Dear reader,

Daniel Zimmermann

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

While things have somehow
improved in this regard, the reg-
sutlatory situation here is still far
from being perfect. Companies
producing high-end equipment
in particular find it difficult to
roll-out their product simultane-
ously throughout the region and
dentists are being forced to im-
pport devices by themselves for
which they have to pay larger
terms.

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 den-
tsists.

Yours sincerely,
Daniel Zimmermann
Group Editor
Dental Tribune International

Correction

In Dental Tribune Asia Pacific
No.1+2, Vol. 10, the article on
page 13 about IDEM included
incorrect information. This year
was the seventh time that the In-
ternational Dental Exhibition &
Meeting was held in Singapore.

A keener eye on post-market activities

Ing Loong Yang
Hong Kong/Singapore

The recent sweeping changes
to the medical device regulations
in Singapore are certainly a welcome
relief for many medical practi-
tioners 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 now enjoy the exemption scheme,
will be required in hde-registrations.

An immediate question that arises
is whether the registrants are still
subject to the registration condi-
tions and duties, as prescribed in
the medical device regulations.
For instance, must these regis-
trants ensure that the devices comply
with the prescribed safety and
performance requirements, or no-
tify HSA of any change that may
daffect the safety, quality or efficacy of the device? Technically, the an-
swer is yes, until HSA decides to
amend the law.

For Class B devices, industry
players may have learnt to live
their time, as it has been announced that
the registration fees for this risk
class of devices will be reduced
from September this year.

A new news 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 enjoy
the product registration exemption
or reduced registration fees can af-
ford to be complacent. The HSA has
already made it clear that dealers
will continue to be required to de-
clare the list of such products in the
manufacturer’s and importer’s licences
and update this list biann-
ually. “We will manage risk by
putting more emphasis on post-
market vigilance, compliance, audit
and endorsement,” said Associate
Professor John Liu, CEO of HSA.

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

On many occasions I have heard
of trade shows during the year.
I usually come to visit a lot
of booths, but this year I
was convinced to visit a
booth that interested
me.

Light-curing micro-hybrid composite
Universal range of application
High filler content
Excellent physical properties
Easy and fast application

Dental desensitising varnish
Treatment of hypersensitive dentine
Easy desensitisation
Fluoide release
Easy and fast application

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