audits using a risk-based approach. It is estimated that 10 - 15% of the current number of dealers will benefit from this exemption and save the cost of GDPMDS certification fees.

Greater Emphasis on Post-Market Measures

7 "Responding to stakeholder feedback, HSA has rolled out a series of enhancements this year to enable expedited access for medical devices. To ensure that patient safety continues to be safeguarded with the expedited access, we have continually strengthened our post-market vigilance, compliance, audit and enforcement activities. This will enable us to detect safety signals from the market early and investigate adverse events promptly. We will continue to work with the industry and healthcare professionals to refine the regulatory framework and facilitate the access of more new and innovative devices into the market to better meet the medical needs of our patients. The close collaboration between HSA, healthcare professionals and industry is key to assuring the safe use of medical devices in Singapore," said Dr Raymond Chua, Group Director of HSA's Health Products Regulation Group.

8 HSA has stepped up its vigilance activities to encourage more voluntary reporting of adverse events for medical devices by the healthcare professionals and mandatory reporting by the industry. Regular roadshows are conducted to heighten the awareness of adverse events reporting, including the distribution of brochures and electronic guidance documents to guide healthcare professionals on the reporting. Other post-market surveillance initiatives, which include random checks and device sampling in the market, as well as environmental scanning for overseas alerts and local safety signals, are also strengthened. Tighter controls on the licensees and dealers will also be imposed to assure the quality of dealers bringing in these medical devices. HSA will continue to enhance the post-market surveillance

framework for medical devices and explore more measures going forward to expeditiously pick up and track signals to enhance patient safety.

Extensive Consultation with Industry

9 These changes and initiatives are the result of extensive engagement and consultation with the industry and medical and dental specialists since April 2012. Over 10 consultations were conducted with the involvement of more than 100 industry players.

10 The feedback received has been very helpful to HSA in appreciating key issues faced by stakeholders, and has fed into the design of the enhancements announced today. At the same time, HSA has been mindful to ensure that appropriate safety and quality standards are met to protect patient safety, and that post-marketing vigilance is a key component in safeguarding patients' health and safety.

Positive Feedback Received from Industry

11 "The recently announced enhancements by HSA, are certainly in the right direction, especially the expedited evaluation route, as speed to market is always a major concern for the Medtech industry. HSA has also shown to be more open to hearing industry feedback and acting on them in a timely manner. Singapore Manufacturing Federation (SMF) will continue to work closely with HSA and to provide industry feedback as well as partner with them in future activities, for the betterment of the Medtech Industry," commented Ms Jacqueline C. Monteiro, Deputy Chairman of MedTech & Life Sciences Industry Group, SMF.

12 "The new expedited routes provide more options and quicker turn-around time for medical device companies who deal with Class C and D products. On behalf of the industry, we like to thank HSA for their continued efforts to hear us and then make improvements on their regulatory processes. AMDI will continue to be the voice of the industry and work closely with HSA on all matters," said Mr Henry Tan, President of Association of Medical Device Industry (Singapore).

13 Ms Elise C. Rada, Executive, Marketing Support of Servicom Medical (Singapore) Pte Ltd said, "The new routes not only help to reduce our resources needed to put up each application, the faster application processing time also enables our products gain faster access to the market, giving us a competitive edge." Regulatory Affairs Singapore Team, Johnson & Johnson Medical Asia Pacific also agreed, "A step in the right direction. Speed to market should improve which will benefit the industry."

**HEALTH SCIENCES AUTHORITY
SINGAPORE
21 DECEMBER 2012**

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. As the national blood service, it is responsible for providing a safe and adequate 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/> .

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework. It ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards.

DEVICES EXCLUDED FROM EXPEDITED REGISTRATION ROUTES FOR CLASS C AND D MEDICAL DEVICE APPLICATIONS

Risk Class	List of devices
C	Hip, knee and shoulder joint replacement implants (e.g. non-bioactive metal/polymer implants)
D	<ul style="list-style-type: none">• Active Implantable Medical Devices (e.g. pacemakers, neurostimulators)• Implantable devices in direct contact with the central circulatory system or central nervous system• Hip, knee and shoulder joint replacement implants (e.g. bioactive implants)• Devices incorporating a registrable drug in an ancillary role• IVD Devices intended for:<ul style="list-style-type: none">○ HIV test kits (screening and diagnosis)○ Blood / tissue donor compatibility tests

REVISED CLASS C AND D DEVICE REGISTRATION FRAMEWORK (EFFECTIVE 01 JANUARY 2013)

Risk Class	Evaluation Route	Qualifying Criteria	Target Turn-Around Time (working days) ¹	Evaluation Fee (\$) ²
C	<i>Expedited (New)</i>	<i>Approval from at least one of HSA's independent reference regulatory agencies³ and marketed in this jurisdiction without any safety issues for at least three years OR Approvals from at least two of HSA's independent reference regulatory agencies³</i>	120	3,000
	Abridged	Approval from at least one of HSA's reference regulatory agencies ⁴	160	3,500
	Full	No approval from HSA's reference regulatory agency ⁴	220	5,700
D	<i>Expedited (New)</i>	<i>Approvals from at least two of HSA's independent reference regulatory agencies³</i>	180	5,400
	Abridged	Approval from at least one of HSA's reference regulatory agencies ⁴	220	5,700
	Full	No approval from HSA's reference regulatory agency ⁴	310	11,400

¹ Excluding company's response time to queries

² Do not include application fee

³ US FDA, EU Notified Bodies/Australian Therapeutic Goods Administration, Health Canada and Ministry of Health, Labour and Welfare, Japan

⁴ US FDA, EU Notified Bodies, Australian Therapeutic Goods Administration, Health Canada and Ministry of Health, Labour and Welfare, Japan