Medicines Australia

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

Dear Sir/Madam

Consultation: Proposed clarification of the regulatory requirements for medical device systems and procedure packs

Medicines Australia welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) proposals in relation to clarification of the regulatory requirements for medical device systems and procedure packs.

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.

As Medicines Australia represents the medicines industry, who primarily utilise procedure packs to assist in the administration of a registered medicine, it will be important to ensure the perspectives of industry associations, such as the Medical Technology Association of Australia (MTAA) and Pathology Technology Australia, who represent the device industry, are taken into account to create a fully fit for purpose scheme. Ensuring flexibility for evolving technologies such as cell and gene therapies and increasing use of companion diagnostics for personalised medicines is also important. 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.

For further information or clarification on any element of our submission, please contact Betsy Anderson-Smith on banderson-smith@medaus.com.au. We look forward to hearing from you regarding the outcome of this consultation.

Yours sincerely

Vicki Gardiner

Dr Vicki Gardiner

Director of Policy and Research

Medicines Australia

1. **Do you support the proposals for change in this document, why or why not?**

In particular:

(a) the proposed definitions -system, procedure pack, and compatibility

Medicines Australia agrees that the proposed changes to the definitions are appropriate and improve clarity of the guidance.

(b) the proposed changes to the special conformity assessment procedure set out in Regulation 3.10 and Clause 7.5, Schedule 3, of the Australian MD Regulations

Medicines Australia has no objections to the proposed changes to the special conformity assessment procedure, noting that Medicines Australia members primarily utilise procedure packs to assist administration of a registered medicine. These typically represent a low risk category, with components being in a finished market ready state and not subject to significant processing such as re-sterilisation procedures.

(c) the adequacy of the requirements for Records specified in Clause 7.6, Schedule 3, of the Australian MD Regulations, for SOPPs using the special self-declared conformity assessment procedure

The required retention period for documentation of at least 5 years from the date of manufacture is considered to be adequate.

2. **If you do not support the proposed changes, do you have any suggestions for an alternative way to improve regulation of these medical devices?**

Medicines Australia has no objections to the proposed changes in the context that Medicines Australia members primarily represent the medicines industry who utilise procedure packs to assist administration of a registered medicine.

If the proposed amendments take effect, what impacts—including any that we may not have anticipated and are therefore unintended—do you anticipate the requirements may have for yourself and other stakeholders (such as consumers, healthcare professionals, health organisations, industry etc.)?

Overall the changes proposed increase international alignment and provide clarification of requirements. As noted above, since Medicines Australia members primarily utilise procedure packs to assist administration of a registered medicine, the impacts of the changes for these types of goods are not considered to have any major unintended consequences.

3. **Are there any groups/categories of systems or procedure packs (e.g. - IVD systems, orthopaedic loan kits) that should be given particular consideration?**

The proposals for changes are appropriate for the types of system or procedure pack (SOPPs) typically supplied by MA members. However, considering the rapidly evolving treatment paradigms in the area of oncology, consideration needs to be given to ensure changes will accommodate:

- Cell and gene therapies that may have more complex requirements
- The increasing use of companion diagnostics or personalised medicines

4. **Are there any further issues and questions we should consider when implementing these changes (including areas that can/should be clarified in our guidance)?**

In anticipation of Brexit clarification on any specific requirements relevant to UK sourced devices should be addressed for Sponsors.

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

The transitional arrangements seem reasonable for the types of SOPPs typically supplied by MA members.