Regulatory Affairs Department Australia/New Zealand
Pfizer Australia Pty Ltd
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Submission to the TGA's consultation on the proposed clarification of the regulatory requirements for medical device systems and procedure packs – Version 1.0 September 2019

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

In particular:

(a) the proposed definitions – system, procedure pack, compatibility

(b) the proposed changes to the special conformity assessment procedures 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.

Pfizer supports the proposals for change in this guidance document as the purpose of the proposals is to be consistent with the EU, and the document appears to achieve that goal.

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?

No comment.

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.)?

No comment

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

No comment

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)?

In relation to the Declaration of Conformity (DoC) – Clause 7.5, it would be helpful to include an explanation in relation to the "SOPP manufacturer". Specifically, where a SOPP is assembled from ready-made products by a third

party contract manufacturer for the person whose name the SOPP is supplied under, please clarify which party is considered to be the legal manufacturer of the SOPP, and which party is required to self declare compliance through the Australian DoC.

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

No comment