Singapore eases registration of devices

SINGAPORE: Manufacturers of dental impression materials, surgical instruments or abutments breathed a sigh of relief when the Singapore Health Science Authority (HAS) recently announced that it would lower its regulatory requirements for low risk medical devices, Dental Tribune Asia Pacific has learned. Registration fees for Class B products like dental abutments and scaling systems will also be lowered soon, the government agency responsible for medical product regulation said.

Beginning in May, manufacturers of Class A devices will only be required to register their devices with HAS for the purposes of market monitoring. The registration fees for approximately 5,400 Class B products will be reduced from $82,500 to $81,600 from September. According to the HAS, about 70 per cent of all medical devices registered in Singapore currently fall under Classes A and B.

“The changes reflect a flexible and responsive regulator that is willing to listen to the concerns of the industry and that HAS will continue to enhance the framework to facilitate access to safe medical devices.”

Dr Amy Khor Lean Suan, Minister of State at the Ministry of Health, said: “I am confident that these enhancements, for lower-risk devices in particular, will address the concerns of the industry and that HAS will continue to enhance the framework to facilitate access to safe medical devices.”

Since 2008, medical devices, including dental equipment, have had to be registered with the HAS. Prior to that, regulation was voluntary and followed international regulatory standards, like those of the US Food and Drug Administration. The guidelines had continuously sparked unrest among importers and doctors over the past few years who blamed the regulations for preventing medical and dental professionals from using state-of-the-art equipment and for increasing health-care costs.

The restructured regulations will benefit dental manufacturers. (DTI/Photo courtesy Koelnmesse, Singapore)

First vitamin B12 toothpaste

A German natural cosmetics manufacturer has launched a toothpaste that could benefit people unable to absorb vitamin B12 from food. Developed in partnership with the German Vegetarian Union, the toothpaste allows the absorption of the essential nutrient through the oral mucosa.

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