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17th October 2019

Medical Devices Reform Unit
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Via Portal or e-mail: devicereforms@health.gov.au

Dear Sir/Madam

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

On behalf of Becton Dickinson (BD), we appreciate the opportunity to provide comments to the Therapeutic Goods Administration (TGA) on the above consultation.

Responses to the specific questions posed in the consultation document are 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?
   b) Include relevant additional details captured by the General Safety and Performance Requirements in the EU MD and IVD regulations?

BD Australia does not agree with aligning with IMDRF EP or Labelling, however would consider the inclusion of certain IMDRF concepts into an alignment with the European GSPR framework following further consultation.

A majority of medical devices and IVDs currently included in the ARTG are/will be supported by European Conformity Assessment Certificates. Therefore, alignment of the Australian Essential Principles with the General Safety and Performance Requirements (GSPR) of the EU Medical Device Regulations (MDR) and In Vitro Diagnostics Regulations (IVDR) is appropriate wherever possible.

Importantly it must be noted that the IMDRF Labelling requirements and IMDRF Essential Principles are voluntary in nature and may not be appropriate in some regions, inclusive of Australia where additional requirements are a burden on a small trade zone unless providing a significant improvement in safety.

BD Australia is part of a multinational company whom set up their products, design, development and labelling to be inclusive of as broad a requirement as possible. However local nuances occur from time to time, and when this becomes restrictive in nature, the cost is pushed back to the country. The local employment or rework cost of Australia's economy should not be disregarded but rather understood against whether any additional requirements provide significant additional benefit or not.

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

BD supports the provision of additional clarity under Proposal 2. However, we recommend that TGA consults with the industry on the proposed additional clarity, to ensure there is flexibility in relation to how manufacturers achieve compliance to the six areas identified in Proposal 2. Overall, the requirements should align with existing international standards as much as possible; implementation, inclusive of location within Regulation, should be consulted and not immediately assumed by general acceptance of this proposal.

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

BD are in partial agreement in relation to the restructure of the Australian Essential Principles to maintain alignment with the respective GSPR of the EU Medical Device Regulations (MDR) and In-Vitro Diagnostics Regulations (IVDR). However, we do not support alignment of the Australian Essential Principles with IMDRF Requirements as per response provided to Question 1.

Equally we do not support the explanatory note seen in Proposal 3 where the Labelling requirements are suggested to be pulled out of the Essential Principles and placed elsewhere in Regulations (similar to that seen by the IMDRF voluntary pathway). This may lead to controversy if not confusion around whom is responsibility for the "information to be provided" in relation to the safe use of a device. The international manufacturer has always seen labelling as part of the design and development of their device, not a separate country step in a separate checklist; if as the Manufacturer reviews additional labelling requirements they determine it adds no value to their globally distributed product the extra requirements will become a country/importer cost.

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

BD does not support the proposal for inclusion of ARTG details on electronic labelling of software medical devices without any physical packaging. Proposal 4 would result in the departure of the Australian medical device regulations from alignment with the EU MDR and IVDR along with FDA and Health Canada. In order to maintain consistency with other major international regulatory best practice (USA, Canada, Europe) and considering the relatively small size of the Australian medical device market in comparison to the global market, BD disagrees with Proposal 4.

BD is aware through industry forums and workshops that there is a technological movement to GTIN/UDI based databases that are a significant benefit to various departments within healthcare, as well as the industry and consumer groups, when properly supported. Such databases would allow association with marketed products and their ARTG.

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.)?

Adoption of Australian specific requirements that are not in alignment with the EU MDR and EU IVDR unless duly justified as an undertaking to protect the well-being of Australian patients and users will result in significant additional costs and have an impact on the timely availability of medical technology.

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

BD strongly recommends that TGA provides a minimum of 18 months transition period from the date of application of EU MDR and EU IVDR, i.e 18 months from May 2020 and May 2022 respectively.

Allowing only a 6-month transition as currently proposed by TGA is not enough for sponsors to obtain the remediated technical documentation from manufacturers to support the new applications.

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)?

BD strongly recommends that the changes to the text in the Australian Essential Principles should clearly distinguish between the requirements for medical devices and IVDs.

As iterated in responses to questions 1 to 6, BD supports the alignment of the Australian Essential Principles with the General Safety and Performance Requirements (GSPR) of the EU Medical Device Regulations and In Vitro Diagnostics Regulations wherever possible and appropriate. However, we wish to re-iterate that we do not support the inclusion of the IMDRF Essential Principles/Labeling Requirements or any Australia specific labelling requirements such as the inclusion of the ARTG details on the e-labelling for software medical devices without any physical packaging.

BD appreciates the ongoing engagement and opportunity for input to the TGA's proposal for changes to the Australian Essential Principles. Should you have any questions regarding our consultation feedback, we welcome the opportunity to discuss further.

Yours Sincerely

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