

From: Brandon Bransgrove [REDACTED]
Sent: Wednesday, 26 July 2023 1:36 PM
To: Device Reforms
Subject: Re: [SEC=OFFICIAL] TGA Public consultation is now live on a proposed application audit framework for medical devices

Submission - Proposed application audit framework for medical devices.

We manufacture and sell blood glucose monitoring systems.

The TGA is not recognised by the EU, US, Japanese or Canadian health departments. There is no mutual recognition treaty for IVDs with Europe for example.

We have to fly auditors in from Europe and Japan (TUV SUD) annually, as well as randomly for so-called unannounced audits.

We have to pay for travel time (sitting in a plane) hotels meals audit time etc. For Europe the cost this year is even higher because we have to comply with the new IVDR. The quote is \$80,000 for 2 products.

These costs have been borne by us for decades. For many years the TGA promised that the IVD mutual recognition treaty was coming.

Instead for many years we were made to pay the TGA for Audits and TUV because the TGA would not accept TUV audits of Australian companies. The TGA would accept TUV audits of European companies though.

Now the TGA does accept TUV audits of Australian companies it is proposing more double ups of the auditing. Obviously that would be unnecessary and wasteful.

Here are some ideas that would help establish an IVD industry in this country, rather than strangle it;

- TGA gets trained and approved by the US FDA to do audits
- TGA gets approved as a notified body for Europe
- TGA gets approved to audit for Canada
- TGA gets approved to audit for Japan.

If TUV SUD can do it, why can't the TGA?

In addition to the TGA we have the Australian Health Dept that subsidises imported products via the National Diabetic Supply Scheme, but wont give us the same subsidy, which means we sell virtually nothing in this country anyway.

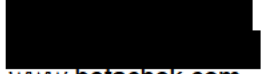
We should leave like everyone else has.

Regards,

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