ResMed

October 17, 2019

Australian Government
Department of Health
Therapeutic Goods Administration
Submitted online and to devicereforms@tga.gov.au

Re: Comments on September 2019 Consultation: Proposed changes to medical device Essential Principles for safety and performance

ResMed appreciates the opportunity to provide comments to the Therapeutic Goods Administration (TGA) on the above captioned Consultation. We appreciate that the TGA intends to bring Australian regulations into alignment with the IMDRF guidance documents and the European Union (EU) Medical Devices Regulations (MDR). This is beneficial for Australian patients and harmonized medical device regulations provide efficiency opportunities for device manufacturers.

Company Overview

ResMed develops, manufactures, and markets medical devices and cloud-based software applications that diagnose, treat and manage sleep apnea, chronic obstructive pulmonary disease, and other respiratory conditions. ResMed Pty Ltd is one of only a few medical device companies that continues to utilise Australia as a manufacturing base. From our facility in Bella Vista (NSW), ResMed exports Australian made products to more than 120 countries around the world and employs approximately 1400 Australians, who make a positive change in people's lives.

Responses to 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?

ResMed welcomes and supports the alignment of the Australian Essential Principles to the IMDRF Essential Principles and Labelling documents. ResMed assumes that the scope of these changes will be identical to the IMDRF documents. For example, the requirement to include a bibliography or reference section in instructions for use will be limited to IVD devices.

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b. include relevant additional details captured by the General Safety and Performance Requirements in the EU MD and IVD regulations?

ResMed welcomes and supports the alignment of the Australian Essential Principles to the EU MD and IVD regulations.

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

ResMed welcomes and supports any additional clarity regarding the TGA's compliance expectations.

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

ResMed supports the restructure of the Essential Principles and Labelling requirements.

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

As a manufacturer of cloud based software, ResMed does not support the inclusion of the ARTG number on the electronic label of software. To include the ARTG in the electronic label of software would require the ARTG number to be known prior to completing product development, yet a prerequisite for applying for an ARTG listing is the declaration from the device manufacturer that the device meets Australian regulations and that the Essential Principles have been met.

ResMed understands and supports the intent of the TGA's proposal to ensure that software medical devices without any physical packaging are included on the ARTG prior to being available on the Australia market. This could be achieved by utilising the proposed Australian UDI database since these software medical devices would need a UDI visibly displayed within the software.

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.)?

Aligning the Australian regulations to the European medical device framework and the IMDRF guidance documents should provide efficiency opportunities for device manufacturers. ResMed anticipates a significant amount of administrative work to update medical device design history files for devices already listed on the ARTG, so welcomes the longer proposed transition period for these devices.

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

ResMed has concerns with the proposed compliance timing for new medical devices (i.e November 2020). This is likely to restrict access to new medical devices for Australian patients in the short to medium time period. Currently, only five notified bodies have been designated under the EU MDR which is creating a bottleneck for manufacturers to be certified. If Australian Sponsors are intending to use conformity assessment evidence from a EU Notified Body to support ARTG listings (i.e the most commonly used evidence), then access to new medical devices for Australian patients will be restricted until the bottlenecks in Europe are resolved.

ResMed supports the extended transition timing of 4 years for devices already with an ARTG listing.

ResMed appreciates the opportunity to comment on the proposed changes to the Essential Principles for safety and performance. We look forward to working with the TGA to ensure the sustainability of the Australian regulatory system for medical devices and timeliness of patient access to medical devices.

Sincerely,

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Johanna Wright
Director Regulatory Affairs

ResMed Pty Limited 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia
T +61 (2) 8884 1000 **F** +61 (2) 8884 2000 **E** contact@resmed.com.au **ABN** 30 003 765 142 **ResMed.com**