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December 17, 2010

The Coordinator
Re: Comment on Reforms in the Medical Devices Regulatory Framework
Office of Devices Authorisation
PO Box 100
WODEN ACT 2606
odaconsult@tga.gov.au

Re: Reforms in the Medical Devices Regulatory Framework

Dear Sir/Madam,

Thank you for the opportunity to provide comment on the Reforms in the Medical Devices Regulatory Framework Discussion Paper. Welch Allyn Australia is unable to comment on Proposals 1 and 2 as we are currently not a licensed Manufacturer in Australia. However, we have commented on areas that could directly impacted Sponsors of Medical Devices in Australia.

Welch Allyn offers the following comments on Proposal 3 and Proposal 4 for consideration.

Proposal 3

3 Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices.

(i) amend the way in which a kind of medical device is included in the ARTG;
and
(ii) enhance the ability to identify devices that have been approved by the TGA for supply in Australia.

In response to **Proposal 3(i) – Amending the way a kind of device is included on the ARTG**, Welch Allyn understands this change and the reasons it is needed. However, consideration must be taken into the length of time taken to have medical devices added to the ARTG, including the costs involved. We recommend the following:

1. Class I products are still automatically included on the ARTG (including the required product numbers):
2. Any additional products included in that registration, should also be automatically included with a 24 hour turn around using a variation process.
3. Class I products continue under the current *Post-market vigilance and monitoring requirements* program.

The above recommendations would allow the supply of approved goods to the Australian market, but still reduce the regulatory burden on the TGA. The Sponsors requirements would continue to apply.

For Class I measure, Class IIa and Class IIb products, the following is recommended:

1. Continue using the current method for application of Manufacturers Evidence with a 2 week turn around with the relevant Certification and documentation.
2. For all Device Applications, include the relevant product codes of those that will be registered. The application fee should not change. We do not believe this would be a significant burden on the Sponsors.
3. Have a variation submission process for adding additional part numbers to products that have been issued the relevant conformity assessment documentation. This variation should be at a minimal fee.

This will allow the products to be delivered to Market in the quickest time possible, however, ensuring the products being delivered meet the Essential Requirements.

In response to **Proposal 3(ii) – Enhancing the identification of approved devices**, to apply the ARTG number of the information that accompanies a medical device. There are 2 ways that this method could be applied, both of which would add increased pressure to both the Manufacturer and the Sponsor of the goods.

This information could be supplied with the product, directly applied by the Manufacturer. However, as a number of Sponsors exist for the same products in Australia this would require the manufacturer to have knowledge of all ARTG numbers for all Sponsors. The Manufacturer would then be required to apply the relevant ARTG Number against the products being shipped to specific Sponsors. This would certainly have an impact against both the time to deliver the product to the market and also the costs involved, in particular increasing the cost of the product to Australia.

An alternative to the above would be to have the Sponsor label the product individually as they are either receipted or prepared for dispatch by the Sponsor. This would undoubtedly increase the costs for Sponsors. It is indicated on page 23 of the Reforms Discussion Paper that, Cost Implications "*should not adversely impact on regulatory costs as sponsors are already required to publish their contact details on the information that accompanies a medical device. This amendment would only require sponsors to add the ARTG number to their contact details.*"

Welch Allyn strongly apposes this proposal as this would add significant time and labor to the dispatch of the devices to the market. The current requirement to add a Sponsor Label allows us to apply 1 uniform label onto all required products on dispatch. To add the individual ARTG number to each device will require additional resources to initially identify the product and the affiliated ARTG number. We would then apply the label in accordance with section 13.2 of the Regulation.

If Sponsors/Manufacturers are to register medical devices on the ARTG and include the individual part numbers as indicated under Proposal 3(i), surely this information could be published as indicated in Proposal 4, allowing Public and Industry to easily identify the purchased part registered on the ARTG, thus removing the need for Proposal 3(ii).

Under **Proposal 4 – Publication of device product information on the TGA Website,** Welch Allyn states the following:

On a device being approved and listed on the Australian Register of Therapeutic Goods, devices of all Classes should be published and the available information include:

- the ARTG Number;
- the relevant part numbers on that device listing;
- the device class;
- the manufacturers details (address etc); and
- the sponsors details (address etc).

This information should be a direct correlation of what the Manufacturer or Sponsor applied for during the device application. This would therefore make the Sponsor or Manufacturer accountable for this information. However, the onus of ensuring the accuracy of the information is kept up to date and current, should be monitored as part of the Therapeutic Goods Administrations Post Market Surveillance protocol.

We do suggest that product applications that are declined should be kept separately and only visible to the Sponsor or Manufacturer as this may become a confusing area of the clinical or end users.

Welch Allyn appreciates the invitation to comment on these reforms.

If we can supply any additional information, please don't hesitate to contact me directly.

Yours truly,

Grant Bennett
Quality Assurance &
Regulatory Affairs Manager, Australia