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13th February 2019

Ref: 75-tga-med-dev-reg-framework-13feb19

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

Dear Sir/Madam

Consultation: Changes to a number of definitions and the scope of the medical device regulatory framework 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 "Changes to a number of definitions and the scope of the medical device regulatory framework in Australia".

AbbVie supports the proposal to include in Australian legislation the adoption of EU definitions where no definitions currently exist. In most situations, AbbVie is aligned with the proposal to retain the current Australian definitions. There is benefit to the general public to regulate medical devices "without intended purposes" as there are some risks associated with the use of these devices which are not too dissimilar to medical devices that have been registered with "intended purposes".

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

Yours Sincerely

ABBVIE PTY LTD

[redacted]

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Questions: Definitions		
Page 10; Q1	Do you have comments about the proposed changes to the definitions (refer Appendix A)?	Yes, please refer to comments following in the table.
Table A1- The Main Definitions		
	Proposal for amendments: **"medical device"** For clarity and consistency purposes we propose that the EU definition **replaces the definition of 'medical device' in the Australian legislation.** Because, in principle, the intent of this definition in the EU MD Regulation is consistent with our interpretation of the products that are regulated as medical devices we do not anticipate any impact (rather than greater clarity and consistency) on the regulation of medical devices in Australia.	Agree to replace with the EU definition.
	Proposal for amendments: **"accessory"** For clarity and consistency, we propose that the EU **definition replaces the present definition of 'accessory' in the Australian legislation** (section 3 of the TG Act). Section 41BD(1)(b) of the Act is not proposed to be amended at this time.	Agree to replace with the EU definition.

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	Proposal for amendments: **"sponsor"** In Australian legislation, the term **sponsor** refers to an importer, exporter or manufacturer of therapeutic goods. Specifically, for medical devices the sponsor is a person in relation to whom a medical device is included in ARTG (i.e. it covers a broad range of responsibilities, while the definition of **sponsor** in the EU MD Regulation is very narrow and is only used in the context of clinical investigations of devices). Therefore, because the EU definition of 'sponsor' is substantially different to the established Australian meaning, **we do not propose to align it with the European definition.** Rather, we propose to clarify this term in the Australian legislation to mean the **sponsor** is the person in relation to whom a medical device is included in the ARTG, respectively covering all related sponsor's responsibilities.	Agree to retain the current Australian definition and for the clarification of the responsibilities in relation to medical devices included in the ARTG.
	Proposal for amendments: **"intended purpose"** The term 'intended purpose' is crucial in the context of medical devices. The intended purpose of a medical device defined in the Act is broader than the EU definition. The EU definition in addition to label and	AbbVie prefers to align with the EU definition and does not agree with the TGA proposal. As this definition deviates from the EU, AbbVie as the local sponsor, may not have visibility to the documentation required for this specific requirement (i.e. any technical documentation describing the mechanism of action of the device).

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	instructions for use, only refers to **promotional or sales materials** or material provided with a **clinical evaluation** as the source to determine the intended purpose of the device. However certain engineering and other technical documentation may provide better clarity regarding the intended purpose of the goods. For this reason, the **TGA does not propose to align** with this EU MD Regulation definition.	The engineering and technical documentation may have different intended purpose/s during the different stages of manufacture or refurbishment, especially when these medical devices are manufactured from third party manufacturers. If the medical device is to be modified in a later stage of manufacture, the intended purpose may change and therefore will not comply with the proposed Australian definition.
Table A2- Other Definitions-proposed to be reflected in the Australian legislation		
	Proposal for amendments: **"benefit-risk-determination"** Medical device regulatory requirements largely have regard to the balance between anticipated or real benefits weighed against the risks associated with the use of a medical device. Therefore in order to improve clarity and consistency and respectively compliance, the TGA proposes to define this in the Australian legislation.	Agree – The definition included in the Australian legislation will improve clarity and consistency.
	Proposal for amendments: **"clinical evaluation"** The EU definition is consistent with the interpretation of this term in Australia, and	Agree to incorporate EU definition in the AUS legislation.

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	with its use in the guidance document: Clinical Evidence Guidelines: Medical Devices. Therefore for clarity and consistency the TGA proposes to incorporate this definition in our legislation.	
	Proposal for amendments: **"implantable device"** Because the definition of **implantable device** in the EU MD Regulation and **implantable medical device** in the Australian MD Regulations are more or less consistent, we do not, on replacement of the latter with the former definition, anticipate any impact on the regulation of an **implantable medical device** in Australia. For clarity and consistency with the EU MD Regulation of an implantable device, we propose that the EU definition replaces the present definition of **implantable medical device** in the Australian legislation.	Agree to replace with the EU definition.
	Proposal for amendments: **"instructions for use"** There are numerous references in the Australian legislation to **instructions for use**, which are critical to the safe operation of a medical device, but at present the term is not defined. Therefore, for clarity and consistency, we propose to incorporate the definition of	Agree to incorporate definition in the Australian legislation and to propose for the same definition as adopted in the EU.

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	instructions for use in the Australian legislation.	
	Proposal for amendments: **"interoperability"** **Interoperability** is used in the EU MD Regulation in the revised equivalent of the Essential Principles (see Cl 14.5 of Annex 1, Chapter II, Requirements regarding design and manufacture). Specifically, Cl 14.5 requires 'Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the **interoperability** and compatibility are reliable and safe.' Essential Principle 9.1 in the Australian medical regulations presently sets out requirements for medical devices intended to be used in combination with other devices or equipment. It does not include specific requirements equivalent to Cl 14.5. However, Essential Principle 9.1 is consistent with Cl 14.5 and therefore, for clarity and to achieve consistency, it is appropriate to incorporate the EU MD Regulation definition of **interoperability** in the Australian legislation.	Agree to incorporate the EU definition in the Australian legislation.
	Proposal for amendments: **"invasive device"** Because the definitions of **invasive device** in the EU MD Regulation and **invasive**	Agree to incorporate the EU definition in the Australian legislation.

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	medical device in the Australian MD Regulations are more or less consistent, we do not, on replacement of the latter with the former definition, anticipate any impact (additional to clarity and consistency) on the regulation of an **invasive medical device** in the Australian legislation. Therefore for clarity and consistency we propose to incorporate the EU MD Regulation definition of **invasive medical device** in the Australian legislation.	
	Proposal for amendments: **"label"** The current definition of **label** in the Australian TG Act is drafted mostly having regard to the goods other than medical devices. The definition in EU MD Regulation is more or less consistent with the interpretation applied to the term label for medical devices. Therefore, we do not, on replacement of the definition, anticipate any impact (additional to clarity and consistency) on the regulation of labelling requirements for a medical device in the Australian legislation. For this reason, we propose that the EU definition of **label** (specific for medical devices) is incorporated in the Australian legislation.	Agree to incorporate the EU definition in the Australian legislation.
	Proposal for amendments: **"lay person"**	Agree to incorporate the EU definition in the Australian legislation.

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	Currently, in Australia, the concept of **lay person** is used only in reference to self-testing in vitro diagnostic medical devices (IVDs). However, with rapid innovation in the medical technology sector, consumers are being offered ever more sophisticated products and services without the oversight of a healthcare or medical professional. **Lay person** is specifically referenced in the EU MD Regulation in the revised equivalent of the Essential Principles (see Cl 22.1 of Annex 1, Chapter II, Requirements regarding design and manufacture). Clause 22 deals with the protection against risks posed by medical devices which are intended by the manufacturer for use by **lay persons**. For example, Cl 22.1 requires 'Devices for use by **lay persons** shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the **lay person's** technique and environment. The information and instructions provided by the manufacturer shall be easy for the **lay person** to understand and apply.' Additional obligations are included in Cl 22.2 and 22.3. Therefore it is proposed to incorporate this	

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	definition in the Australian legislation to ensure that the term **lay person** is well understood.	
	Proposal for amendments: **"reprocessing"** The EU MD Regulation states in Article 17 that **reprocessing** and further use of single-use devices may only take place where permitted by national law and in accordance with that Article. In the Australian context, it somewhat relates to the State and Territory regulations which are generally guided by Australian Standard 4187 and AS/NZS 4815. There is no intention to change this situation, and this consideration is not within the scope of our proposals. The introduction of this definition in our legislation, may however add clarity to the **reprocessing** process. For this reason, the TGA proposes to incorporate this definition.	Agree to introduce the EU definition in the Australian legislation.
	Proposal for amendments: **"risk"** At present in the Australian MD Regulations, **risk** is used, but not defined, and takes its ordinary meaning. **Risk** is referred to extensively in the Australian MD Regulations, including in the Essential Principles in Schedule 1, and in the classification rules (Schedules 2 and 2A).	Agree to incorporate the EU definition in the Australian legislation.

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	Therefore for clarity and consistency the TGA proposes to incorporate the EU definition of **risk** in the Australian legislation.	
	Proposal for amendments: **"single-use-device"** Devices for a single use are currently referred to in the Essential Principles in Schedule 1 of the Australian MD Regulations, which require that information about whether a device is intended for a single use only is provided with the medical device, and with the instructions for the use of a medical device. The EU MD Regulation refers to **single-use devices** principally in relation to the **reprocessing** of such devices, in Article 17. The TGA proposes to incorporate this definition for consistency and to provide greater clarity on the kinds of devices which will qualify as **single-use devices**.	Agree to incorporate the EU definition in the Australian legislation.
	Proposal for amendments: **"user"** The term **user** is currently used, particularly in the Essential Principles in Schedule 1 of the Australian MD Regulations. For consistency and clarity the TGA proposes to incorporate the EU definition in the Australian legislation.	Agree to incorporate the EU definition in the Australian legislation.

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Table A3- Definitions not proposed to be aligned with		
	Proposal for amendments: **"adverse event"** There is no specific definition of **adverse event** in Australian legislation, although section 41MP of the Act and Regulation 5.7 of the Australian MD Regulations detail information about device malfunctions and other events which must be provided to the TGA, and the timeframes within which the information must be provided. The EU MD Regulation definition of **adverse event** is limited to the clinical investigation of a device. However in Australia, the term **adverse event** has already an established meaning, encompassing the entire life cycle of a device from clinical investigation to use and withdrawal from the market. For these reasons, the TGA proposes not to adopt the EU definition of **adverse event.**	Agree to not adopt the EU definition.
	Proposal for amendments: **"CE marking of conformity or CE marking"** The EU MD Regulation uses this term in the context of requiring manufacturers to affix **CE marking of conformity** to medical devices as a public demonstration that relevant third party assessment (or, in the case of Class I medical devices, self-assessment) has been undertaken,	Agree to not adopt the EU definition.

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	however there is no such requirement in Australia. The Australian legislation does not require devices to carry CE marks, rather any medical device (unless exempt) must be included in the ARTG in order to be able to be legally imported, exported and/or supplied in Australia. Therefore this definition is not required in the Australian legislation.	
	Proposal for amendments: **"common specifications"** Article 9 of the EU MD Regulation gives the European Commission authority to prepare a **CS** where no **harmonised standards** exist, where the relevant **harmonised standards** are considered insufficient, or where there is a need to address public health concerns. In Australia, the legislation does not refer to **common specifications**. However, section 41CB of the Act gives the Minister powers to establish medical device standards. It is taken that this power is similar in intent to common specifications and therefore it is **unnecessary** to define this term in the Australian legislation. Further, **common specifications** are most likely to be dependent on the public health concerns in a particular regulatory jurisdiction, and these concerns may	Agree to not adopt the EU definition.

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	somewhat vary between Australia and the EU. Future EU **common specifications** will be considered for relevance in the Australian context prior to being adopted into our domestic requirements. The TGA proposes not to adopt this definition.	
	Proposal for amendments: **"conformity assessment"** The Australian definition of **conformity assessment** is more appropriate in the Australian context, which differs from the EU context in several legal and constitutional respects. For this reason, the TGA proposes not to adopt this EU definition.	Agree to not adopt the EU definition.
	Proposal for amendments: **"conformity assessment body"** A conformity assessment body is defined in the Australian legislation in the context of requirements for Australian conformity assessment bodies. This term is also used in context of the use of overseas regulator conformity assessment documents for the purposes of inclusion medical devices in ARTG. Therefore this term has somewhat different legal meaning in Australia, and for this reason, TGA proposes not to adopt	Agree to not adopt the EU definition.

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	this definition.	
	Proposal for amendments: **"distributor"** In accordance with the Australian legislation this function is to be performed by either a **sponsor** themselves or by another person (physical or legal) on behalf of the sponsor. For the definition of 'sponsor' refer the Act, section 3. Specifically this definition (among other things) refers to a person who exports, imports or manufactures the goods on behalf of another person, and this definition provides that such person is not a sponsor. Which effectively implies that any person (physical or legal) who distributes the devices **on behalf of the sponsor**, is not within the scope of the TG Act, and **all responsibilities regarding a medical device remain with the sponsor.** However, any person **who wants to legitimately distribute** (i.e. supply) **medical devices on their own initiative** (i.e. not on behalf of another person who is the sponsor) **must include the device in the ARTG** themselves, and become the sponsor. This is further explained in Act, Division 3, Part 4-11 - Medical devices not included in the Register and related matters. The concept of **sponsor** has a well-established meaning in Australia with the	Agree to not adopt the EU definition.

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	well-defined responsibilities for a medical device. TGA does not propose to change the regulatory role of the sponsor, and for this reason (in general terms) considers that incorporating the definition of **distributor** in the Australian legislation may not be necessary.	
	Proposal for amendments: **"falsified device"** Many penalty provisions in the Act are drafted with reference to **counterfeit** therapeutic goods, particularly section 42E, which sets out a criminal offence of manufacturing, supplying, importing or exporting counterfeit therapeutic goods in or from Australia. Section 42EA provides for a civil penalty for the same offence. Section 61(4A)(fa) empowers the Secretary to release, to certain bodies, therapeutic goods information relating to cases or possible cases of counterfeit therapeutic goods. **Counterfeit** is a concept with a well-established history in the Australian therapeutic goods context and internationally, and for this reason the TGA proposes not to adopt this EU definition, and to retain the Australian terminology of **counterfeit.**	Agree to not adopt the EU definition.
	Proposal for amendments:	Agree to not adopt the EU definition.

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	"fully refurbishing" **Fully refurbishing** is defined, but not used, in the EU MD Regulation, although two references to **refurbishing** are made in Annex VI, relating to the UDI system (regarding which we will be consulting separately). Regulation 1.5 of the Australian MD Regulations provides a comprehensive definition of **refurbishment** and gives specific examples of activities which may constitute **refurbishment**. This more detailed definition is intended to give manufacturers, hospital staff and consumers, better understanding of their obligations. Accordingly, the TGA proposes not to adopt this EU definition.	
	Proposal for amendments: **"harmonised standard"** The Australian legislation has a provision that allows determination of certain standards for the purposes of demonstrating compliance with the Essential Principle and conformity assessment procedures. This definition therefore may not be consistent with the established meaning in our legislation; therefore the TGA proposes not to adopt this terminology.	Agree to not adopt the EU definition.
	Proposal for amendments:	Agree to not incorporate the EU definition.

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	"health institution" The term 'health institution' in its general meaning is well-understood in the Australian context, and therefore it does not appear to be necessary to explicitly define it. Therefore the TGA proposes not to incorporate this definition in our legislation.	
	Proposal for amendments: **"importer"** TGA does not propose incorporating the definition of an **'importer'** for the same reasons as outlined for item (34) **'distributor'.**	Agree to not adopt the EU definition.
	Proposal for amendments: **"making available on the market"** This definition currently falls within **supply** as defined in section 3 of the Act, which applies to all types of therapeutic goods, and has a well-established meaning in the Australian therapeutic goods context. The Act contains numerous references to **supply**, particularly in relation to criminal offences and civil penalties for the supply of medical devices. For this reason TGA proposes not to adopt this EU definition.	Agree to not adopt the EU definition.

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	Proposal for amendments: **"notified body"** This definition is only required in the context of the use of comparable overseas regulatory approvals and defined in this context. TGA does not propose to adopt this definition.	Agree to not adopt the EU definition.
	Proposal for amendments: **"performance"** In accordance with the Australian legislation, the meaning of performance of the device is as intended by the manufacturer. Therefore it does not appear to be necessary to include a separate definition for the performance. For this reason, the TGA does not propose to adopt this definition.	Agree to not adopt the EU definition.
	Proposal for amendments: **"placing on the market"** The TGA proposes not to adopt this EU definition for the same reason as for item (27) 'making available on the market'.	Agree to not adopt the EU definition.
	Proposal for amendments: **"putting into service"** The TGA proposes not to adopt this EU definition for the same reason as for item (27) 'making available on the market'.	Agree to not adopt the EU definition.

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	Proposal for amendments: **"recall"** **Recalls** of medical devices are already provided for by section 41KA of the Act. This section, read together with the (URPTG), sets out a comprehensive procedure for the **recall** of all types of therapeutic goods by Commonwealth, State and Territory governments. At present the word recall is not defined in the Act however has a well-established meaning. For this reason the TGA proposes not to adopt this definition.	Agree to not adopt the EU definition.
	Proposal for amendments: **"serious adverse event"** This EU definition of **serious adverse event** is limited to the clinical investigation of a device. The term **serious adverse event** already has an established meaning in the Australian setting and denotes a broader concept that is not limited to the device trial/investigation phase. There is currently no definition of **serious adverse event** in Australian legislation. However, expectations around reporting of adverse events are prescribed in the Australian MD Regulations, and Regulation 5.7 details adverse events that will require reporting, i.e. this term has a well-established meaning. For this reason, the TGA proposes not to	Agree to not adopt the EU definition.

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	adopt the EU definition.	
	Proposal for amendments: **"withdrawal"** At present, the word **withdrawal** is not defined in the Act, but rather has a broadly accepted ordinary meaning when the device is no longer available on the market. As the term **withdrawal** has an established meaning, the TGA does not propose it is necessary to define this term.	Agree to not adopt the EU definition.
Page 10; Q2	Are you a consumer, patient, consumer advocacy group, healthcare provider, industry stakeholder, industry representative body or other?	Industry stakeholder
Page 10; Q3	Will you be affected by the proposed definition changes? If yes, how?	Yes, AbbVie is the sponsor of medical devices included in the ARTG.
Page 10; Q4	What benefits or disadvantages might be there for patient, consumer or public health and safety in these proposed definition changes?	Benefits to all stakeholders with regards to the provision of definitions not previously available in TGA legislation, as it assists with compliance and providing clarity for documentation preparation.
Page 10; Q5	If you are an Australian business, please provide information on potential impacts relating to these changes including: –the number of products affected –benefits or disadvantages related to the safety and performance of your products –changes to administrative or regulatory obligations of sponsors	No substantial impact.

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	–any operational impacts on your business –costs that these changes may impose on your operations.	
Questions: Products without intended medical purpose		
Page 10; Q6	Are you a consumer, patient, consumer advocacy group, healthcare provider, industry stakeholder, industry representative body or other?	Industry Stakeholder
Page 10; Q7	Are you affected by the proposal to regulate as 'medical devices' a prescribed list of specified groups of products that don't have an intended medical purpose? If yes, how?	AbbVie is not impacted.
Page 10; Q8	What benefits or disadvantages are there for patients, consumers or public health and safety in regulating specified products without an intended medical purpose as medical devices?	The benefits to patients/consumers or the public is ensuring that there is a level of assurance that products without an intended purpose are safe to use and have similar requirements applied to as medical devices with intended purposes. This will reduce the risks that patients/consumers or the public are exposed to.
Page 10; Q9	Would a prescriptive list of specified products that do not have an intended medical purpose regulated as medical devices simplify the regulatory expectations around such products?	This list would be helpful to reduce any ambiguity and provide clarity. In addition, any lists for exempt products should be included on one consolidated list.
Page 10; Q10	If you are an Australian business, please provide information on potential impacts relating to these changes including:	Increasing the scope of legislative oversight will increase regulatory burden on sponsors and manufacturers. It will also demand increased

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	–the number of products affected –benefits or disadvantages related to the safety and performance of your products –changes to administrative or regulatory obligations on sponsors –any operational impacts on your business –costs that these changes may impose on your operations.	resources and time from the TGA. Clarification is sought on any foreseen changes in legislative timelines for evaluation for new products, changes to products or discontinued products. If there are kits/packs/products with multiple 'devices', the ability to combine applications so that they may be evaluated and approved together would be helpful for sponsors. For products with no intended medical purpose, clarity on whether these products would qualify for exemptions or have the option available for an abridged approval route would be helpful.

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