RESMED

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Reforms in the Medical Devices Regulatory Framework

Purpose

The purpose of this document is to provide ResMed's comment and input to a consultation by the TGA on Reforms in the Medical Devices Regulatory Framework in Australia.

Background

ResMed is a leading developer, manufacturer and marketer of products for the screening, treatment and long-term management of sleep-disordered breathing (SDB) and other respiratory disorders. ResMed operates in over 68 countries via 18 direct offices and a network of distributors with extensive knowledge and experience of local markets.

ResMed provides comprehensive treatment solutions including masks, airflow devices (CPAP, automatic and bilevel), homecare ventilators, patient monitoring systems and screening tools.

Within Australia, ResMed both manufacture and distribute medical devices. The majority of these devices are classified as "Medium Risk" Devices.

All comments provided are from the perspective of a medium risk device manufacturer and distributor operating in Australia. Comments will be provided as direct responses to the questions posed in the TGA consultation paper, *"Reforms in the Medical Devices Regulatory Framework".*

Response

1. *Reclassification of joint replacement implants*

A new classification rule is added to Schedule 2 of the medical device Regulations to reclassify all hip, knee and shoulder joint replacement implants from Class IIb to Class III medical devices.

Due to the scope of activities undertaken by ResMed, this question is not currently applicable.

2A. Use of third party assessment bodies for Australian manufacturers

That Subregulation 4.1(1) is removed from the medical device Regulations, so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification.

ResMed supports this proposal. The current approach of restricting Australian medical device manufacturers to TGA conformity assessment certification is overly burdensome for companies like ResMed that manufacture in Australia and distribute both locally and internationally.

If a company has been assessed by a recognised notified body to allow CE Marking of medical devices in accordance to the Medical Device Directive (MDD) certification and they both supply locally and export, they should not require a TGA conformity assessment. In

reality, the audit and certification requirements for both sets of regulations are essentially identical, with only minor changes between the requirements for the EU and for Australia.

ResMed is in the position of being both an Australian manufacturer and a sponsor of EU manufactured devices. Given the Australian- and the EU-manufactured products are the same type of medical devices it is not consistent for the TGA to accept MDD certification for the EU manufactured devices, yet require a different assessment for the Australian manufactured devices.

If an Australian Manufacturer does not hold (MDD) CE Mark certification, as they may only be distributing in Australia or exporting to non EU countries, the TGA (or a TGA-designated third party under proposal 2C) should continue to perform conformity assessments on those companies.

2B. Increasing pre-market scrutiny for implantable medical devices

(i) ***Devices requiring a TGA Conformity Assessment Certificate to be issued***

Subregulation 4.1(2) of the medical device Regulations be amended to require a TGA conformity assessment certificate to also be issued for all Class III and AIMD implantable medical devices.

(ii) ***Applications to be selected for auditing***

Regulation 5.3 of the medical device Regulations be amended to require applications for all Class IIb implantable devices to also be selected for an application audit prior to inclusion in the ARTG.

Due to the scope of activities undertaken by ResMed, this question is not currently applicable if restricted to implantable medical devices.

2C. Recognition of third party assessment bodies

(i) ***Confidence building for EU Notified Bodies designated under the MRA***

That the TGA commence discussions with the EC over a program of confidence building with the designated Notified Bodies under the MRA, which might include sharing of product assessments and observed audits of medical device manufacturers.

For low and medium risk devices, certificates issued by an EU Notified Body, established per directive 93/42/EEC, should be acceptable. For higher risk devices, the TGA may be involved in the process either through restricting acceptable certificates to EU Notified Bodies designated under the MRA, or though TGA review of specific device NB assessments.

Given there are no details currently proposed on the confidence building arrangements for the revised MRA, it is difficult to make specific comment. However, this process should not be burdensome for EU Notified Bodies, and should have minimal costs. The Australian marketplace only represents a small proportion of the global medical device market, and EU Notified Bodies should not be discouraged by regulatory or cost overheads from representation in Australian assessment processes.

In addition, ResMed would question whether the intent of this proposal should also include any third party certifying body assessed by the TGA as capable of performing conformity assessment to Australian requirements.

(ii) ***Recognising Australian third party assessment bodies***

That further consultation be undertaken to investigate the development of a system whereby Australian based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers.

This proposal has the potential to provide flexibility for Australian manufacturers and should be pursued. The expressed aim of a 'level playing field' should be applied to ensure Australian third party assessment bodies are not disadvantaged with respect to either EU Notified Bodies or the TGA (in its role as an assessment body).

3. Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices

(i) amend the way in which a kind of device is included on the ARTG; and

ResMed agrees with the proposal to list devices and/or models supplied under the same ARTG entry. For low and medium risk devices not requiring assessment, sponsors should be able to update/vary their entries to add new models as an automatic update to the ARTG entry (i.e. IT processing). There should be no pre-market oversight by the TGA or fees associated with the update. Higher risk devices which currently require an application audit should continue to require an assessment.

ResMed strongly opposes any requirement for Class IIb (other than Class IIb implantable) devices to undergo an assessment to allow the addition of a new model to the ARTG (within an existing inclusion). This is a significant change to the level of assessment currently required for these devices. It will add significantly to the regulatory overhead for these devices and is not justified by the risk level of these devices.

(ii) enhance the ability to identify devices that have been approved by the TGA for supply in Australia.

ResMed opposes the proposal to enhance the ability to identify devices as the benefit of this proposal does not outweigh the regulatory overhead. ResMed's current medical device inclusions are easily visible on the TGA ebs public access website, and if the proposal 3 (i) proceeds, the details of individual variants/models will be equally accessible. Other major medical device regulated markets like EU, USA & Canada do not require device specific approval number identifiers to be displayed on the device. The use of a specific Aust I number on a device by a consumer as a pathway to the latest information on the device is not appropriate as this generally resides with the manufacturer or sponsor (see Proposal 4 comments).

The statement that this change "should not adversely impact on regulatory costs" is not correct. Sources of increased cost include:

- As an Australian manufacturer ResMed uses global labelling that identifies the ResMed Ltd Australian address. For these devices we do not currently need to have additional labelling specific to Australian regulatory requirements. The requirement for an Australia specific Aust I number will either require additional Australia specific labels be generated (requiring additional manufacturing and logistics overhead), or the addition of Aust I numbers to devices marketed in EU, Americas, Asia Pacific, etc.
- Many devices have limited labelling footprints which restricts the volume of information that can be attached to the device. The requirement for additional country specific labelling information can drive the need for more regionalised device models/product codes. This adds to both manufacturing and particularly logistics overhead, ultimately adding to device cost in the marketplace.

- Given its regulatory importance, labelling is a tightly controlled process. For a device requiring a newly generated Aust I number, this would require an otherwise fully released device await ARTG inclusion and generation of the Aust I number before going back to the global manufacturer (in Australia or overseas) and undertaking an additional labelling approval/update process for a device already released in other markets. This activity can entail significant complexity, time and cost across regulatory, quality, development, manufacturing and logistics disciplines. This will delay the release of products into the Australian market.

4. Publication of device product information on the TGA Website

For low and medium risk devices (Class IIb and below) ResMed is strongly opposed to this proposal. It would completely change the effective inclusion process for these devices as it would act as a default assessment and approval process for each new model of device.

The suggested information for public publication like the Instructions for Use and the Summary of Safety and Effectiveness data can be/are specific to individual models of devices that are nevertheless the same kind of medical device, and therefore the same ARTG inclusion. Requiring this information for devices that currently do not require an application audit will act as a default assessment process, significantly changing the currently accepted balance of device risk/regulatory requirements.

Maintaining the current TGA published information in no way diminishes the relevant device information available to patients or clinicians, as appropriately tailored information (manuals, product bulletins, clinical reviews, etc.) is freely available through our distribution network, or online at ResMed's internet portal. This information can also be updated for currency as required by ResMed through our information channels in a way that TGA published information cannot (at least not without further assessment and review processes adding further to the regulatory burden).

Information to be potentially published for higher risk devices should be tailored to match information already required for the relevant application audit so as to minimize the need for manufacturers/sponsor to 'rework' information.