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Monday 18 February 2019

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Attn: Medical Device Reforms Section

Dear Madam/Sir:

Sponsor comment – Proposal to introduce a Unique Device Identification (UDI) System for medical devices in Australia

Beiersdorf Health Care Australia Pty Ltd is a sponsor of therapeutic goods, including medical devices in Australia. Beiersdorf Health Care Australia Pty Ltd is a wholly owned subsidiary of its principal, Beiersdorf AG, Germany, manufacturers of medical devices presented through its iconic brand names including 'Elastoplast', 'Curitas', and 'Hansaplast' distributed globally. The range of medical devices covered range from Class I to Class III products.

We welcome the opportunity to comment on the TGA consultation proposal to introduce a Unique Device Identification (UDI) Sytem for medical devices in Australia as published by the TGA in January 2019 (TGA Publication Number D18-11349466).

Our feedback, as returned to the TGA within the consultation period is as outlined below against the questions raised:

Question 1: Do you agree with our proposal to establish the UDI System in Australia, taking the IMDRF UDI Guidance (when it is finalised) as the basis for informing Australia's regulatory and legislative requirements?

If a UDI System were to be established, then final guidance from IMDRF UDI should form its basis.

Question 2: The Australian UDI System will apply to all devices placed on the market except custom-made devices and certain other devices. For example, in Australia some products are regulated as devices while the same groups of products are not considered to be medical devices in some other jurisdictions. Also should UDI in Australia apply to Class I medical devices, particularly those other than Class Im (with measuring function) and/or Class Is (supplied sterile)? While it is highly desirable to align internationally, do you have proposals for possible exemptions from UDI requirements?

The proposed Australian UDI system should recognise that the European MDR offers an exclusion for medical devices for retail sale and adopt the same exclusion for 'certain other devices'. This exlusion in the European MDR releases medical devices from having batch-related flexible unique device identification. This exclusion could be extended to all Class I devices in Australia. Furthermore, for Class I Medical devices, no UDI should be required on artworks but instead through the manufacturer's declaration of conformity.

Question 3: It is proposed to have the power to accredit one or more Issuing Agencies. What requirements should this accreditation be subject to?

In keeping with global harmonisation, the powers proposed should be consistent with the UDF FDA (as 'Issuing Agency') and in the EU (as 'Issuing Entity'). The requirements should not introduce any unique Australian parameters.

Question 4: Sponsors will be required to have an agreement with the device manufacturer to legally enter the required UDI information into the AusUDID – what should be taken into account for making the legislative amendments to clarify these responsibilities? For example, where more than one sponsor has pre-market authorisation for the device?

To protect commercial interests, each sponsor would need to maintain an agreement with the device manufacturer. If it is the case that the same device manufacturer offers the identical device to various sponsors, it would be managed by the device manufacturer.

Question 5: It is proposed that the TGA establish and manage the AusUDID. Are there any concerns with this proposal? Are there alternative organisations that could establish and manage the AusUDID? What are the advantages and disadvantages of these alternatives?

Not directly. However, the AusUDID database should ensure it offers open data exchange with any new Issuing Agencies, for example GS1. Sponsors should have the task of ensuring correct UDID details are nominated once and this data used on a secure but open platform so that data entry is not repeatedly entered on various sites.

Question 6: What core data elements and other relevant information should be entered in AusUDID?

We do not see the need for a label to be considered as a core data element, especially for Class I medical devices.

Question 7: How should we link the ARTG and UDI database? What information should they share?

No particular comment except we continue our plea to ensure consistency with global protocols – for example, EUDAMED only connects the general product information database with incident and adverse event reporting.

Question 8: Should different transitional arrangements be implemented for different classes and categories of devices? Is the alignment with EU transitional times appropriate?

Proposed transitional arrangements must be aligned with transitional arrangements in Europe. This means recognising that the GTIN (global trade identification number, or the 'barcode') must be considered suffiient for retail-only products without any additional data matrix code requirements.

Question 9: What impacts (including unintended impacts) do you anticipate for you and other stakeholders?

Artwork changes to products will have high logistical and project-management impacts of time and company resources.

Question 10: Are there any other issues and questions we need to consider when implementing this change?

Any implementation of this proposal must remain consistent with the European MDR and avoid unique Australian requirements at all costs.

We trust these comments will be taken into consideration in the TGA's consultation exercise. Should any further information be required, please do not hesitate to contact the undersigned directly.

Yours sincerely
BEIERSDORF HEALTH CARE AUSTRALIA PTY LTD

[redacted]

Ken Lee