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15th February 2019
Ref: 77-tga-udi-15feb19

Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Consultation: Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia
Due Date: 18th February 2019

AbbVie Pty Ltd (AbbVie) would like to thank the Therapeutic Goods Administration (TGA) for the opportunity to review and comment on the consultation document "Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia".

AbbVie supports the proposal for the implementation of a globally harmonized UDI system in Australia.

Should you have any queries regarding this submission please do not hesitate to contact me via phone on [redacted]

Yours Sincerely
ABBVIE PTY LTD

[redacted]

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Page; Question No.	Question	Rationale or Comment
Page 16; 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?	AbbVie supports the proposal for the implementation of a globally harmonized UDI system in Australia.
Page 16; Q2	a) 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.	For products that are considered as devices only in Australia and not in other jurisdictions, clarity is sought on the availability of justified exemptions or alternative options to maintain device traceability. This added manufacturing requirement will impact the feasibility of introducing such products into the Australian market.
	b) 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)?	AbbVie is in agreement with the inclusion of Class I medical devices.
	c) While it is highly desirable to align internationally, do you have proposals for possible exemptions from UDI requirements?	At this time, AbbVie does not propose any exemptions for these requirements for our current devices and products.
Page 16; Q3	It is proposed to have the power to accredit one or more Issuing Agencies. What requirements should this accreditation be subject to?	AbbVie supports the accreditation of issuing agencies with a global reach and understanding of multiple international markets currently using UDI. Alternatively the drafting of regulations to align implementation requirements are encouraged.

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Page 16; 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?	AbbVie recommends a harmonised approach with the current US FDA's GUDID process.
Page 16; Q5	a) It is proposed that the TGA establish and manage the AusUDID. Are there any concerns with this proposal?	AbbVie supports the establishment and management of the AusUDID by the TGA, including the development of clear processes to manage any changes and, the communication and collaboration requirements with all affected stakeholders.
	b) Are there alternative organisations that could establish and manage the AusUDID?	AbbVie supports the use of the US FDA GUDID as a model, regardless of the organisation responsible for the establishment and management of AusUDID.
	c) What are the advantages and disadvantages of these alternatives?	No comment
Page 16; Q6	What core data elements and other relevant information should be entered into AusUDID?	No comment
Page 17; Q7	How should we link the ARTG and the UDI database? What information should they share?	AbbVie encourages minimal duplication of regulatory information to streamline and simplify product management for all stakeholders. Linking and sharing of information is supported to facilitate this.
Page 17; Q8	a) Should different transitional arrangements be implemented for different classes and categories of devices?	AbbVie agrees with the proposal to prioritise the implementation for higher risk products.

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	b) Is the alignment with EU transitional times appropriate?	As the EU will not confirm attribute identifiers until mid-2019, AbbVie supports staggering the enforcement requirements and the two year timeframe of transition time after these have been identified.
Page 17; Q9	What impacts (including unintended impacts) do you anticipate for you and other stakeholders?	For instances where there are changes to the UDI, it would be preferred to have a system that enables easy update to the TGA system. AbbVie expresses concern around the dependence on AusUDID system connectivity and functionality upon product management and compliance. It is noted that the US GUDID system access is compromised multiple times per month.
Page 17; Q10	Are there any other issues and questions we need to consider when implementing this change?	AbbVie recommends using the GS1 standards as the primary option, and advocates alignment with US UDI attribute identifiers.

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Specific comments on the text within the consultation document seeking clarification:

Line Number	Current Text	Proposed Change	Rationale or Comment
Page 14, Incident and adverse event reporting	Any reports of incidents or adverse events in particular must include the relevant Unique Device Identifier. Also, any corrective action will be required to include a device's Unique Device Identifier	Please clarify whether this requirement applies to "Medicine Adverse Events" which are reported to Pharmacovigilance and Special Access Branch, for combination products that include both a medicine and a device component.	If this requirement applies to "Medicine Adverse Event" report, for combination products of a medicine and a device, relevant information of the medical device investigation report, a consolidation of data from various sponsor databases would be necessary to ensure information is linked. (e.g. QA complaints database with Medicine Adverse Event report CIOMS)
Page 14, Core UDID data elements No. 23	If, applicable, critical warnings or contra-indications	It would be helpful to understand the expected timeframes around sponsor updates to AusUDID following label changes to critical warnings and contraindicationss.	Sponsor companies will need to implement processes to ensure AusUDID is updated within relevant timelines.

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Line Number	Current Text	Proposed Change	Rationale or Comment
Page 14, Core UDID data elements No. 24	Status of the device (...field safety corrective action initiated).	It would be helpful to understand the definition of a field safety corrective action initiated and the expectations of sponsor companies with respect to managing this section of AusUDID database, to ensure information is updated in a timely manner. For example, when would a field safety corrective action be considered completed, and in what timeframe should AusUDID be updated-.	Sponsor companies will need to implement processes to ensure AusUDID database is updated within relevant timelines and will therefore need to understand definitions and regulator expectations.

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