Cook Medical Australia's comments to the TGA's Public consultation paper:

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

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Cook Medical Australia

Cook Medical Australia is a Brisbane-based company which is part of the world's largest privately owned medical device company. Throughout its 50 year history, Cook Medical has pioneered many of the medical devices currently used to perform minimally invasive medical procedures.

The Brisbane manufacturing facility is Cook Medical's Asia Pacific headquarters, employing over 450 staff locally and more than 1,000 across the region. The organisation exports products it manufactures to over 135 countries across the world.

Cook Medical Australia has grown to become a centre of excellence for aortic intervention and women's health products. Employees work in areas ranging from research and development to the production of endovascular grafts which are expertly crafted by hand in the Brisbane manufacturing facility.

1. Whether or not you support the idea of a new-to-market risk communication scheme

Cook Medical does not support the new-to- market risk communication scheme as it is currently broadly envisioned by the TGA.

2. The potential value and uses of the new-to-market risk communication scheme

Potential benefits

Cook Medical sees merit in informing users that a product has only been available for a short time. However, it should be recognised that whilst a product might be new to Australia, it may have been available in other markets for a number of years. Although this scheme may heighten user's awareness of adverse events and motivate reporting, Cook Medical would question whether there is a more direct way to encourage clinicians and patients to submit adverse event reports.

Potential risks

As the TGA has identified, there is a risk that people might perceive a product's inclusion in the scheme, as meaning that the product should be avoided. Like the newly implemented "monitoring communications" scheme, there is the potential to confuse users of whether a product is safe to use. If this scheme were to be implemented, the TGA would need to take measures to avoid confusion and explain to users how they should utilise the information provided by the scheme.

3. How a new-to-market risk communication scheme might best be designed, promoted and evaluated

Selection of products for inclusion in the scheme

The current criteria for inclusion of medical devices in the scheme are vague and subjective, e.g. "a TGA evaluator considers that it is sufficiently different". While it may be relatively obvious when a pharmaceutical is a new formulation, understanding whether a new device is novel can be difficult, requiring an in-depth understanding of the biomechanics of the product and its comparators. Cook Medical would suggest that instead, the products have clearly defined requirements for entry into the scheme, e.g. products that are subject to the annual reporting requirements.

Further modifications may need to be made to the design of the scheme to take into account that, unlike the overseas models cited, the scheme aims to encompass medical devices, not just pharmaceuticals.

Communication to health professional and consumers

Symbol

Cook Medical recommends that the TGA consult with other regulatory agencies about the proposed symbol. The TGA states that European Medicines Agency is implementing a communications scheme this year for pharmaceuticals. We believe that it would be rationale to select a symbol that is internationally recognised, especially in the context of regulatory harmonization.

Source of information

The TGA lists numerous possible sources of communication including IFUs, patient information leaflets, promotional materials, product packaging, the ARTG and the National Product Catalogue (NPC). In the UK example cited, the source of information was formularies, medicine compendiums and advertising materials. As a sponsor of medical devices, we would have a preference for Australia to follow the UK lead and utilise the ARTG, the NPC (assuming all relevant products are included in the NPC) and promotional materials. For sponsors, the practicalities of implementing special labelling and IFUs for the Australian market could be burdensome and potentially difficult to control. For example, as products can have a three year expiry date, theoretically products could be sitting on a hospital shelves, labelled as "new" when the symbol had been removed two years prior.

Removal of products from the scheme

The current criteria for removing products from the scheme are generic and open ended. There should be a set time frame for inclusion on the scheme and there should be defined rules for keeping a product in the scheme. There needs to be a clear delineation between the role of the new-to-market risk communication scheme and the role of the early warning system.

Communications about a scheme

Cook Medical agrees with the TGA that implementation of the scheme will need to be accompanied by education of stakeholders. It should be made clear that this scheme does not involve additional monitoring but is rather intended to increase transparency.

Cook Medical noted that the changes to the early warning system were implemented in early June, with very little warning or education provided. Advanced warning of implementation of the scheme would be appreciated, with possibly some direct communication such as emails/letters to sponsors informing them of the changes and timelines involved.

Evaluation of a scheme

The TGA should be able to evaluate the impacts on adverse event reporting and patient/user understanding of the risk benefit profiles of products.

4. How a new-to-market risk communication scheme will impact you

Any measures that increase adverse event reporting are useful to sponsors and manufacturers as they require timely feedback on the failure of products. However, we do not believe that these measures alone will be sufficient to significantly increase the rate of reporting of adverse events associated with new medical devices.

Australia is a small medical device market, and creating labelling, product information and marketing materials specific to Australia, will be an additional burden for sponsors. Furthermore, if there is confusion about the safety of products included in the scheme, this could potentially have a negative impact on the uptake of new products.