20 April 2020
Reg ref: 86-scope-of-regulated-software-based-products-02apr20

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

Closing date: 13 May 2020

Dear Sir/Madam

CONSULTATION: Scope of Regulated Software based products

AbbVie Pty Ltd welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) consultation on the Scope of Regulated Software Based Products.

Overall, AbbVie acknowledges that there is a need for clarity regarding what should be classified as a software-based product that requires regulatory oversight (vs. those that should be exempted/excluded). AbbVie supports continued convergence with international requirements in the interest of reducing local regulatory burden. Many multi-national organisations responsible for supplying medical devices in Australia, often as part of a mixed portfolio of pharmaceuticals and devices, rely on the use of evidence of assessment from the EU, for example. It is noted that the TGA strives to be broadly aligned with other Regulators, but additional definitions are proposed, e.g. whether or not the software is intended for use by a healthcare provider (EU regulation is more stringent in this case), whether the software is intended for creating virtual anatomical models (not regulated in the EU). Such deviations will potentially lead to increased regulatory burden and possibly inadvertent confusion for the Sponsor regarding whether a product does or does not comply with the Australian essential principles when an EC certificate is utilised.

Subsequently, AbbVie highlights that any divergence from global regulatory requirements, including classification rules as per definitions and intended use (especially with the EU) can counter the TGA's objective of reducing unnecessary regulatory burden.

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Please see AbbVie's position below for the specific questions outlined in the TGA's consultation document:

• What kinds of software-based products should be exempted from inclusion in the ARTG? What are they and why should they be exempted?

AbbVie is aligned with the TGA's proposal that any software-based products that are considered as medical devices (by definition), but do not pose significant harm to the individual (e.g. through inappropriate use or failure of the product) and/or for which an alternate mechanism of oversight is in place be exempted from inclusion in the ARTG. The preference is to consider the EU's approach to the exemption of software in order to promote consistent assessments for device inclusions between Australia and the EU whilst striving toward reducing toward unnecessary regulatory burden.

• What kinds of software-based products should be excluded from regulation by the TGA? What are they and why should they be excluded?

AbbVie proposes that software products carrying an intended use or claim that does not include a therapeutic purpose and thus, falls outside the scope of the definition of a medical device, should be exempted from inclusion in the ARTG. This is a similar approach adopted by the EU. This includes any products that are to be used **solely** for educational or general information purposes, displaying of recording information, managing data, enabling communication and encouraging healthy lifestyles. AbbVie notes and is aligned with the TGA's list of intended purposes that are not considered to fit the definition of a medical device and thus are also considered exempt, as per pages 13 to 15 of the consultation paper. In the instance of medication/adherence, AbbVie proposes that the list of examples also include medication reminders (for example, smartphone notifications, calendar reminders).

On the topic of software-based products that are intended to be used for monitoring only (and do not provide any form of diagnosis), AbbVie proposes that these should not be classified as medical devices. For example, a paper-based questionnaire is not considered as a device but may be classified as one if it were included in a software program. Additionally, AbbVie considers it appropriate that the scope of proposed exclusion/exemption of software that are used for monitoring purposes be broadened beyond mild/self-limiting conditions. The same rules can be applied for all conditions if the software serves to track symptoms and does not provided any diagnosis, but rather aids the

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user with understanding their symptoms or tracking information to provide to their healthcare professional. This would align with the definition of a medical device.

• Please provide details of any existing regulatory oversight that you consider would negate the need for the TGA to regulate particular software-based products; or describe what evidence or product characteristics could be used to determine that particular types of software pose no potential for significant harm to an individual.

Software-based products that are already embedded into medical devices and serve to control the means in which the device operates (e.g. operating software within an infusion pump) would have existing regulatory oversight with respect to the medical device itself (and the Manufacturer's obligations to comply with registration details and Essential Principles). In these situations, further regulatory oversight of the software itself would not be required. Software that is driving or influencing the use of a medical device is covered by the regulations either as a part/component of a device or as an accessory for a medical device. If the software product is stand-alone, then the user interface (and any materials provided with the product) should provide appropriate disclaimers such that the 'output' of the software does not pose significant harm to the individual (e.g. recommendations are for guidance only, and should not be used solely for the purpose of making a clinical decision or diagnosis). Evidence to support this could be considered as a product characteristic in determining the level of risk.

• Which approaches from international jurisdictions, if any, should be used to inform the Australian approach to this issue?

AbbVie considers the guidance materials released by both the EU and Health Canada to be acceptable sources of reference in developing an Australian approach, given that both guidance documents incorporate IMDRF recommendations. Alignment with EU regulations would also allow for the continued use of certifications issued by MDR-certified EU notified bodies as evidence to support registration listings in Australia in lieu of conformity assessments for applicable classes. AbbVie reiterates that potential impact on local regulatory burden should definitions lead to different classification rules, given a significant number of local Sponsors rely on EU evidence. The guidance document published by Health Canada would be useful in developing inclusion/exclusion criteria for requirements for regulation by the TGA and could provide useful in developing a decision tree to assist Sponsors.

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Additional Comments:

AbbVie supports the TGA's proposal regarding "clinical decision support software" possibly being excluded or exempted from regulation so long as it's not intended for the Healthcare Professional to solely rely on any recommendation generated by the software to make a clinical decision, and meets the criteria detailed in page 16 of the consultation document. AbbVie would recommend the provision of a decision tree to allow Sponsors to use as a source of defining whether such software would require listing on the ARTG given the number of criteria that must be addressed. This is especially important given that the regulatory definition of a medical device involves the prevention, diagnosis or treatment of a disease or condition.

It is also noted that the consultation documents speak to both "*excluding*" and "*exempting*" software products, with no clear guidance on which is applicable for each circumstance. Given that there is a difference in the extent of required regulatory oversight (e.g. Suppliers of *exempted* products must report adverse events to the TGA and are subjected to conditions proposed to be prescribed in the Regulations), it is important that the guidance provides clarity to Sponsors on devices that would fall under each classification category, to differentiate between those that fall outside the scope of legislation (exclusion), and those that fall within but do not require entry onto the ARTG (exemption). As mentioned above, the availability of a decision tree on the TGA website will assist Sponsors in understanding the appropriate category for which a software product is classified (much like the existing decision tree available for determining appropriate classes for medical devices). Furthermore, AbbVie seeks clarity from the TGA on whether excluded products will be listed anywhere on the TGA's website for reference purposes. Additionally, will the TGA be introducing a formal process for requesting software-based products to be excluded/exempted? Or is the expectation that Sponsors complete their own assessment and maintain evidence to support these?

On a broader note, the current TGA guidelines for device classification rules are subjective and can lead to different regulatory assessments. AbbVie welcomes the opportunity for the TGA to revise and possibly introduce additional tools that will help provide further clarity and which devices (including software based products) require inclusion on the ARTG, and appreciate the provision of specific examples and reasons for exemption and exclusion, where applicable.

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