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 by 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 dentistry.

Yours sincerely,
Daniel Zimmermann
Group Editor
Dental Tribune International

Correction
In Dental Tribune Asia Pacific No.1-2, Vol. 10, the article on page 15 about IDEM included incorrect information. This year page 15 about IDEM included incorrect information. The major changes during the year.

The recent sweeping changes to the medical 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 application 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 might have to be registered by December 2012, 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 issue has been published yet regarding the potential issues HSA might see a need to address. In any case, the recent changes do not mean that dealers manufacturing and importing products that would continue to be required to declare the list of such products in the manufacturer’s and importer’s licences and update this list biannually. “We will manage risk by putting more emphasis on post-market vigilance, compliance, audit and enforcement,” said Associate Professor John Lam, CEO of HSA.

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 or reduced registration fees can afford to be complacent. The HSA has already made it clear that dealers will continue to be required to list all such products in the manufacturer’s and importer’s licences and update this list biannually. “We will manage risk by putting more emphasis on post-market vigilance, compliance, audit and enforcement,” said Associate Professor John Lam, CEO of HSA.

The way forward

General dentistry has undergone major changes during the last 20 years, not just in the way clinicians treat their patients, but particularly in the way patients request treatment and their increased expectations of outcomes. In particular, the practice of restoring patients’ compromised teeth has become less complex in some ways, yet more challenging in others. Tooth replacement is increasingly being performed through the use of restorations supported by dental implants, and numerous elegant and predictable clinical approaches have been developed.

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 weigh the aesthetic aspects of the treatment foremost in mind when dealing with sites located within the appearance zone.

Contact Info
Yang Ing Loong is a Hong Kong-based partner of Sidley Austin, a global law firm with approximately 1,700 lawyers in 18 offices. He can be contacted at iyang@sidley.com.

Contact Info
Prof. Urs Belser is professor at the University of Geneva’s School of Dental Medicine. He can be contacted at urs.belser@unige.ch.

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First class composites
Innovative composites
Modern bonding systems
Materials for long-term prophylaxis
Temporary solutions
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