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MTAA Submission to TGA consultation:

Proposed changes to the medical device Essential Principles for safety and performance

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1. Executive Summary

On 5th September 2019, the TGA opened the consultation: *Proposed changes to medical device essential principles for safety and performance*. This consultation, as stated by the TGA, "focuses on the proposed changes to the essential principles for safety and performance of medical devices. The changes set out in this consultation are intended to facilitate better regulatory compliance and consequently improve safety and quality of medical devices, through alignment with international best practice."

The proposed changes are intended to align with the EU Medical Device Regulation (MDR) 2017/745 wherever possible and appropriate, in accordance with Recommendation Twenty of the 2015 Report of the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) which made 58 recommendations for reforming the therapeutic goods regulatory framework[1]. Recommendation Twenty (reproduced below) is one of the 56 Report recommendations endorsed by the Government.

> ***Recommendation Twenty***
>
> *The Panel recommends that:*
>
> 1. *The regulation of medical devices by the Australian NRA is, wherever possible, aligned with the European Union framework including in respect of the:*
>
>   A. *Classification of medical devices;*
>
>   B. *Essential Principles/Requirements.*
>
>   C. *Adoption of a risk-based approach to variations to medical devices.*
>
> *Should the Australian NRA seek to apply specific requirements, there must be a clear rationale to do so.*

MTAA supports alignment with the EU MDR wherever possible and appropriate. MTAA supports the proposals outlined in the TGA consultation paper except Proposal 4 to include the ARTG number in the information provided with SaMD without any physical packaging.

MTAA's responses to Questions (page 13 in the TGA consultation) and our detailed comments are provided in the next pages.

[1]Expert Review of Medicines and Medical Devices Regulation - The Department of Health website, accessed 16/09/2019: https://www1.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation

2. MTAA responses to questions

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

a. *align [considering the Australian regulatory and legal context] with the IMDRF Essential Principles and Labelling documents?*
b. *include relevant additional details captured by the General Safety and Performance Requirements in the EU MD and IVD regulations [as compared with the IMDRF documents]?*

In your answer, please provide reasons for your position.

MTAA supports alignment with the EU medical device regulations wherever possible and appropriate. The great majority of devices included in the ARTG rely on a CE Marking approval and we expect this to continue after the EU transitions to the new MDR.

Therefore, we support the adoption of the EU General Safety and Performance Requirements (GSPR), including those that are currently not in the IMDRF Essential Principles and Labelling requirements (Appendix 2 in the TGA consultation document). The adoption of the EU GSPR into Australian medical device regulations should be implemented after an appropriate transitional period from the EU implementation. The proposed timelines for implementing the revised Essential Principles are:

- 6 months from the May 2020 EU implementation deadline, i.e., starting from November 2020 in Australia, for new medical devices to be included in the ARTG following successful completion of an application submitted to the TGA on or after the commencement date of the amended regulations;
- 4 years transitional period for applications for ARTG inclusion submitted to the TGA before the date of the proposed amendment takes effect (November 2020).

Compliance with the IMDRF Labelling requirements not in the EU GSPR (Appendix 3 in the TGA consultation document) should be optional, because the IMDRF guidance documents are voluntary not mandatory.

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

In your answer, please provide reasons for your position.

MTAA believes that additional clarity in the 6 areas listed under Proposal 2 (page 10 of the TGA consultation document) will help manufacturers and sponsors generate and obtain the required information for applications, which in turn will shorten the time to approval.

Additional clarity should however not degenerate into overly prescriptive requirements regarding the methods to achieve compliance. TGA should provide clarity regarding expected outcomes for compliance in guidelines but should allow for flexibility in relation to the methods to achieve those outcomes. This would allow companies to achieve compliance by adopting the most effective and efficient solutions for their specific situation.

Specific requirements such as those for infection and contamination control should align with existing international standards.

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

In your answer, please provide reasons for your position.

MTAA position with regards to medical device regulations has been to maintain alignment with the EU medical device regulations, therefore we recommend restructuring of the Essential Principles for non-IVD medical devices according to the GSPR in the EU MDR.

We do not support alignment with the 2018 IMDRF version of the EPs (Appendix 4 of the TGA consultation document) because the IMDRF EPs have not been adopted by any major jurisdiction such as the EU or U.S.

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.

The IMDRF countries themselves have not adopted the IMDRF EP's in their legislation yet, therefore there are no benefits for Australia to align the EPs with the IMDRF. If and when all the IMDRF regulators adopt the Essential Principles, the TGA then can revisit the matter and consider harmonization with the IMDRF EPs.

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?

In your answer, please provide reasons for your position.

This proposal assumes that software medical devices without any physical packaging would be better controlled if their e-label include the ARTG number, i.e., "to make it clear under which ARTG entry the device will be supplied". It is not clear why this assumption is being made, as currently only Class III devices/ AIMD can be individually traced to specific ARTG entries. All other device classes - I, Is, Im, IIa and IIb - are entered in the ARTG as *kind of devices*, hence there is no direct traceability between device designation and a particular ARTG entry.

Historically the TGA has not required sponsors to include the ARTG number on the labelling of medical devices or medical device packaging. This has been consistent with international best practice, as neither the European Commission nor the U.S. FDA require manufacturers to include regulatory approval numbers (EC Certificate of Conformity number and the PMA or 510k number respectively) on the device labelling or IFU.

In addition, due to the comparably small size of the Australian medical device market (2% to 3% of global market), it is questionable whether the additional costs of maintaining Australian-only versions of labels and IFUs can be justified.

Software medical devices without physical packaging should be treated in the same way as any other medical devices. They should be identified by software release, version and revision (the software equivalent of model designation) and included in the ARTG as kind of devices if their risk classification is I, IIa or IIb.

Implementing an UDI database in Australia will ensure traceability between model designations and ARTG entries for medical devices classified as I, Is, Im IIa and IIb. Further details are available in the joint MTAA, IVD Australia [currently Pathology Technology Australia], ADIA and AusBiotech policy paper titled *UDI implementation in Australia, May 2018*.[2]

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.)?*

MTAA members have been consistent in their position that Australian medical device regulations should continue to align with the EU medical device regulations wherever possible and appropriate.

Australian-only or -specific requirements should not be adopted unless duly justified to protect the safety and well being of patients and users, otherwise they only add to the cost and time of making medical devices available to patients and users without any added value. It has been our understanding that the TGA agrees with this approach.

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

Introducing the revised Essential Principles in November 2020 would allow for a time lag of approximately 6 months from the EU MDR implementation deadline of May 2020 for new medical devices (please refer also to the BSI figure with MDR transition timelines).

MTAA members have indicated that having less than 12 months transition period for new applications is not enough, especially for manufacturers who are not transitioning to the EU MDR. For example, a sponsor wanting to include a medical devices in the ARTG after November 2020 will need more than 6 months to obtain the updated technical documentation from the manufacturer showing compliance with the new EU MDR GRSPs.

We would like to recommend a case-by-case approach to enforcing deadlines for new device applications after November 2020, as not every application will rely on an existing EU MDR approval.

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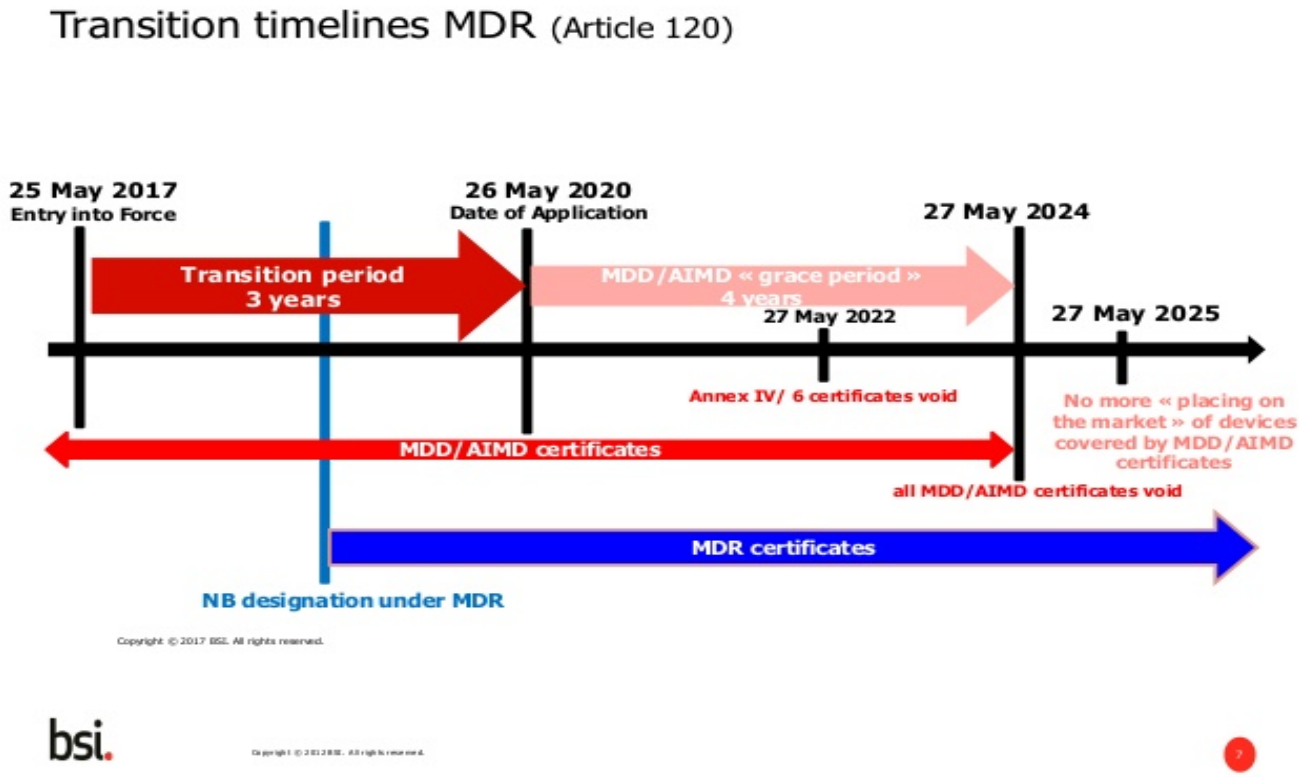
[2] Joint MTAA, IVD Australia, ADIA and AusBiotech Policy Paper: UDI implementation in Australia, May 2018: https://www.mtaa.org.au/sites/default/files/uploaded-content/field_f_content_file/201805_joint-mtaa-ivda-adia-ausbiotech_policy_on_udi_implementation_in_australia.pdf



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)?

MTAA has no further issues, questions or requirements with regards to implementing changes to the Essential Principles.

We would like to thank the TGA for engaging with industry in shaping the future regulation for medical devices in Australia.