Medical Devices Branch
Therapeutic Goods Administration
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WODEN ACT 2606

Email: devicereforms@tga.gov.au

Dear Madam/Sir

Accord provides this submission to the TGA's consultation: *Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia* (Consultation Paper).

Accord is the peak national industry association representing the manufacturers and marketers of formulated hygiene, cosmetic and specialty products, their raw material suppliers, and service providers. Accord member companies make and/or market fast-moving consumer and commercial goods including hygiene, cosmetics and specialty products, sunscreens, food contact sanitisers, industrial and agricultural sanitisers, household pesticides, disinfectants and specialty commercial products. Member companies include large global consumer product manufacturers as well as small dynamic Australian-owned businesses with over half our members operating as SMEs (<200 employees). A list of Accord member companies is available on our website: http://accord.asn.au/about/members.

While Accord supports in-principle the use of a UDI for high risk implantable medical devices we do not support the application of the scheme for Class 1 medical devices.

Accord supports international alignment of regulatory approaches where possible. We note that both the EU Regulation on medical devices (EU MDR) and US Food and Drug Administration (FDA) provide exclusions and/or certain exemptions for medical devices. For example, the EU MDR excludes medical devices for retail sale and adopts the same exclusion for certain other devices. The exclusion by the EU MDR releases medical devices from having batch-related flexible unique device identification.

In the US Class 1 medical devices are entirely exempt from UDI requirements if the FDA has exempted them from the good manufacturing requirements of 21 CFR 820. Class 1 devices that contain a Universal Product Code (UPC) on their labelling and packaging are deemed to meet UDI labelling requirements. A range of other general exemptions exit such as for individual single-use devices, devices used solely for research.

For Australia the TGA should consider a similar system of exemption for Class 1 devices as exists in the EU and US and recognise that Class 1 products complying with either EU MDR or US FDA requirements are deemed to comply for the purposes of Australian regulatory requirements. Australia has a robust system of product safety and mandatory recall procedures for consumer goods and the TGA should rely on these regulatory requirements for low risk Class 1 medical devices rather than creating an additional cost burden for industry.

With regard to accrediting one or more Issuing Agencies, Accord supports the process as adopted by the EU and USA which recognises a number of Issuing Agencies. Australian requirements for recognising Issuing Agents should be fully harmonised and not create any unique Australian requirements.

In conclusion, Accord does not support the adoption of a mandatory UDI system for Class 1 medical devices and encourages the TGA to consider exemptions for certain categories in line with those already recognised by the EU and US. Implementation should not precede the regulatory activities in the EU while details for the EU scheme are being finalised and be consistent with those already applying in the US.

I trust our comments are of assistance. The contact person for this matter is Ms Dusanka Sabic, Accord's Director of Regulatory Reform. Ms Sabic can be contacted on 02 9281 2322 or by email at dsabic@accord.asn.au.

Yours sincerely

Authorised for electronic submission

Bronwyn Capanna
Executive Director

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