Submission to TGA consultation: Proposed changes to the medical device Essential Principles for safety and performance

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Submission Information

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Comments

On behalf of the Johnson & Johnson Family of Companies, we appreciate the opportunity to provide comments on the Therapeutic Goods Administration (TGA) proposed changes to the medical device Essential Principles for safety and performance.

It should be noted that we have contributed to and broadly support the submission made by the Medical Technology Association of Australia (MTAA). Our response to the questions posed in the consultation paper is provided below.

1. Do you agree with the proposal to update the Australian Essential Principles to:

a. align with the IMDRF Essential Principles and Labelling documents?

We do not support alignment with the IMDRF Essential Principles (EPs) but rather the General Safety and Performance Requirements (GSPRs) specified in the European Union (EU) Regulations. The majority of medical devices supplied in Australia leverage CE approval, so we believe alignment with the IMDRF principles will likely lead to regulatory divergence and increased regulatory burden for manufacturers and sponsors. Although the IMDRF EPs appear to capture all the requirements from the EU GSPRs, the difference in wording will likely lead to differences in interpretation.

We also oppose mandating compliance to the IMDRF labelling requirements which will likely introduce unique requirements and limit our ability to leverage globally harmonised labelling.

Recommendation Twenty from the Government's response to the Review of Medicines and Medical Devices Regulation recommends that the regulation of medical devices, wherever possible and appropriate, align with the EU framework. Unless the TGA confirm that compliance with the EU GSPRs is equivalent to the proposed revised Essential Principles and the manufacturer does not have to address a separate set of principles, this proposal will not be aligned with the Government's recommendation.

b. include relevant additional details captured by the General Safety and Performance Requirements in the EU MD and IVD regulations?

As above, we support complete alignment with the EU GSPRs. The EU GSPRs provide the additional clarity needed in the current framework and support improved safety and performance of medical devices.

2. Do you agree with the proposal to provide additional clarity regarding expectations for compliance as specified under Proposal 2?

We support providing additional clarity on existing requirements but caution becoming overly prescriptive and decreasing flexibility in how manufacturers demonstrate compliance.

3. Do you agree with the proposal to restructure the Essential Principles and Labelling requirements for clarity and readability?

Alignment with the IMDRF EPs, whether in content or in structure, at the expense of alignment with the EU GSPR would result in a departure of Australian medical device regulations from alignment with the EU medical device regulations. We support restructuring the TGA Essential Principles to align with the EU GSPRs.

4. Do you agree with the proposal that software medical devices without any physical packaging should include the ARTG number on the electronic label?
Are there other devices where the ARTG number should be provided?

We do not agree with the proposal to include the ARTG number on the electronic label for software medical device. The rationale "to make it clear under which ARTG entry the device will be supplied" does not apply to medical devices below Class III so it is unclear why this should apply to all software regardless of class. Software medical devices without physical packaging should be treated in the same way as any other medical device.

Furthermore, the EU does not require regulatory approval numbers on labelling so this would not promote global convergence and introduce a unique Australian labelling requirement.

5. What financial or other effects—including any that are unintended—do you anticipate the changes to the Essential Principles may have for yourself, your business, and other stakeholders (such as consumers, healthcare professionals, health organisations, industry, etc.)?

Differences between the EU GSPR and TGA EPs will require the manufacturer to review a separate set of principles and address any gaps. The costs will be dependent on the work required to address these gaps and provide documented evidence.

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

The TGA have proposed a 6 month transition for new devices post the EU Medical Device Regulation (MDR) implementation i.e. November 2020. However, we believe a minimum of 12 months is required to cover new devices which are CE marked just prior to the MDR deadline of May 2020 and will not have been assessed against the EU GSPRs.

7. Are there any further issues, questions, or requirements we should consider when implementing this change (including areas that can/should be clarified in our guidance)?

Please clarify the intent of adopting the IMDRF EPs rather than considering complete alignment with the EU GSPRs.

Johnson & Johnson appreciates the ongoing engagement and opportunity for input to the TGA's regulatory reform. Should you have any questions regarding our consultation feedback, we welcome the opportunity to discuss further.