FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE

2 AUGUST 2012

HSA LOWERS FEES FOR MEDICAL DEVICE SPECIAL AUTHORISATION ROUTES

The Health Sciences Authority (HSA) announced lower fees for medical devices brought under the Special Authorisation Routes (SAR) to facilitate greater access to unregistered medical devices necessary to fulfil unmet medical needs. This includes low cost, low volume medical devices.

2. The SAR allows licensed importers and healthcare professionals to import unregistered medical devices for unmet medical needs due to lack of registered alternatives under Guidance Note (GN)-26 Named Patient, and GN-27 Private Hospitals and Medical Clinics (PHMC). These would require qualified practitioner and PHMC institutions' endorsement. SAR also allows importers to import for re-export purposes, and to import for non-clinical purposes like research and training under GN-28 Import for Re-export and GN-29 Non-Clinical Use respectively.

3. The revised fees for SAR are part of the enhancements to the medical device regulatory framework announced earlier this year to expedite access and manage regulatory costs for medical devices. Healthcare professionals and the medical device industry, particularly the Small and Medium Enterprises, had provided feedback to HSA that the current fees charged for GN-26 and GN-27 are high for some products in comparison to the cost and volume of the products which they import. Hence, as part of HSA's review, a survey was sent to all doctors, dentists and importers on the specific low cost and low volume medical devices that they use or import, including the cost and annual volume of the items.

4. Following streamlining and enhancement of the processes for the SAR routes, the SAR routes have been re-costed and the revised fee structure shown below will be implemented on 1 August 2012:

SAR Types	Current Fees ($)	New Fee Structure ($)
GN-26 (named-patient) *Requests by healthcare practitioners to import unregistered medical devices for use in specific named patients due to lack of registered alternatives.*	500	**150**
GN-27 (PHMCA licensed facility)	500	**350**

SAR Types	Current Fees ($)	New Fee Structure ($)
Requests by licensed importers to import unregistered medical devices for use in specific PHMC-licensed healthcare institutions due to lack of registered alternatives.		
GN-28 (import for re-export) *Requests by licensed importers to import unregistered medical devices for re-export purposes.*	500	**250**
GN-29 (non-clinical use) *Requests by licensed importers to import unregistered medical devices for non-clinical purposes e.g. exhibition, training purposes, in-vitro diagnostic medical devices for research-use only purposes, etc.*	500	**250**

5. "Taking into account concerns expressed about access and cost issues and to ensure that medical devices continue to be optimally available for patient care, HSA has further streamlined processes for reviewing and approving SAR applications. This is reflected in the lower SAR application fees that we are implementing," said Dr Raymond Chua, Group Director of HSA's Health Products Regulation Group.

6. "AMDI welcomes the revision of the fees for the Special Authorisation Routes by HSA to make it more affordable for SME. It clearly shows that HSA listens and understands the industry. AMDI will continue to work with HSA to review on the medical device framework," said Mr Henry Tan, President of Association of Medical Device Industry (Singapore).

7. To ensure that GN-26 and GN-27 will not be inappropriately used to by-pass registration of medical devices, HSA will be refining the application criteria for devices eligible for the SAR routes following further engagement with industry and healthcare professionals. This will enhance the SAR application system in terms of consistency and clarity.

8. "I am pleased to know that HSA is taking steps and finding solutions to address certain issues that the industry is presently facing. This announcement on fee revisions will certainly benefit many companies. Singapore Manufacturers' Federation (SMa) looks forward to continue working closely with HSA to regularly review and enhance the regulatory framework for medical devices to ensure appropriate use of these routes," shared Ms Jane Fong,

Committee Member of SMa Medical Technology Industry Group, an industry group of SMa.

9. The medical device regulatory framework will continue to be reviewed and further enhanced.

HEALTH SCIENCES AUTHORITY
SINGAPORE
2 AUGUST 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.