ACCORD

Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

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Dear Dr Kelly

ACCORD is pleased to provide the following comments regarding the Discussion Paper on *Reforms in the Medical Devices Regulatory Framework* published on 25 October 2010 (the Discussion Paper).

ACCORD Australasia is the peak national industry association representing the manufacturers and marketers of formulated consumer, cosmetic, hygiene and specialty products, their raw material suppliers, and service providers. ACCORD members market fast-moving consumer and commercial goods primarily in Australia and New Zealand. The value in annual retail product sales in Australia is estimated to be in the vicinity of $10 billion. A list of members is attached for your information.

ACCORD is of the view that all regulation should be efficient and effective. We support regulatory reform initiatives that deliver these outcomes. However, from our reading of the Discussion Paper, we do not believe that a more efficient and effective Medical Devices framework will be achieved through this process. While we are supportive of some of the proposals put forward, overall, the proposals appear to increase the regulatory burden on industry with little evidence provided for such an increase. We are also of the view that these changes will move us further from international harmonisation.

We support the Proposal 2A, use of third party assessment bodies for Australian manufacturers.

In March 2009, ACCORD responded to the TGA's consultation on the *Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia*. In our submission, we supported 3rd party certification and the certification of these conformity assessment bodies (CABs) to be undertaken by the National Association of Testing Authorities (NATA). ACCORD remains of this opinion.

We also tentatively support the Proposal 3(i), provided that the assessment requirement is removed for devices that are Class IIb and above.

Currently medical devices (with some exceptions) can be included as a group on the ARTG under a single entry if they have the same sponsor, manufacturer, risk classification and the GMDN Code and term. This means that there are no further assessment requirements for medical devices that are added to an existing ARTG entry. As far as we are aware, there have not been any failures in the system to warrant increased assessment of these devices.

ACCORD tentatively supports creating a list of all medical devices that are included under an ARTG entry, provided that no fee will be applied, and the TGA eBS system can cope with the increased information. This will address the need identified by the TGA to improve its ability for post-market surveillance of medical devices.

We do not support Proposal 3(ii) to publish the ARTG number on the information that accompanies a medical device. We believe that Proposal 3(i) will sufficiently address the need identified by the TGA to improve identification of medical devices. Therefore proposal 3(ii) will be an additional regulatory burden on industry without delivering any foreseeable benefits, particularly for medical devices that are also low risk and/or fast moving consumer goods.

The TGA indicated in its Discussion Paper that it believes that this change, i.e. the proposed addition of the ARTG number, should not adversely impact on the regulatory costs as sponsors are already required to publish their contact details on the information that accompanies a medical device. This is a gross underestimation of the increased regulatory cost to industry. Our Members have indicated that the proposed addition will require a change to every label template, and re-packaging/re-labelling of every medical device will incur significant cost. For some of our multinational companies, this will also mean an Australian-only labelling template to meet a unique Australian regulatory requirement.

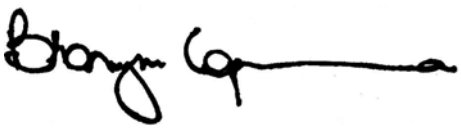
ACCORD does not support Proposal 4, particularly for lower classes of medical device. As for Class III and AIMD devices, rather than applying a blanket requirement to all of these devices, we believe that the TGA should consider the types of devices that are likely to deliver benefits from an increase in published information. For example, devices that are classified as Class III due to its use being related to a Class III device should not be captured.

This proposal is also likely to greatly increase the regulatory cost particularly for industry. Therefore the benefits should be at least equal to those costs.

We also do not support the publication of rejected applications. We do not see the value of such information being disclosed. The information has the potential to confuse and more importantly undermine customer confidence in individual sponsors unnecessarily, as only those medical devices that are approved are available on the market.

Thank you for this opportunity to provide comments on the Discussion Paper. Should you have any questions in relation to the issues raised please contact Ms Dusanka Sabic, Director, Regulatory Reform on 02 9281 2322 or by email at dsabic@accord.asn.au.

Yours sincerely



Bronwyn Capanna
Executive Director

17 December 2010