16 October 2019

[redacted]

Medical Devices Reform Unit
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Closing date: 17 October 2019

Dear Sir/Madam

CONSULTATION: Proposed clarification of the regulatory requirements for medical device systems and procedure packs

AbbVie Pty Ltd welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) consultation on proposed clarification of the regulatory requirements for medical device systems and procedure packs (SOPPs).

AbbVie has reviewed the consultation document and provided comments in the form of annotations directly on the document. Please find it attached to this cover letter.

AbbVie also provides responses to each of the questions below.

Questions

1. Do you support the proposals for change in this document, why or why not? In particular:

(a) the proposed definitions -system, procedure pack, and compatibility

(b) the proposed changes to the special conformity assessment procedure set out in Regulation 3.10 and Clause 7.5, Schedule 3, of the Australian MD Regulations

(c) the adequacy of the requirements for Records specified in Clause 7.6, Schedule 3, of the Australian MD Regulations, for SOPPs using the special self-declared conformity assessment procedure,

AbbVie Pty Ltd
ABN 48 156 384 262

Level 7, 241 O'Riordan Street
Mascot NSW 2020
Australia

+61 0438 913 682 (OFFICE)
+61 2 9035 8741 (FAX)
abbvie.com

AbbVie's response

AbbVie is supportive of the TGA's proposal to introduce changes as proposed in points (a), (b) and (c), in the interest of aligning with EU requirements. AbbVie has a number of comments with regards to the examples provided under 'procedure packs' within the consultation document. Please refer to the attached annotated document.

Furthermore, AbbVie proposes to introduce additional clarification under the requirements for SOPPs that are *medical devices used for a special purpose*, that manufacturers of such packs have the option of performing testing to demonstrate that any manipulation of processing of individual device components within an SOPP does not have any adverse effect on the device's ability to perform as per its intended use. This would be *in lieu* of a written agreement between the SOPP manufacturer and the original manufacturer of the original device. An annotation to this effect is included in the attachment.

2. If you do not support the proposed changes, do you have any suggestions for an alternative way to improve regulation of these medical devices?

AbbVie's response

AbbVie is supportive of the proposed changes. To assist Sponsors, AbbVie suggests that the TGA provide useful tools online to determine whether an SOPP can be regarded as a medical device used for a special purpose (as per Regulation 3.10), so that the appropriate evidence can be sourced and kept on file for auditing purposes.

3. If the proposed amendments take effect, what impacts—including any that we may not have anticipated and are therefore unintended—do you anticipate the requirements may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?

AbbVie's response

Upon the proposed amendments taking effect, AbbVie anticipates that Sponsors that currently supply SOPP's which contain devices that are above Class 1 will need to re-assess the availability of adequate evidence (in the form of conformity assessments either with the TGA or with a recognized international body or regulator), particularly with respect to those that would fall within the definition of *a medical device used for a special purpose*.

AbbVie Pty Ltd
ABN 48 156 384 262

Level 7, 241 O'Riordan Street
Mascot NSW 2020
Australia

+61 0438 913 682 (OFFICE)
+61 2 9035 8741 (FAX)
abbvie.com

Sponsors will also need to undertake additional consideration when determining how future SOPP's should be registered (either with evidence or through self-declaration assuming it meets eligibility criteria). AbbVie does not foresee significant impact on the end user.

4. Are there any groups/categories of systems or procedure packs (e.g. - IVD systems, orthopaedic loan kits) that should be given particular consideration?

AbbVie's response
AbbVie has no comment regarding this topic.

5. Are there any further issues and questions we should consider when implementing these changes (including areas that can/should be clarified in our guidance)?

AbbVie's response
As per AbbVie's response to Question 3, online tools to assist Sponsors in determining whether a proposed SOPP meets the requirements of a medical device used for a special purpose would be of great benefit.

6. Do you have any comments regarding the transitional arrangements proposed in this paper?

AbbVie's response
AbbVie has no further comments as this stage.

Please feel free to contact the undersigned if you would like further clarification on any aspect of this submission.

Yours sincerely
ABBVIE PTY LTD

[redacted]

[redacted]

AbbVie Pty Ltd
ABN 48 156 384 262

Level 7, 241 O'Riordan Street
Mascot NSW 2020
Australia

+61 0438 913 682 (OFFICE)
+61 2 9035 8741 (FAX)
abbvie.com