<18 February 2019>

Submission of comments on "*TGA Consultation: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia*"

Comments from:

Name of organisation or individual

Boehringer Ingelheim Pty Ltd

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
Q1 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, provided there is a level of consistency amongst other international guidelines.	
Q2 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?	Possible exemption: If the Medical Device is, single use and co-packed (inhaler) or is an integral part of the medicinal product (e.g. prefilled syringe or Autoinjector), as the medical device is clearly identified via the identification of the medicinal product. Additional identification with a UDI has no added value in traceability and transparency.	
Q3 It is proposed to have the power to accredit one or more Issuing Agencies.	Ideally, the same accredited issuing agency should be used internationally. Thus, medical devices that already have	

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What requirements should this accreditation be subject to?	UDIs applied can be used in an international environment. (e.g. US: GS1, HIBCC, ICCBBA)	
Q4 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?		
Q5 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?	There is no concern with the TGA establishing and managing the AusUDID. This is similar to the European Union and USFDA managing their own databases. Disadvantages of other organisations establishing and managing the AusUDID include data safety, data security and information protection.	
Q6 What core data elements and other relevant information should be entered into AusUDID?	• Information relating to the manufacturer • risk class of the device • reprocessed single-use device (y/n) • status of the device (on the market, no longer placed on the market,	

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	recalled, field safety corrective action initiated).	
How should we link the ARTG and the UDI database? What information should they share?		
Should different transitional arrangements be implemented for different classes and categories of devices? Is the alignment with EU transitional times appropriate?	Alignment with the EU timelines are highly appreciated related to the criticality of the Medical Device	
What impacts (including unintended impacts) do you anticipate for you and other stakeholders?	Administrative impact to collect and enter data into the system.	
Are there any other issues and questions we need to consider when implementing this change?	There is a need to define what information is publicly available and not available. There is also a need for timelines, in case of changes and if the database need to be updated.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	

Please add more rows if needed.