

31 October 2019

Medical Devices Branch  
Therapeutic Goods Administration  
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Dear Medical Devices Branch

**Re: AusBiotech's response to the TGA's proposed changes to the medical device Essential Principles for safety and performance**

AusBiotech is pleased to provide comments to the Therapeutic Goods Administration (TGA) in response to its proposed changes to the changes to the medical device Essential Principles for safety and performance.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology (devices and diagnostics), food technology, industrial and agricultural biotechnology sectors. Within AusBiotech, the medical device and diagnostic industries are represented by AusMedtech, an industry group dedicated to the development, growth and prosperity of the Australian medical technology industry.

The AusMedtech Regulatory Affairs Expert Panel (ARAEP) is a subcommittee of AusMedtech, providing expert advice on operational and policy-related regulatory matters. This response has been led by the Panel and its Chair, Grant Bennett.

## Response to Questions

AusBiotech is supportive of measures that further enhance patient safety and, therefore, supports the TGA's implementation of its suite of reforms to enact Australia's response to the Review of Medicines and Medical Devices Regulation.

The TGA has sought feedback in relation to a number of questions set out on Page 13 of the consultation document. Our recommendations are as follows:

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

- a. align<sup>1</sup> with the IMDRF Essential Principles and Labelling documents?

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<sup>1</sup> Considering the Australian regulatory and legal context.

*No: The IMDRF Essential Principles are highly complex and do not bring any additional assurance of safety or efficacy when compared to the EU General Safety and Performance Requirements (EU GSPR). They are difficult to understand and our member feedback includes concerns that it will be difficult to demonstrate compliance with these principles.*

*Furthermore, since the EU GSPR represent the state of the art at this point in time, our members have indicated a strong recommendation that the principles do not place additional compliance requirements over and above those outlined in the EU GSPR. Given the global nature of the sector, members already adhere to the EU GSPR. Harmonisation is an important goal that the TGA and industry share, yet we do not consider that applying an additive approach is consistent with this goal. Therefore, we question why the Australian Regulation should be the sum of all the requirements, instead of simply and more reasonably, adopting the best and most relevant ones.*

*Adding all these requirements, from different sources, would increase the overall burden (time and cost) of regulatory compliance, which seems contrary to the “benefits of proposed changes” listed by the TGA in the consultation paper.*

- b. include relevant additional details captured by the General Safety and Performance Requirements in the EU MD and IVD regulations<sup>2</sup>?

*Yes: As noted in the TGA proposal, most of the devices included in the ARTG are based on CE marking. Furthermore, the EU MDR GSPR currently represents best practice in terms of requirements to demonstrate safety and efficacy of medical devices. For these two reasons, it makes sense to adopt the EU GSPR in the Australian Regulation.*

*However, we recommend that when adopting the EU GSPR, the TGA should not change or modify the intent or wording of these principles. For example, making it mandatory to include a “summary of safety and clinical performance” in the IFU of all devices (as per Appendix 1, page 16 of the TGA proposal) would be an additive requirement when the EU MDR only request this type of information for Class III and implantable devices.*

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

*While AusBiotech supports initiatives to provide additional clarity on compliance expectations, the corresponding proposed changes are not sufficiently described in the TGA proposal to enable a clear view regarding how these proposals deliver additional clarity. AusBiotech would welcome further discussions on this point, but at this stage do not believe that the details included allow for a comprehensive answer to this question.*

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

*Yes: These are workable and worth pursuing.*

**4. Do you agree with the proposal that software medical devices without any physical packaging should include the ARTG number on the electronic label?**

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<sup>2</sup> As compared with the IMDRF documents.

*No: Implementing such a change would be an additional burden for manufacturers, with minimal benefit. Any additional requirements related to the ARTG, because they are specific to Australian goods, add some complexity for any manufacturer providing goods (or intending to provide goods) for markets beyond Australia. Therefore, the benefit to complexity ratio should be carefully considered, including in the context of other options and initiatives.*

*Notably, the TGA has shared its plan to implement a Unique Device Identification (UDI) system, which will introduce a unique identification for all medical devices, including software, making the need for including the ARTG number redundant. There is no doubt that the UDI database to be implemented in Australia will make the link between each device UDI and ARTG entry number.*

*Furthermore, the ARTG number is currently not provided on 'physical' medical devices and it is not clear why a differential approach would be considered.*

*Such a requirement would be a new burden for the industry and present no actual benefits for users.*

Are there other devices where the ARTG number should be provided?

*As above, AusBiotech considers the efforts made by the TGA and other stakeholders regarding the UDI system may overcome the need to consider applying the ARTG number. At least, it is suggested that exploring the inter-relationships between the UDI approach and the ARTG number addition before making changes to the requirements for ARTG number application, would be worthwhile.*

**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.)?**

*If the new requirements are aligned with the European requirements, and the timing for implementation is reasonable, it is anticipated that the additional burden (while it will be high), will not be different from the EU MDR burden. Given the global focus of the sector, the additional costs of these changes need to be made for the EU market, and could therefore be "absorbed".*

*AusBiotech considers, however, that the requirements outlined in the paper that are additional to those required elsewhere, place new costs for business that are solely for Australian compliance purposes. It does not appear that there are benefits being realised by other stakeholders, such as patients, that would enable these costs to be considered reasonable.*

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

*The proposed transitional period seems reasonable. It would be helpful to receive further clarity from the TGA when the "four years for transition" would start for medical devices included in the ARTG before the date of amendment.*

*It will also be important to consider these transitional arrangements in the context of any other changes, so that multiple changes are not overly burdensome at a single point but also are efficiently applied.*

**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)?**

*n/a*

AusBiotech and its ARAEP appreciate the opportunity to respond to this consultation.

If relevant, the industry would appreciate advance notice of implementation of the changes and the opportunity to comment on any subsequent amendments proposed. AusBiotech looks forward to working with the TGA on behalf of its members in relation to further consultations on possible changes to Australia's medical device regulatory framework.