12 December 2010

The Coordinator
Office of Devices Authorisation
PO Box 100, Woden ACT 2606 Australia

Re: Comment On: Reforms in the Medical Devices Regulatory Framework

Dear Sir/Madame:

ConMed Corporation (ConMed) is a major medical device manufacturer specializing in surgical instruments and devices, with sales in excess of AUD$700 million. Approximately 60% of the Company's revenues are derived from products designed for the orthopedic surgery markets of Arthroscopy and Powered Surgical Instruments. The Company also sells products for general and other surgical specialties including Electrosurgery, Endoscopy, Endosurgery, Gastroenterology, Patient Care, Integrated OR Systems and Pulmonology. ConMed distributes its products globally through its own U.S. sales network, international direct marketing in nine countries and specialty distributors in other countries. The company strategy is to provide customers with a steady stream of new and innovative products. Our Australian entity, ConMed Linvatec Australia (CLA) acts as sponsor for a diverse range of the Corporation's products, but also represents products from other Australian and International manufacturers. The company holds 289 ARTG inclusions covering many thousands of different medical device products supplied to every State in Australia.

ConMed is writing regarding the Therapeutic Goods Administration's (TGA) recently announced plan to strengthen its regulation of Medical Devices. ConMed welcomes the release of the Health Technology Assessment (HTA) Review in Australia and supports the concept of better health care for all Australians, reduction in unnecessary regulatory burdens and the provision of timely access to new and improved technologies and treatment modalities. However, ConMed is concerned that some of the proposed methodologies as outlined in the TGA Discussion Paper dated 25 October 2010[1] will be problematic and lead to delays and deny access in Australia to the full range of the company's existing products and new products developed in the future. ConMed provides the attached submission to detail industry concerns and to present alternate solutions.

Furthermore, ConMed is active in the Medical Device Industry but is not aware of patient, user, healthcare professional, and industry body or regulator feedback to suggest that the current regulatory framework in Australia has systemic failures. We do not concur that a relationship between the recent US FDA internal reviews of the 510k process can be inferred, as that process has no bearing on the marketing of Medical Devices in Australia. We do believe that individual failings of the current system, where known to the TGA (e.g., Notified Body competency, inadequate ARTG submissions, post-market failings) should be publicized and addressed directly with

[1] Reforms in the Medical Devices Regulatory Framework – Discussion Paper. Australian Government Department of Health and Ageing, Therapeutic Goods Administration. 25 October 2010.

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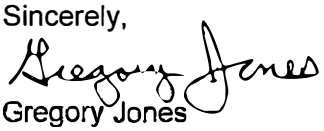
individual manufacturers, sponsors, Notified Bodies, etc, without the need for whole-of-sector reforms. Additionally, it is unclear how TGA will implement the proposed changes for 2011 and beyond without interrupting the marketplace by potentially reducing the number of industry participants able to afford the additional financial burden imposed by these changes.

In closing, ConMed Corporation appreciates the opportunity to comment and looks forward to continuing to work with TGA to supply much needed products to that marketplace.

Sincerely,



Gregory Jones
Vice President
Corporate Regulatory Affairs and Quality Assurance
ConMed Corporation
525 French Road
Utica, New York 13502

Proposal 1 – No Comment

Proposal 2 B– Third Party Assessment Bodies and Supporting Reforms

The TGA Discussion Paper[1] details the TGA proposal for requiring a TGA conformity assessment certificate to be issued for the highest risk (including Class III) implantable medical devices. However, recommendation 8c of the HTA Review is to "increase the rigor of regulatory assessment of higher risk medical devices" and "to ensure an appropriate level of evidential review is undertaken". The TGA Discussion Paper[1] details concerns with the designation processes and relative competence of some of the Notified Bodies (NBs) operating in the European Union (EU), noting that 'not all NBs are created equal'. The TGA Discussion Paper[1] similarly details the TGA proposal for requiring lower risk (Class IIb implantable) medical device applications to be selected for auditing.

Problem: The TGA recovers the full cost of its regulatory activities within the scope of the Act[2]. The proposed requirement for a TGA conformity assessment certificate would be cost prohibitive, especially if site visits were required to manufacturing facilities for affected Class III devices throughout Europe and the USA (the TGA needs to clarify the full extent of proposed desk/site assessment activities proposed. e.g., [i] Will full assessment fees be charged for all existing re-inclusion applications for Class III devices? [ii] Will site visits to Europe / USA be required and at what cost?). Current TGA resourcing levels are such that significant delays would result, delaying the release of new and innovative products into the Australian market. The need for additional skilled resources by the TGA would similarly lead to additional costs and delays during recruitment and training and likely lead to the establishment of an internal and/or external assessor base with the same NB competence issues this proposal is aimed at overcoming. The additional cost, resource and time burden would potentially discourage ConMed from applying for ARTG inclusions for both the current (reapplication cost burden) and new (improved technology) products in the future. This is contrary to the stated objective of the HTA Review – improving process efficiency, reducing regulatory burden, facilitating medical innovation, and timely and affordable patient access to devices. Users with current access to safe and efficacious quality products could be denied continued access under this proposal. The proposal to audit Class IIb implantable medical device applications will similarly lead to an increased regulatory cost burden and additional delays.

Cost Implications for ConMed Corporation: Based on current Class III inclusions - >$1,000,000

- TGA Conformity Assessment Fees & Charges
- TGA Travel Costs
- Recurrent surveillance costs (5 years)
- Design Examination Fees & Charges

Whilst an abridged assessment (e.g., for multiple simultaneous common applications) would potentially reduce the costs, this would only be material in the event that assessments were limited to a Level 2 'type' desk Application Audit recognizing

[2] Therapeutic Goods Act 1989.

existing CE and Design Examination Certificates, without the need for site visits (to overseas manufacturers).

Similarly, the proposal to undertake a mandatory Level 2 Application Audit for all new Class IIb inclusion applications would alter the cost benefit decision to release new technology products in Australia.

Alternate Solutions: An appropriate level of evidential review would be achieved via (i) TGA designation of a reduced number of reputable NBs 'accredited' to issue EC Certificates (under 93/42/EEC) recognized by the TGA. Reputable manufacturers are keen to continue to be associated with reputable NBs. The list could be published on the TGA website. The cost and resource requirements for both the TGA and manufacturer would be limited to assessing and the ongoing accreditation of a select group of NBs; (ii) alternatively, or in addition to option (i), initially recognize EC Certificates issued by currently-designated Mutual Recognition Agreement (MRA) NBs until such time as others can become 'accredited'. Whilst the TGA Discussion Paper[1] details that "The sub-proposals are not intended to be considered in isolation and the TGA would not propose to proceed with one without the others", it is noted that the "confidence building arrangements" under Proposal 2C(i) have not been agreed and the nature of this process (and associated delays) are therefore unknown. A solution would be to mandate that MRA NBs and a number of non-MRA NBs are to be 'accredited' before transitioning to Proposal 2. The proposal to audit Class IIb implantable medical device applications will also lead to an increased regulatory cost burden and additional delays, but is similarly mitigated by TGA recognition of EC Certificates from 'accredited' NBs.

It is further noted that the European Commission's Notified Body Operations Group is currently focused on reforms aimed at bringing about improvements in the Notified Bodies sector[3]. This includes the development of criteria defining detailed and binding requirements for NBs; a revised process for the designation of NBs, allowing representatives of other EU member states to intervene and issue a "second opinion" prior to the final decision by the relevant designating authority; and a peer review process with criteria set for designating authorities. The TGA should defer action to allow such reforms to take place.

Proposal 2B Transition Period

The TGA has proposed that no transition period is required and that any application received for Class IIb implantable devices (after the regulation comes into effect) will be selected for application audit.

Problem: The proposed cost recovery burden would be effective immediately, be significant and be unbudgeted by manufacturers and/or sponsors.

[3] NBOG, November 2010. www.nbog.eu/resources/NBOG_meeting_July_2010_contant.pdf and EU notified body operations group makes headway, Regulatory Affairs Medtech, 4 March 2009.

Alternate Solution: Whilst not mitigating the cost benefit decision to not release new technology products in Australia, a minimum transition period of 12 months should be defined.

Proposal 3 – Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices

Recommendations 8a and 8c of the HTA Review reinforces the need for the TGA to continue as the national regulator and to increase the rigor of regulatory assessment of higher risk medical devices. However, the TGA Discussion Paper[1] goes significantly further than this requirement and indicates that the TGA is proposing to amend the way all (not just higher risk) kinds of devices are included on the ARTG. Higher risk devices (e.g., Class III and above) included as a group under a single ARTG entry already have a requirement to provide a Unique Product Identifier and for a variation to be submitted for new variants. The TGA Proposal would fundamentally change the current concept for a "kind of device", especially for Class IIb devices, if an application to vary an existing ARTG record and mandatory assessment (Class IIb or above) were required.

Problem: The TGA Discussion Paper[1] clearly details one issue with Proposal 3 (concern that the regulatory cost involved in pre-market assessment of each model or variation of a device and the maintenance of the ARTG records will impact the retail cost to the healthcare system and consumers). The TGA offers no solution to this issue. However, the issue is not the impact on financial cost (as products are limited by the cost the market will bear) but that repeat assessment costs and the associated time delay for inclusion of subsequent (new) models will result in such models not being made available to the Australian healthcare system and consumers. Development costs mandate that manufacturers must bring products to market in a timely manner and initial ARTG applications are typically based on an initial (smaller) range of models. For Class IIb devices or above, the TGA proposes that subsequent models would undergo mandatory assessment (with associated delays and costs). The cost effectiveness of the initial inclusion could similarly deny access to all models, not just subsequent models. Reduced range and competition would increase healthcare costs as well as deny access to new and improved technologies and treatment modalities. The Proposal for the TGA to charge a fee to vary an inclusion (e.g., current Medical Device Variation fee $360) will result in significant cost impact, particularly where hundreds of new models / products across hundreds of ARTG inclusions are involved.

Problem: It is assumed that the TGA proposes to make the list of assessed devices accessible to healthcare providers and consumers (in the public view of the eBS ARTG), to allow them to identify those devices which have been assessed by the TGA. This will further enhance user perception that devices are approved by the TGA, rather than reinforcing the Australian regulatory framework based on manufacturer responsibility for quality, safety and performance. The listing will be used by healthcare providers and consumers as a catalogue of available products and allow ready access by organizations to their competitors' full listing of approved devices.

The TGA Discussion Paper[1] assesses the cost implications to require sponsors to publish the ARTG number on the information that accompanies a medical device as "should not adversely impact on regulatory costs". The amendment is compared with medicines regulations which require the AUSTR or AUSTL number on the label. However, the majority of medicines / medicine packaging are directed at the consumer, whilst medical device packaging is most frequently directed at the healthcare professional. There is a significant cost differential between compliance with requirements to provide the same 'name and address' details in accordance with Regulation 10.2 and Essential Principle 13.2 (e.g., a single sticky label; a leaflet), in comparison to any one of 289 unique ARTG numbers (held by ConMed Linvatec Australia) having to be placed on thousands of different products. As a minimum, a tailored system would need to be developed, likely requiring significant investment in validated computer software and associated electronic systems and infrastructure.

Alternate Solutions:

- Allow sponsors to update, within a defined period of time (e.g., 30 days), a list of models in a sponsor / TGA restricted area of the eBS ARTG.
- Similarly, define a list of 'variants' (e.g., diameter, length, etc) for which an application to vary the existing ARTG record and (for device Class IIb or above) assessment would not be required. Sponsors would update the list of models within the eBS ARTG, allowing the TGA to maintain records of all models supplied under each ARTG entry.
- Fees, if any, for an ARTG variation should be nominal. Where sponsors upload new model details directly into the TGA eBS ARTG, no fee should be charged.

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

The TGA Discussion Paper[1] proposes the establishment of similar publications for medical devices as currently available for medicines. However, the rationale is based solely on "improving the transparency and accountability in [TGA] decision making processes", whereas the data available for medicines is primarily aimed at consumers and healthcare professionals to allow safe and effective use under nearly all circumstances. A more limited subset of information would be required to achieve the stated aims of TGA transparency and accountability.

Problem: There is no evidence that existing information supplied with a device (Labeling, Information For Use, User Manual, etc.) is deficient. If additional documentation requires TGA agreement before being made available, significant delays will result. Similarly, ConMed is extremely concerned by the proposal to make public commercially sensitive information and would carefully reconsider any decision to lodge an application in Australia, especially for any new device not yet released in the USA and/or Europe.

Alternate Solution: Limit required information to existing labeling and allow additional on-line publication of labeling (Information For Use, etc.) To satisfy transparency and accountability requirements, the Australian community already has

access to information held by the Government under the Freedom of Information Act 1982. Companies must be afforded a defined (e.g., 30 day) response period before any information is made public.