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To Whom It May Concern,

Comment on Reforms in the Medical Devices Regulatory Framework

Please find comments from Fisher & Paykel Healthcare regarding the TGA Discussion Paper "Reforms in the Medical Devices Regulatory Framework".

If you wish to discuss any of these points further, please contact me.

Best Regards,

Adele Bindon

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Introduction

Fisher & Paykel Healthcare Limited is a New Zealand-based medical device designer and manufacturer. From our New Zealand office we sell to over 120 countries. In dong so, we comply with the various regulations around the world.

Proposal 1 - Reclassification of joint replacement implants

Fisher & Paykel Healthcare has no comments to submit regarding this proposal.

Proposal 2 - Third Party Assessment Bodies and Supporting Reforms

Fisher & Paykel Healthcare has no comments to submit regarding this proposal.

Proposal 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;

We agree with the general principles of this proposal. That is, the listing of model numbers on each relevant ARTG entry. This approach is consistent with other regulators who either want the specific model numbers registered or list the relevant model numbers attached to each licence.

Before this Proposal is developed further, a more exact framework of the costs involved needs to be clarified and communicated with the sponsors. The addition of 1 model number to an already cleared ARTG entry (identical sponsor; manufacturer, risk and GMDN code) should not attract the same application fee as the submission for a whole new ARTG entry. The addition of a model number is purely an administrative task and should attract little or no fees, particularly if the device is Class IIa or below.

Please define the assessment that an application to add a model number to a Class IIb ARTG entry would undergo. Would 100% of the Class IIb (and above) applications be subject to this assessment? What would the effect of the assessment be on the approval time frames of Class IIb devices?

We request the TGA consider the following points with regard to this proposal:

1. Define “model number” and “trade name” as to ensure that the information is consistent.

    a. EN 980 Symbols for use in the labelling of medical devices and ISO 15223-1 Medical device - Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General

requirements use the REF symbol to indicate Catalogue number. This is an appropriate definition to be used.

Figure 1 EN 980 Symbol 5.10 and ISO 15223-1 Symbol 5.15 – Catalogue Number

b. Some model numbers include modifiers to indicate pack size "-10". Will the TGA require the model numbers listed under each ARTG number to be to this level of detail?

2. Our preference would be to have "model number" as the minimum requirement but with an option of also having the "trade name" listed.

3. Ensure that a process is included for removing products from the ARTG entry.

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

We do not see any benefit in implementing this section of Proposal 3 [3 (ii)] in addition to listing the models as outlined in 3 (i) and, therefore, reject this Proposal. The benefits outlined in the Discussion Paper are not sufficient for the additional layer of bureaucracy that will be created.

This proposal places a massive regulatory burden on manufacturers, distributors, and sponsors to create Australian-specific labelling or add an additional process to modify existing labelling to encompass Australian-specific information.

Additionally, this proposal is not consistent with the principles of global harmonisation.

The proposal outlined in 3 (i) should be sufficient to enable anyone to confirm if it is listed on the ARTG.

The introduction of this requirement will not stop disreputable suppliers of medical devices that have not undergone conformity assessment by the TGA from supplying product without an ARTG number or with false ARTG number on the labelling. The additional regulatory burden will only impede already compliant sponsors.

We currently have product on the market that has a useful life of over 10 years. If this Proposal is adopted, all existing products that are on the market will not have an ARTG number on their labelling. There is no risk from products remaining on the market without an ARTG number, so the question must be asked what risk is the TGA is trying to address with the implementation of this proposal?

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

We are unclear on how this proposal will benefit the stakeholders and, therefore, reject this Proposal.

This proposal places increases the regulatory burden on manufacturers, distributors, and sponsors who, in turn, may pass the cost of this increased regulatory compliance onto the consumers and ultimately the Australian government.

The value in publishing the reasons for a rejected application is minor but potentially harmful to the sponsor or manufacturer. Applications can be rejected for a number of reasons – including minor errors such as wrong classification or GMDN code selection through inexperience or lack of knowledge. Also, applications indicate the sponsors and manufacturers intention to market products of a certain type. There is commercial sensitivity around the TGA publishing a rejected application as it will indicate to new or existing competitors their intention prior to them being approved to market the device in Australia.