The Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

15th December 2010

Dear Madame, dear Sir,

Re: Reforms in the Medical Devices regulatory framework- TGA Proposals

Nobel Biocare welcomes the Therapeutic Goods Administration's (TGA's) initiative for the revision of the Medical Device legislation. Nevertheless we would like to take the opportunity to comment on certain parts of the draft legislation as indicated below.

Nobel Biocare AB Sweden is the legal manufacturer for our entire portfolio in relation to our dental implant systems, which is imported, distributed and sold by our Australian company, Nobel Biocare Australia Pty Ltd. Our comments below therefore reflect the position of both of the Nobel Biocare companies.

1.TGA Proposal 2B (ii): Pre-market scrutiny for implantable Medical Devices

The TGA proposal suggests that applications in future will need to be reviewed prior to placing the devices on the market. As such Regulation 5.3 of the medical device regulation is proposed to be amended to call for an application audit prior to inclusion into the ARTG.

Nobel Biocare comment:

In general Nobel Biocare considers the current ARTG system allowing mutual recognition with major markets as a well functioning system that ensures fast availability of new medical device products to the Australian market almost in parallel to other major markets such as EU, US or Canada. In case the proposed legislative change would in future require the submission of an application prior to ARTG listing, we consider, that this will have an impact on the availability of new medical devices to the Australian market resulting in a delay of new products to the patients. As we interpret the new legislative proposal it seems to be a combined EU and US clearance system not allowing for rapid access to new device products. We therefore propose that the review will either be limited to safety and performance of the device as in US allowing an early submission possibility or allowing the manufacturer to declare conformance to essential principles like the EU system. In the EU regulatory framework an application audit prior to placing a new device on to the market is only requested for high risk class products (class III) or if the new product range would fall outside of the approved manufacturing scope of a given company granted by the Notified body (EC license). Nobel Biocare welcomes a continued MRA system for all class IIb products. For any class III product Nobel Biocare encourages the concept of qualifying individual notified bodies as capable of mutual recognition through confidence building.

Should the future TGA legislation proposal not reflect such options as indicated above, Nobel Biocare is concerned about a delay in supply of new medical device products to the Australian market resulting in delayed patient treatments in Australia compared to other major markets. This may therefore affect the doctor-patient relationship.

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2. Proposal 3(i): ARTG inclusion changes

The TGA proposal requests sponsors to itemize the devices and/or various models that are supplied under the same ARTG entry. It is proposed that this list will be accessible to healthcare providers and consumers in the public view of the ARTG. In addition, it is also proposed that as new models become available, sponsors will be required to submit an application to vary the existing ARTG record to add a new model of that kind of device.

Nobel Biocare comment:

Nobel Biocare appreciates and understands the perceived need for greater transparency and clarity that may be provided by linking an individual entry with a particular device. The expectation to make additional information available to the public via the ARTG database, as well as the attempt to create transparency on variation applications on what you describe as new models, however, would need further clarification. Nobel Biocare would be grateful if you could kindly consider the following comments:

- It is important for Industry to receive clarity on the definition of what a "model" is and when notification to TGA of a "new model" might be applicable taking as well into consideration our comments on TGA Proposal 2B (ii): Pre-market scrutiny for implantable Medical Devices). It would be a challenge if every minor change to a device triggers the requirement to amend the ARTG entry. Minor changes may appear to be a needed TGA submission for 'new model', when in actual fact these minor changes to the device have no impact on the use, function, safety, quality and efficacy/performance of the device. All legislations in place in other major markets allow in their legislations that the manufacturer has the responsibility and possibility to perfom in-house decision analysis to decide on minor and major changes, resulting in only major changes warranting submission. Of course latter decisions are subject to routine audits by independent bodies or Health Authorities

- For example, for Nobel Biocare's dental implants (Class 2b), there may be some minor changes that may reflect a 'new model' but which however may not have any impact on its indication, use, safety, quality and performance.

Nobel Biocare would be grateful if TGA continuously consults with the Industry to determine what constitutes a significant change taking as well into consideration our comments on TGA Proposal 2B (ii): Pre-market scrutiny for implantable Medical Devices). An alternative solution may be to include a requirement for a model name (but not a model number) with TGA notification needed only when a significant change takes place.

3. Proposal 3 (ii): Enhancing identification of approved devices

The TGA proposes to require sponsors to publish the ARTG number on the information that accompanies a medical device (e.g. the product labels, instructions for use or packaging of the device).

Nobel Biocare comment:

Nobel Biocare understands TGA's intention to increase the transparency of ARTG number for medical devices and enable healthcare providers and consumers to identify medical devices approved for supply into the Australian market. However, our reservations are as follows.

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It is not clear from the TGA proposal if the ARTG number is to be included on the label, instruction for use or packaging and we recommend that there will be flexibility for the manufacturers based on the rational given below.

The challenge that we may face is that Nobel Biocare's dental products come in tiny packaging with limited space on the labels hence there may not be sufficient space to add the ARTG number. The current supply of products is feasible to many countries globally including Australia by allowing a universe label in English for many of the major markets. Hence, it is challenging especially for smaller to mid-sized companies to have a special packaging just for the Australian market only which includes the ARTG number.

Implementation of this proposal (Proposal 3ii) on the product label will be hugely problematic as Nobel Biocare will have to have special production runs for Australia, market new labels, increase headcount in doing labeling as well as Quality Assurance. We therefore would suggest that the ARTG number could be added on either the label or the Instruction for use, but that the manufacturer has the option where to place.

4. Proposal 4: Publishing device information on the TGA website

TGA has proposed for a more comprehensive information about a range of approved devices being available through the publicly accessible version of the ARTG which is published on the E-business TGA website.

Nobel Biocare comment:

Nobel Biocare respects and supports the principle of transparency but would like to give the following feedback on this proposal:

Having more detailed information on medical devices for the public may create unwarranted confusion to the public as the public may not be medically inclined and hence may not understand the medical language or terminologies used. This may create misunderstanding, hinder patient treatment regimen, result in poor medical compliance and affect patient- doctor relationship. Hence, such additional information should only be given at the discretion of the doctor to his/her patients and be limited in its content.

In addition, the inclusion of this scheme will significantly increase our business costs as the information is checked, reviewed, edited, legally approved and then receive the final approval for publication. These compliance costs will result in excessive costs burden for business and hence will escalate healthcare costs for Australian patients.

We also strongly feel that there may not be any benefit in informing the public on rejected applications in the website as we understand that the TGA's primary responsibility is to approve supply to the Australia market.

Overall, we conclude with a note that the new proposed reforms by TGA in the present state may result in a very large initial one-off cost and significant ongoing costs for regulators as well as Industry. In addition, for any change in legislation, Nobel Biocare recommends a transition time of 2-3 years as the proposed transition time is too short and are challenged to meet it.

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We, at Nobel Biocare, thank you for the initiative and proposals and look forward to your kind consideration and favorable response on our comments.

Yours sincerely,

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Regional Director

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