Inquiry into the Regulatory Standards for the Approval of Medical Devices (Senate Community Affairs Committees)

1 SUBMISSION - TGA CONFORMITY ASSESSMENT CERTIFICATION

We submit that the Senate Community Affairs Committees should direct the Therapeutic Goods Administration (TGA) to implement forthwith changes in its requirements for Australian Medical Devices manufacturers exclusively to hold TGA Conformity Assessment certification, allowing instead certification by Australian third party assessment bodies, as recommended by their own and external enquiries.

In particular, that TGA implements:

1. Recommendation 8 of the Report of the Review of Health Technology Assessment (HTA) in Australia (HTA Review), released by the Minister for Health and Ageing, the Hon Nicola Roxon, and the then Minister for Finance and Deregulation, the Hon Lindsay Tanner, on 27 February 2010:
   That the Therapeutic Goods Administration (TGA) in the context of international harmonisation:
   (...)
   Respond to the issues raised in consultations regarding third party conformity assessment by July 2010, with a view to implementing changes agreed by government by 2011;

2. Its own published response to its Consultation Paper of December 2008 on the *Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia*, which includes Proposal 2A – Use of third party assessment bodies for Australian manufacturers:
   Subregulation 4.1(1) currently requires a TGA conformity assessment certificate to be issued to manufacturers who manufacture medical devices in Australia, before the devices can be included in the Register.

   The TGA proposes to remove Subregulation 4.1(1) from the Therapeutic Goods (Medical Devices) Regulations 2002, so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification.

   This will allow Australian manufacturers to either maintain their existing TGA certification, or use other equivalent certification issued by acceptable third party assessment bodies to support medical device entries in the ARTG, as is currently available to overseas manufacturers.

2 CLARIFICATIONS AND BACKGROUND

Clarifications:

The Title of the current enquiry refers to “Regulatory Standards for the Approval of Medical Devices”. Respectfully we submit that “Regulatory Standards” is incorrect terminology. The approval for supply of Medical Devices in Australia is wholly determined by the *Therapeutic Goods (Medical Devices) Regulations 2002* - Statutory Rules 2002 No. 236 as amended, made under the Therapeutic Goods Act 1989. The Regulations are not “standards”, nor any “standards” are Regulations. Use “Regulations for the Approval of Medical Devices”. See also following paragraph.

Item (d) of the terms of the reference of the enquiry states “the processes in place to ensure that approved products continue to meet Australian standards”. An “Australian Standard” is a Registered trade marked term to describe a standard issued by Standards Australia pursuant to a Memorandum of Understanding with the Commonwealth of Australia. Although there are

Australian Standards relating to Medical Devices, none of them is required for the "Approval of Medical Devices" in the *Therapeutic Goods (Medical Devices) Regulations 2002* and associated Guidance documents in the first place. Australian Standards are completely independent of Medical Device Regulations. It follows there is no Regulatory requirement for Medical Devices to "continue to meet Australian standards".

Background

The *Therapeutic Goods (Medical Devices) Regulations 2002* follow closely, but not totally, the European Union Medical Device Directive 93/42/EEC (MDD). Under this Directive, Medical Device manufacturers need to obtain Conformity Assessment Certification from certain accredited third party inspection bodies, known as "Notified Bodies" in the European Union.

TGA accepts readily such EU Certificates for the approval of Medical Devices in Australia from all manufacturers except those from Australia, which instead can only obtain their Certificates directly from TGA.

This non-level playing field incredibly penalising Australian manufacturers has been objected since the Exposure Draft for the *Therapeutic Goods (Medical Devices) Regulations 2002*. TGA has consistently refused to equalise conditions for all Medical Device manufacturers.

At length, TGA released in December 2008 the Consultation Paper "*Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia*".

Max Boccardo Associates responded in full to this Consultation Paper. TGA acknowledged this submission on 6 July 2009, and promised a response to all received comments. On 10 November 2009, TGA advised that a response would follow a Review of Health Technology Assessment to be conducted by the Commonwealth of Australia.

Eventually, TGA released on 25 October 2010 the Consultation Paper *Discussion Paper Reforms in the Medical Devices Regulatory Framework*, followed by Public Seminars during November 2010. This Consultation Paper included inter alia responses to the Conformity Assessment Certification issues previously canvassed, and agreed that based on Industry response, the TGA monopoly on Certification for Australian manufacturers should be replaced by the use of Third party bodies. However, TGA instead of announcing the implementation of the changes, only proposed that "further consultation" should be undertaken.

Again, Max Boccardo Associates responded in full to this Consultation Paper. TGA acknowledged the response only by way of an e-mailed circular of 14 February 2011, which included:

> "The TGA has undertaken to prepare a response paper to the regulatory reform consultation, with proposals for progressing reforms. It is likely that reforms will be addressed in a staged approach; timing will be dependent upon the need for further consultation, the development of Regulatory Impact Statements and Cost Recovery Impact Statements, and the drafting of changes to the legislation."

No more has been heard from TGA on this issue.

On 20 July 2011 *The Australian* newspaper carried an advertisement from The Department of the Senate on Senate Committee Activities indicating the subject Inquiry, giving the extremely brief closing time of 29 July.

3 RESPONSES FROM TGA TO ITS ENQUIRIES OF DECEMBER 2008 AND OCTOBER 2010 AND TO REVIEW OF HEALTH TECHNOLOGY ASSESSEMENT OF FEBRUARY 2010

For the purposes of this submission, the appropriate parts of these responses are:
Recommendation 8 of the Report of the Review of Health Technology Assessment (HTA) in Australia (HTA Review) (released by the Minister for Health and Ageing, the Hon Nicola Roxon, and the then Minister for Finance and Deregulation, the Hon Lindsay Tanner, on 27 February 2010):

(from TGA Consultation Paper *Discussion Paper Reforms in the Medical Devices Regulatory Framework*):
"Recommendation 8 focuses on the role of the TGA in ensuring medical devices supplied to the Australian market are manufactured under appropriate quality controls, are safe to use and efficacious in their application. This recommendation is the focus of this discussion paper.

Recommendation 8:
That the Therapeutic Goods Administration (TGA) in the context of international harmonisation:

a) Continue its role as the independent national regulator solely responsible for assessing the safety, quality and efficacy of therapeutic goods for entry on to the ARTG and marketing in Australia;
b) Respond to the issues raised in consultations regarding third party conformity assessment by July 2010, with a view to implementing changes agreed by government by 2011;
c) Increase the rigour of assessment of higher risk medical devices by 2011, to ensure an appropriate level of evidential review is undertaken to ensure safety, quality and efficacy of these devices prior to entry on the ARTG and to provide a sound evidence basis for Commonwealth HTA processes; and
d) Develop protocols for information sharing with other HTA agencies through the Single Entry Point (SEP), subject to commercial-in-confidence constraints on the outcomes of its safety assessments."

From TGA Consultation Paper *Discussion Paper Reforms in the Medical Devices Regulatory Framework*":

Proposal 2A – Use of third party assessment bodies for Australian manufacturers
Subregulation 4.1(1) currently requires a TGA conformity assessment certificate to be issued to manufacturers who manufacture medical devices in Australia, before the devices can be included in the Register.

The TGA proposes to remove Subregulation 4.1(1) from the *Therapeutic Goods (Medical Devices) Regulations 2002*, so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification.

This will allow Australian manufacturers to either maintain their existing TGA certification, or use other equivalent certification issued by acceptable third party assessment bodies to support medical device entries in the ARTG, as is currently available to overseas manufacturers.

Currently acceptable certification includes certificates issued under the European MDD 93/42/EEC by a recognised Notified Body. The range of assessment bodies and/or types of

certificates that will be acceptable may change in the future (see Proposal 2C).

This will result in Australian medical device manufacturers being subject to the same regulatory requirements and processes as overseas manufacturers; including being required to gain TGA conformity assessment certification for some higher risk devices (see Proposal 2B).

The TGA has issued conformity assessment certificates to approximately 120 Australian medical device manufacturers. Some of these manufacturers would no longer be required to hold TGA certification, and may opt to utilise CE certification to support their ARTG entries.

Transition arrangements are not required for this part of the proposal.

4 SUPPORTING ARGUMENTS FOR THIS SUBMISSION

It is suggested that the two Responses to previous enquiries quoted above should speak for themselves. It is clear that despite the overwhelming responses from Industry and the Commonwealth of Australia own review, TGA still appears reluctant to relinquish its monopoly power over Conformity Assessment for Australian Medical Device manufacturers. This was anticipated in the submission from Max Boccardo Associates of 17 December 2010 to the TGA Consultation Paper of 25 October 2010, relevant parts of which shown in full in Appendix A:

> (...) Without immediate and definite action, this Proposal merely pays lip service to the TGA's own conclusion from the December 2008 Consultation.
>
> The Response to that Consultation is that Australian manufacturers ought to be able freely to choose a third party conformity assessment body. This should be implemented forthwith.
>
> Also coming out from the responses to the December 2008 Consultation is the clear message that the TGA has an unresolvable conflict of interest in reconciling being the ultimate Regulatory Authority on Medical devices in Australia, which no one is denying or challenging, with providing quasi-commercial services as a third party Conformity Assessment body on a monopoly basis, which is almost universally opposed. (...)
>
> Calls from the TGA for "Further consultation (...) to discuss options for a system to designate Australian third party assessment bodies..." appear to be simply delaying tactics to avoid the clear outcome of the December 2008 Consultation. (...)

APPENDIX A – EXTRACTS FROM RESPONSE TO TGA CONSULTATION PAPER OF 25 OCTOBER 2010

<table>
<tr><td>Proposal 2A</td><td>Use of third party assessment bodies for Australian manufacturers
That Subregulation 4.1(1) is removed from the medical device Regulations, so as to no longer require Australian medical device manufacturers to hold TGA conformity assessment certification.</td><td>Proposal headline is fully supported, as it was in our “Response to TGA Consultation paper on Use of Third Party Conformity Assessment Bodies for Medical Devices Supplied in Australia (December 2008)”.
However Proposal 2A alone supports only partially the headline. Proposal 2A is only the first part of a two-step process, and ineffectual on its own. Without immediate and definite action on Proposal 2C (ii), Proposal 2A merely pays lip service to the TGA’s own conclusion from this Consultation.
Simply removing Subregulation 4.1(1) still leaves Australian manufacturers, in the general case, in the same underprivileged position, i.e. subject only to monopoly TGA conformity assessment certification. This makes nonsense of the previous Consultation and its Response.
The only effect of Proposal 2A is on those manufacturers who already have “CE certification to support their ARTG entries”, which is contrary to the spirit if not to the letter of the December 2008 Consultation.
Proposals 2A and 2C (ii) should be treated inseparably as one. See also comment below on 2C (ii).</td></tr>
<tr><td rowspan="2">Proposal 2C</td><td colspan="2">2C Recognition of third party assessment bodies</td></tr>
<tr><td>(ii) Recognising Australian third party assessment bodies
That further consultation be undertaken to investigate the development of a system whereby Australian based assessment bodies can be designated to issue conformity assessment certificates to Australian manufacturers.</td><td>Proposal headline is fully supported, as it was for Proposal 2A. But even more so than for 2A, Proposal 2C (ii) does not support its own headline. Without immediate and definite action, this Proposal merely pays lip service to the TGA’s own conclusion from the December 2008 Consultation.
The Response to that Consultation is that Australian manufacturers ought to be able freely to choose a third party conformity assessment body. This should be implemented forthwith.
Also coming out from the responses to the December 2008 Consultation is the clear message that the TGA has an unresolvable conflict of interest in reconciling being the ultimate Regulatory Authority on Medical devices in Australia, which no one is denying or challenging, with providing quasi-commercial services as a third party Conformity Assessment body on a monopoly basis, which is almost universally opposed. TGA has two clear options:
– It can leave the field of conformity assessment (strongly preferred), in which case it can, and perhaps should, play a leading role in controlling and supervising the independent third party conformity assessors of medical device manufacturers in Australia; or
– It can stay as a conformity assessor in competition with other independent bodies (barely acceptable option), in which case it absolutely must first find an independent controlling body for all conformity assessors, including TGA. We suggest the only candidate for the role of independent controller is JAS/ANZ.
Calls from the TGA for “Further consultation (...) to discuss options for a system to designate Australian third party assessment bodies...” appear to be simply delaying tactics to avoid the clear outcome of the December 2008 Consultation.</td></tr>
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