Dear reader,

Daniel Zimmermann

Being a dental trade journalist, I usually come to visit a lot of trade shows during the year. On many occasions I have heard Western manufacturers to complain about the registration of dental products in Asia.

While things have somehow improved in this regard, the regulatory situation here is still far from being perfect. Companies producing high-end equipment in particular find it difficult to roll-out their product simultaneously throughout the region and dentists are being forced to import devices for themselves for which they have to pay larger fees.

Unfortunately, the situation is unlikely to change in the years to come, despite efforts to establish common regional standards. It will hinder Asian professionals to keep up with international developments.

The recent sweeping changes to the dental device regulations in Singapore are certainly a welcome relief for many medical practitioners and industry players. But the changes might not necessarily be good news for all those involved, in particular, diligent companies who had taken the initiative to have their products registered before these new rules were first announced.

Firstly, there will be no refund of registration fees in respect of non-sterile Class A devices registered before 1 May 2012. It remains to be seen whether the registered non-sterile Class A devices, which now enjoy the exemption scheme, will be required in the future. An immediate question that arises is whether the registrants are still subject to the registration conditions and duties, as prescribed in the medical device regulations. For instance, must these registrants ensure that the devices comply with the prescribed safety and performance requirements, or notify HSA of any change that may affect the safety, quality or efficacy of the devices? Technically, the answer is yes, until HSA decides to amend the law.

For Class B devices, industry players may have learnt to hide their time, as it has been announced that the registration fees for this risk class of devices will be reduced from September this year. An important question is whether the registrants are still subject to the registration conditions and duties, as prescribed in the medical device regulations. For instance, must these registrants ensure that the devices comply with the prescribed safety and performance requirements, or notify HSA of any change that may affect the safety, quality or efficacy of the devices? Technically, the answer is yes, until HSA decides to amend the law.

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The message is clear: while premarket approval requirements for medical devices have been relaxed, HSA will be casting a keener eye on post-market activities.

The increase in the use of dental implants is also partly due to the developments in the design of the implants themselves and of the components available to complete the restoration. All of these advances, however, would be of little use without well-defined decision-making criteria when considering treatment in the context of either damaged or missing teeth. Accurate diagnosis is essential, and the clinicians involved must always have the aesthetic aspects of the treatment foremost in mind when dealing with sites located within the appearance zone.

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