Medicines Australia

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

Dear Sir/Madam

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

Medicines Australia welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) proposals in relation to changes to the medical device Essential Principles.

Our submission has been prepared with the expert input of Medicines Australia's Regulatory Affairs Working Group (RAWG). Members are selected for their regulatory experience and industry knowledge, and bring a whole-of-industry perspective to the consideration of regulatory issues that stand to impact to our sector. Our feedback on the specific questions included in the consultation paper are contained in Attachment 1.

Medicines Australia represents the medicines industry, whose primary focus is developing registered medicines which may require use of devices to assist administration or to undertake companion diagnostic tests to facilitate patient selection for personalised medicines. In this context ensuring flexibility of the regulatory framework for evolving technologies such as cell and gene therapies and increasing use of companion diagnostics for personalised medicines is important. As members operate globally, aligning requirements with internationally accepted standards such as in the EU is important, as this will facilitate companies in Australia having ready access to relevant conformity assessment documents to reduce regulatory burden and red tape. In anticipation of Brexit it will also be important to ensure any requirements support uninterrupted supply where the UK may be part of an existing supply chain and provide clarity to Sponsors on the expected steps to be taken.

[redacted] We look forward to hearing from you regarding the outcome of this consultation.

Yours sincerely

[redacted]

Dr Vicki Gardiner

Director of Policy and Research

Medicines Australia

Questions

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?**

In your answer, please provide reasons for your position.

Medicines Australia supports the proposed updates that will ensure alignment with the international standards established under IMDRF. The adoption of international standards simplifies regulatory compliance and reduces regulatory burden by allowing use of common documentation across jurisdictions. The existing Comparable Overseas Regulator pathway essentially already follows this approach.

As noted in the consultation paper the majority of devices supplied in Australia rely on EU conformity assessments. Medicines Australia members operate globally and are thus currently in the process of implementing the changes required under the EU Medical Device Regulations, in accordance with the agreed transition period. On this basis adoption of the additional General Safety and Performance Requirements as per the EU regulations are acceptable. Nonetheless, based on a number of practical challenges that have arisen with implementation of the new Regulations in the EU, it is important that there is a proactive process for ensuring that any evolving changes are rapidly considered to ensure continued alignment of the Australian and EU frameworks. This is essential to avoid any unique Australian requirements.

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.

Medicines Australia agrees that further clarification of the regulatory expectations to assist Sponsors to achieve compliance is a helpful approach that industry will value.

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.

Medicines Australia agrees with the proposed restructure on the basis that it provides a clearer framework for identifying the key principles and those specific to different device types. This will assist Sponsors in navigating the relevant requirements to ensure all relevant information is taken into account when preparing a submission. Alignment with the EU approach will also facilitate communication of Australian requirements to personnel in global headquarter functions who are responsible for authoring relevant submission documentation. This in turn will further assist compliance and facilitate inspections utilising the Medical Device Single Audit Program (MDSAP).

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

Medicines Australia supports inclusion of the ARTG number to facilitate identification of approved software based on options that are practically feasible dependent on how the software is supplied. Inclusion of the ARTG number on electronic labels or as part of the product description on the site where software is available for download from a website represent practically feasible options.

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

In your answer, please provide reasons for your position.

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.)?**

On the basis that the proposed amendments will support international convergence of technical requirements, no unique Australian requirements will be introduced and there will be a pragmatic and practical approach to alignment of transition periods. This will enable continuation of use of Comparable Overseas Regulator pathways and the additional burden for local Sponsors will be minimised, as the impact will primarily be at a global headquarter level.

Regardless, a comprehensive communication plan to enable other stakeholders to understand the rationale for the proposed changes and the potential implications in the event a particular device is no longer deemed suitable for supply in Australia needs to be in place before the changes are implemented. This will help to avoid unhelpful media reporting and enable patient support groups to be prepared and assist in developing any communication plans so that they feel included and involved in the process.

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

It should be clarified that the transitional arrangements start from the date of inclusion of the device on the ARTG. As per the EU transition periods, devices should be allowed to remain on the market for one year after the EC certificate becomes void.

Transitional arrangements also need to ensure that there is flexibility to maintain alignment with the EU. For example, use of the Comparable overseas regulator pathway based on EU evaluation reports should still be acceptable in Australia post the implementation of the amendments to the regulatory framework. A commitment should be made by the Australian Sponsor that updated documentation subject to the EU transition periods will also be submitted in Australia.

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)?**

Any considerations relevant to Brexit should be proactively communicated to Sponsors to ensure continuity of supply.