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Cook Medical Australia

Cook Medical, based in Bloomington, Indiana, USA, is a privately owned medical device company. Throughout its 54 year history, Cook Medical has pioneered many of the medical devices currently used to perform minimally invasive medical procedures. The company has grown to now serve 13 specialties with over 16,000 products.

Cook Medical's Australian business, Cook Medical Australia, is based in Brisbane and employs more than 500 people in manufacturing, R&D, operational and sales capacities. The Brisbane facility is also Cook Medical's Asia Pacific (APAC) headquarters and provides support for the more than 1,200 staff across the APAC region. As a manufacturer, Cook is one of only a few medical device companies that continue to utilise Australia as a manufacturing base. From this facility, Cook Medical exports Australian made products around the world. Through our R&D function, Cook Medical Australia has grown to become a centre of excellence for the design, development and manufacture of endovascular aortic devices and products designed for use in reproductive health.

Background

As a manufacturer and supplier of medical devices in Australia, Cook Medical welcomes the opportunity to comment on the consultation paper: *Proposed to introduce a Unique Device Identification (UDI) system for medical devices in Australia*. Cook Medical manufactures and distributes a wide range of medical devices globally. Therefore, while supporting the patient safety benefits of traceability and identification of medical devices, Cook Medical seeks ensure global harmonization in UDI systems and labelling requirements.

Responses to applicable questions

Questions for consideration –

- **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?**

Cook Medical Australia agrees with the proposal to establish the UDI System in Australia, and to the proposal to harmonize with the IMDRF UDI Guidance. Global harmonization is necessary to avoid unnecessary duplication and costs for devices supplied in Australia, while still ensuring that the traceability and reporting benefits of the system are maintained.

- **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?**

Cook Medical agrees that custom-made devices need to be exempt from UDI. Exemptions should be aligned internationally. For example, for single use components within a procedure pack and for individual units within a dispenser box where there is a higher level of packaging containing the UDI which is available at usage. Cook does not propose any specific exemptions from UDI requirements outside of the US and EU MDR UDI requirements.

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

The AusUDID should accept UDIs issued by any of the EU-designated and U.S.-accredited UDI issuing agencies, including GS1 GTIN, HIBC and ISBT-PPIC.

- **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 when making the legislative amendments to clarify these responsibilities? For example, where more than one sponsor has pre-market authorisation for the device?**

Cook Medical supports the inclusion of UDI specific responsibilities into the existing requirements for sponsors and that an agreement will need to be in place with the device manufacturer. The proposed linkage between the ARTG and AusUDID also supports this alignment of responsibilities.

- **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?**

As is the case in the US and EU, the UDI database, AusUDID, should be established and maintained by the regulatory authority. The benefits include accessibility of essential and relevant data to the public free of charge, and ensuring linkage to other TGA databases (ARTG, IRIS, DAEN etc.) for efficiency of maintaining data and optimising traceability.

- **What core data elements and other relevant information should be entered into AusUDID?**

The core data elements should be globally standardized, aligned to the IMDRF guidelines.

- **How should we link the ARTG and the UDI database? What information should they share?**

As the ARTG and the UDI database are to be linked, core UDI data elements which are currently captured in the ARTG should be transferred to the AusUDID, avoiding data entry duplication as much as possible. Linkage can be made, for example, by cross-referencing the ARTG ID and Unique Product Identifier (UPI).

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

The alignment with EU transition times is appropriate as many devices distributed in Australia are CE marked. It is recommended that the timelines are aligned but with an appropriate time lag to allow for industry to update internal systems and processes. There may be concerns around the timeline for a

number of devices which are a higher classification in Australia compared to Europe, provisions may need to be considered in the case.

- **What impacts (including unintended impacts) do you anticipate for you and other stakeholders?**

Most significant impacts will be greatly reduced through proposed international alignment of the UDI system. As it is mentioned that the cost will be covered in device annual fees, one impact is the potential increase in annual fees to accommodate the UDI system. This particularly impacts lower cost devices which are subject to the same requirements as higher classification and/or higher cost devices.

- **Are there any other issues and questions we need to consider when implementing this change?**

Cook Medical has no further comments or questions to consider.