Consultation: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia

Questions

• 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?

Yes, we agree that harmonization between the EU and Australian systems under the IMDRF Guidance would be beneficial in reducing costs of implementation and provide common standards.

• 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?

We would agree that for simple class I medical devices without measuring function and/or which are not supplied sterile, due to their inherent low risk profile applying a UDI would not necessarily be required.

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

We believe that the agencies should be the same as proposed within the EU and USA regulations (including e.g. GS1).

• 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?

We recommend that the same approach as in EU 2017/745 is adopted with regards to EU Representatives (included as "economic operators" in the regulation).

• 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?

We do not have enough information to respond in detail but whatever will create the simplest, most transparent and effective exchange of information will be the preferred approach.

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

In line with EU guidelines, as mentioned before, an harmonization in the treatment of information to be uploaded to the corresponding Databases (EUDAMED and AusUDID) would be desirable.

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

In line with previous response, we have no precise information at this stage to propose specific pieces of information to be shared. Nevertheless we would be in favour of any arrangement that would make the systems compatible with consistent information.

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

Yes, we consider the phased approach according to the risk class to be appropriate and would agree to implement in the same way as in the EU. Furthermore, having different implementation schemes could result in mismatch of requirements for different territories.

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

No new impacts are identified as long as the system is harmonized with those of other jurisdictions.

Maybe we could expect technical problems due to the implementation of UDI in the pack. It would be desirable to make an alignment with Serialization for Medicinal Products in order to avoid the investment in specific machinery for Medical Devices.

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

Yes. Combination products: This would include a Medicinal Product supplied with a Medical Device (e.g. syringe, dosage cup, measuring spoon). We would consider that specific marking of UDI on the Medicinal Product should not be necessary as the MP would contain both information of the MP and MD within the pharmaceutical registration dossier.

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