RESMED

13 June 2013

Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods – Public consultation

Purpose

The purpose of this document is to provide ResMed's comment and input to a TGA public consultation paper titled *evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods*.

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. As such these comments are limited to medical devices.

Response

ResMed is broadly opposed to the implementation of a new-to-market communication scheme as currently proposed for medical devices. Specifically, we have two main concerns:

1) *What is "new"?* The paper suggests that one of the criteria for inclusion in the scheme is that a "product is a new class IIa or above home use medical device". However, the nature of the ARTG Inclusion process for these kinds of medical devices results in a variety of issues:
    a. The kind of medical device, based on GMDN codes, means that for a GMDN 'family' of devices, only the first device marketed under a particular Inclusion can be considered to have the 'new' starting date. Later devices marketed under the same Inclusion would have shorter market exposure times, and indeed the initial device may cease to be marketed, but this would not be visible.
    b. A kind of medical device includes the sponsor in the Australian marketplace. As such it is very common for a device that may have been in the Australian marketplace for many years (under one Inclusion), to then be newly Included when a second or subsequent sponsor wishes to also market the device. There is obviously no increased or different risk in the later Inclusion, but identification as a 'new-to-market' device would be highly misleading.

2) *Location of communication.* The paper suggests that the symbol could be located on a variety of sources including instructions for use, promotional materials, and product packaging. However, this carries a number of significant costs to business due to:
    a. It is often quoted that Australia represents about 2% of the global medical device market. As such Australia can typically not receive a dedicated product code/model of a particular medical device (this is certainly the case for ResMed). Rather it shares a product code/model with a potentially wide range of other countries. There are a number of possible solutions to this problem, none of which are satisfactory.
        i. Assign Australia a dedicated product code to which dedicated labelling materials can be attached. This carries not only the general logistical overhead of a separate product code, but also the additional cost of separately printing dedicated Australian symbol labelled materials.
        ii. Add dedicated Australian symbol labelled materials to an existing overseas product code. This carries not only the cost of the separate printing runs, but also requires re-working an existing product code raising manufacturing activity issues.
        iii. Simply add the Australian symbol to a shared Australian/overseas product code. This brings with it issues of customer confusion in the overseas marketplace, particularly when the timing of introduction to the Australian and overseas marketplace may differ significantly. Indeed if the product code is already marketed overseas when the decision is made to add the Australian symbol, it will require a rework of the existing product BoM.
    b. Some communication sources, like product packaging, can be shared across a variety of different devices with only a small labelling area able to be 'hot swappable' to late printed and/or specific information. Modifying manufacturing systems (like Oracle) for even apparently small changes can have significant overheads.

In addition, there is the issue of ALL the industry codes of conduct which stipulate that a product cannot be labelled 'new' for more than one year post launch/approval. The TGA is recommending the 'new' label be added for "a certain period of time" (or some other variably determined time period), which may contradict these codes. ResMed would note that 'special' labelling for only an initial one year would entail a significant logistical overhead for very little apparent benefit.

Medicines Australia

1.7 New Products

The word 'new' must not be used to describe any product, presentation, PBS listing or therapeutic indication that has been:

i. available to be prescribed and supplied for more than 12 months in Australia, or
ii. promoted for more than 12 months in Australia,

whichever is the period that expires first.

IVD Australia

c. The term should not be used unless clearly qualified;

d. The term "new" may only be used in the first 12 months of promotion;

e. Products and services of other companies or the medical or scientifi

h. not use, the term "[redacted]" or any other term having the same connotation in an Advertisement to describe a Medical Technology after one year from the date of the product's launch, unless appropriately qualified;