To whom it may concern,

Novo Nordisk Pharmaceuticals P/L wishes to provide the following comments to the TGA proposal to significantly change Australian medical devices guidelines.

A. Proposal 3(i) - Amending the way a kind of device is included on the ARTG.

The discussion paper proposes that an amended regulatory system will, in regards to medical devices of Class IIb or higher, require sponsors to obtain prior TGA approval to 1) include new medical devices of the same kind under an existing inclusion number, or to 2) vary the conditions of registration of current devices. The proposed system would also result in an itemised listing of devices sitting within the inclusion number. Whilst the company has no objections to the concept of itemisation, Novo Nordisk disagrees with the proposal that changes 1) and 2) should require prior TGA approval, and certainly not if a threshold for such a revised system is to be set as low as Class IIb. The following reasons for this position are given.

In a general sense, such increased regulation would go completely against one of the key aims of the HTA Review viz. to reduce not increase regulatory burden. More specifically, a Class IIb threshold would encapture durable pen injectors used in very broad therapeutic areas, including the treatment of insulin-requiring diabetes and growth hormone disorders, for which there is limited if any objective evidence of quality-, safety- or efficacy-based problems in the public domain. The TGA Recalls website (http://www.tga.gov.au/recalls/index.htm#devices), for example, informs that **no** consumer level recalls of such pen injectors – which one could interpret as being an indicator of increased risk to public safety – have been effected over the past ten years. Indeed, the vast majority of consumer level recalls described on the website pertain to Class I medical devices, so there appears to actually be an inverse correlation between level of medical device class and propensity for quality-related problems (certainly in terms of absolute numbers).

The discussion paper claims that the amended system will enhance the regulator's ability to monitor the safety and performance of all devices of that kind, and ensure that new devices of a differing kind will not be supplied under a current inclusion number. The current medical devices regulatory system is risk-based, with the sponsor taking full responsibility for compliance with the Essential Principles. As mentioned earlier, there is no publicly available evidence that significant problems with durable pen injectors, and very few problems with any other Class IIb devices, have occurred in the Australian marketplace. And furthermore when such isolated events have occurred, the sponsors have instigated appropriate corrective recall actions in partnership with the TGA. With this information in mind, Novo Nordisk contends that to require prior TGA approval to add new devices under current inclusion numbers, or to vary currently-included devices (without change of 'kind') would increase the regulatory burden excessively in comparison with the incremental public benefit.

The aforementioned arguments notwithstanding, Novo Nordisk would not be opposed to a revised regulatory system in which new devices proposed for supply in Australia under a current inclusion number are added to the ARTG entry without the need for prior TGA approval e.g. via addition by the sponsor of tradenames and other relevant details to the ARTG records via the Electronic Business Services (eBS) facility. Novo Nordisk supports the concept of itemisation to address the disadvantage of the current regulatory system (as described in the discussion paper on page 21) that the TGA does not hold records of the models of devices supplied under each ARTG entry.

B. Proposal 3(ii) – Enhancing the identification of approved devices.

Novo Nordisk does not object with proposals for increased transparency e.g. introduction of requirements to state the ARTG inclusion number on the product labelling, and to publish relevant user instructions on the TGA website. Novo Nordisk contends that it would be excessively bureaucratic to make it mandatory that the inclusion number be specifically located on the main panel of the primary packaging (as required for medicines), were this to be proposed.

C. Proposal 4 – Publication of device product information on the TGA website
As mentioned above, Novo Nordisk does not object with proposals for increased transparency in regards to therapeutic goods. For lower-risk (below Class III) devices, Novo Nordisk believes that it would be appropriate to publish medical device user instructions (where required under the Essential Principles) on the TGA website, and that publication should be the responsibility of the sponsor. Novo Nordisk does not see significant public benefit in making available on the TGA website the other types of information described in the discussion paper, for lower-risk devices.

Thank you for providing Novo Nordisk with the opportunity to comment.

Acknowledgement of receipt of these comments would be appreciated.

Yours sincerely,

Rowan O'Brien.

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