Medicines Australia

Medical Devices Branch
Therapeutic Goods Administration
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Dear Sir/Madam

Consultations on Medical Devices

Medicines Australia welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) consultations relevant to Medical Devices as follows:

- Changes to a number of definitions and the scope of the medical device regulatory framework in Australia
- Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia
- Potential reclassification of active medical devices for diagnosis and patient therapy

Whilst Medicines Australia primarily represents the innovator medicines industry, with the increasing number of biological medicines administered by injection, products are often supplied with an administration device. These may be separate devices or integrated as part of the medicine delivery system. Similarly, companion diagnostics may be developed to allow patient selection to ensure optimal clinical outcomes for new medicines.

In this context Medicines Australia considers that the key criteria for any changes to the current regulatory framework for medical devices is to retain internationally harmonized requirements, such that there are no unique or additional technical requirements in Australia beyond those required in the EU. Changes to definitions in the Australian regulatory framework and introduction of a new classification rule for active medical devices to align with the EU MD Regulation is therefore supported. In addition, the implementation of the proposed UDI, following the principles of the IMDRF UDI working group, is also supported to maintain an internationally harmonized approach.

Transitional arrangements for implementation should also follow timelines overseas, so that any new requirements are not adopted in Australia prior to the EU. This is important for the many Sponsors who rely on recognition of EU device regulation approvals for supply of products to Australia.

On the basis of these key principles additional detailed comments have not been provided for each consultation.

Yours sincerely,

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Dr Vicki Gardiner

Director, Policy and Research

Medicines Australia