Submission on the Discussion Paper regarding the

Reforms in the Medical Devices Regulatory Framework

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1. Introduction

Baxter Healthcare ("Baxter") welcomes the opportunity to contribute to the Discussion Paper regarding the proposed Reforms in the Medical Devices Regulatory Framework (the Discussion Paper).

Baxter develops, manufactures and markets products to treat people with haemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global healthcare company, Baxter applies a combined expertise in medical devices, pharmaceuticals and biotechnology to develop our products.

Baxter appreciates that the current medical devices regulatory framework is in need of enhancement in some areas to better support TGA's role as the independent national regulator solely responsible for assessing the quality, safety and efficacy of therapeutic goods. Patient safety is a core value at Baxter and is supported at all stages of product development, manufacture, supply chain and post-market surveillance activities.

We therefore support in principle Recommendation 8 (c) of the HTA Report to increase the rigour of assessment of higher risk medical devices to ensure an appropriate level of evidential review to ensure safety, quality and efficacy prior to entry on the ARTG.

Our submission relates to proposals 2B (i) and (ii) and 3 (ii) of the Discussion Paper. We have concerns about the implications of both these proposals and we make alternative recommendations for the TGA's consideration.

We also comment on proposal 4.

2. Response to the Discussion Paper

Proposal 2B. Increase pre-market scrutiny for implantable medical devices by amending (i) subregulation 4.1(2) of the medical device Regulations to require a TGA conformity assessment certificate to also be issued for all class III and AIMD and (ii) Regulation 5.3 of the medical device Regulations to require applications for all Class IIb implantable and long-term surgically invasive medical devices to also be selected for an application audit prior to inclusion in the ARTG.

Concern

In Australia Baxter currently supplies some products classified as implantable class III devices. Together these products are sourced from a number of different legal manufacturers and come under several unique product identifiers (UPIs). The time and cost of re-submitting for a TGA conformity assessment certificate regarding each of these products would be a heavy burden on the company and we can imagine that the time required by the TGA in assessing them would also be onerous.

Recommendation

Baxter recommends that:

i. New TGA conformity assessment Certificates are not required for Class III implantable medical devices already registered on the ARTG, but are only required in relation to new implantable medical devices seeking registration.

ii. Similarly the proposed application audits for class IIb implantables should only apply to registration applications for new Class IIb implantables

Proposal 3 (ii). Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices ... by (ii) enhancing the ability to identify devices that have been approved by the TGA for supply in Australia.

Concern

Baxter is concerned that implementation of this proposal for approved medical devices will be logistically untenable.

The most obvious way for sponsors to comply with this recommendation would be to publish the ARTG number on the information that accompanies a medical device (eg, product labels; instructions for use; or device packaging). The nature of this information is very specific to each product however. As products are marketed globally and the Australian market represents a small percentage of the global market, it would be extremely difficult for the Australian affiliate of Baxter to convince our global headquarters of the benefit of including Australia-specific information (ie, ARTG number) on product labels and/or instructions for use.

The alternative would be to over-label the products with this information before each product is despatched. Even though the Discussion Paper states the TGA does not anticipate that adopting this proposal would adversely impact on regulatory costs, Baxter estimates that to set up and operate an overlabelling operation would result in additional costs of ~ $250 to $500 per unit. Clearly this is prohibitive.

Recommendation

Baxter recommends that the TGA adopts Proposal 3 (i) – "amend the way in which a kind of device is included on the ARTG".

This would mean that sponsors would provide the TGA with a list of registered devices identified by model number, product catalogue number or trade name under each ARTG entry. With this information, the TGA could provide a mechanism for public access whereby the database can be searched to identify products that are included on the ARTG and the corresponding ARTG number.

Proposal 4. Publication of device product information on the TGA Website.

Commentary

While Baxter supports this proposal, in our view it should only apply to high risk products where product information in addition to the label itself is apparent. The majority of devices supplied to the Australian market are lower risk class I and Class IIa items. These are generally supplied with product labels only.

Proposal 4 in our view should only be relevant to the minority of devices which belong to the higher risks classes (Class IIb, III and AIMD).

Baxter would be happy to discuss these comments and recommendations further with the TGA.

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