Australian Society of Medical Imaging and Radiation Therapy
The national professional organisation representing medical radiation practitioners
ABN 26 924 779 836

18 February 2019

Consultation: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia – January 2019

The Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) is the peak body representing medical radiation practitioners in Australia. Our aims are to promote, encourage, cultivate and maintain the highest principles of practice and proficiency of medical radiation science, always mindful that the welfare of the patient should be at the centre of everything we do.

ASMIRT would like to provide the following comments to the 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 ASMIRT feel that this is a great initiative.

- 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?

  ASMIRT believe that all devices need to be included on the Australian UDI System.

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

  To maintain standards, ASMIRT recommend that the accreditation be subject to stringent requirements that can be audited.

- 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?

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The original manufacturer should be responsible for the upload and consistent maintenance of the information relevant to their product. Sponsors/Vendors must be cognisant of the information on AUSUDID and any modifications or changes to the UDI information as it arises.

- 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?

  The TGA would be the most appropriate organisation to manage the AUSUDID.

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

  ASMIRT feel that the information entered into the AUSUDID should have information about the originating manufacturer, the vendors descriptor number, what the product is used for, the shelf life of the product, all relevant compliance data, risks relating to the medical device. This would be along the same vein as the Material safety data sheets (MSDS) that are issued with any product supplied.

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

  The two databases should share info and should be similar or contain the same information. The information should be present on both lists.

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

  Access to the 'UID' number and descriptions needs to universally available. The grouping and search engines will need to include common descriptors

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

  By introducing this system, it will make it easier to be able to identify devices – especially in Magnetic Resonance imaging (MRI) procedures where compliance is essential.

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

  ASMIRT are happy to support this proposal.

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