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 sealing 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 5,600 Class B products will be reduced from S$2,500 to S$1,400 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 organisation said that it will look into revising fees for Special Authorisation Route registrations and regulations for higher risk Class C and D devices.

“These changes reflect a flexible and responsive regulator that is willing to listen to the criticisms issues faced by the industry with the introduction of medical device regulation in Singapore, without compromising patients’ well-being,” Dr Amy Khoo 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 have 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.

Shorter service period for Malay grads

Owing to the increasing number of dental professionals graduating from universities, the Malaysian Dental Council has recently approved a reduction in the period of the compulsory national service for dental graduates in the country.

Instead of three years, graduates will have to serve the government for only 24 months in the future, Ministry of Health officials said during the launch of Colgate Oral Health Month 2012 in Bandar Utama last month.

According to statistics released by the Ministry of Health earlier this year, the number of dental graduates has increased by 400 per cent in the last decade. In 2011, 415 graduates registered with the Malaysian Dental Council. With the shorter period, the government hopes to keep graduates enrolled in government service.

Of the more than 4,000 dentists currently practising in Malaysia, almost 60 per cent work in the public sector.

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.

GC, Unison buys Showa Yakuhin

One of Japan’s largest dental products manufacturers GC has acquired Showa Yakuhin Kako through private equity firm Unison Capital. The Tokyo-based pharmaceutical company was put on sale by majority shareholder Tokyo Marine Capital last month and is currently estimated to be worth US$850 million.

High hopes for regulatory head

The Australian Dental Industry Association (ADIA) has called on the Therapeutic Goods Administration (TGA) in Canberra to free the industry from unnecessary regulatory burden with regard to dental goods. In view of the recent appointment of Dr John Skerritt as new head of the country’s body for medical device regulation, ADIA emphasised that future regulatory reform should not be implemented at the cost of patients.

TGA is in charge of the regulation of most of the goods available on the country’s AUS$4 billion (US$14 billion) dental market. Skerritt, who currently holds an administrative position in the Victorian government, was appointed new national manager by the organisation’s board last month. He will assume duties at the end of May.