Proposal summary		Comments
Proposal 1	**Reclassification of joint replacement implants A** new classification rule is added to Schedule 2 of the medical device Regulations to reclassify all hip, knee and shoulder joint replacement implants from Class IIb to Class III medical devices.	Proposal is supported in general terms. We are not clinicians let alone experts on joint replacement implants. We do have wide experience on manufacturing Class IIa and IIb devices for use with Medical gases, especially for Respiratory therapy. But simple logic and common sense have always suggested there is something wrong in the Classification Rules that result in Implantable devices being assigned merely to Class IIb. Upgrading them to Class III appears eminently sensible. Alternatively Class IIb devices ought to be reclassified as Class IIa.
Proposal 2A	**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.	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).
Proposal 2B	**2B Increasing pre-market scrutiny for implantable medical devices**	
	(i) Devices requiring a TGA Conformity Assessment Certificate to be issued Subregulation 4.1(2) of the medical device Regulations be amended to require a TGA conformity assessment certificate to also be issued for all Class III and AIMD implantable medical devices.	Proposal is supported in general terms, and comments to Proposal 1 apply as well.
	(ii) Applications to be selected for auditing Regulation 5.3 of the medical device Regulations be amended to require applications for all Class IIb implantable devices to also be selected for an application audit prior to inclusion in the ARTG.	Proposal is supported in general terms, and comments to Proposal 1 apply as well.
Proposal 2C	**2C** Recognition of third party assessment bodies	
	(i) Confidence building for EU Notified Bodies designated under the MRA That the TGA commence discussions with the EC over a program of confidence building with the designated Notified Bodies under the MRA, which might include sharing of product assessments and observed audits of medical device manufacturers.	Proposal is supported in general terms, but it is strongly objected that this Proposal is linked to Proposal 2C (ii) as commented separately. Proposals 2C (i) and 2C (ii) are fully independent and should be treated separately. One of the many comments in the Response to the Consultation of December 2008 is the many particular weaknesses of the EU Notified Body System, which the TGA has chosen to support holus bolus. It is clear there are perfectly responsible and competent EU Notified Bodies. However, there are also many which may be, to put it politely, not quite so. Any actions which scrutiny and try to ensure a level playing field in the EU Regulatory System is welcome.

	(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.	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 Consolation.
Proposal 3	**3 Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices**	
	(i) amend the way in which a kind of device is included on the ARTG; and	Proposal is not supported. This is because of the poor level of argumentation and of identifying the real cause for the probably valid concerns given in the Rationale for this Proposal. We fully support that it is difficult if not impossible for most users of medical devices to know whether any particular device is or is not included in the ARTG. The real cause for this problem, which we have consistently and repeatedly expressed in all consultations, Seminars and so on from 2002 onwards, is basing the inclusion on the ARTG on "Kinds of device". This is an academic/regulatory term with little connection and resonance with what users of devices know and expect, as well as to how manufacturers identify and sell their devices (a rapidly, continuously changing situation). We submitted detailed comments on the ARGMD and especially highlighted that "models" of devices are poorly defined in the TGA Guidelines for all Classes of devices, especially for Class IIb and lower where the term is almost undefined. It may well be the term is undefinable, and should be replaced by "part number" – of which there may be hundreds if not thousands for some "kinds of device" from a manufacturer Until the TGA thoroughly reviews this, with the widest possible input from manufacturers, imposition of the Proposal will only augment chaos amongst users, as well as imposing additional costs on TGA (processing a flood of applications) and manufacturers (having to apply to TGA for even the most minute change or variation in any of their devices, which still requires a unique part number making it a "model" for the TGA). Without prior clear thinking, this Proposal looks set to become a bureaucratic nightmare.

	(ii) enhance the ability to identify devices that have been approved by the TGA for supply in Australia.	Proposal is fully supported. Even though we have strongly challenged the TGA Regulatory regime established in 2002, and continue to do so, as excessively rigid and strict in the requirements to achieve "inclusion" in the ARTG, it is a fact it exists. And since "inclusion" in the ARTG, as shown by the six digit ARTG number, is its ultimate goal and outcome of the system, it defies common sense that the ARTG number is kept a secret and not displayed on the devices and/or their packaging, and even on brochures and sales and marketing information. Even under the old much missed, relaxed, Aussie-friendly previous regulatory regime, AUST L and AUST R numbers were required to be displayed on all devices. Since 2002 we have consistently argued for displaying the ARTG number, and opposed the very vocal action of the importers of EU-sourced devices for not doing so. It was clear from the Public Consultation held in Melbourne on 23 November 2010 that importers are still active and vocal in trying to maintain the privileges granted to them by the TGA in preferencing devices coming from the EU as opposed to locally manufactured ones. This should end, and a level playing field established.
Proposal 4	**Publication of device product information on the TGA Website**	Proposal is supported in general terms for Class III and higher devices. Proposal is strongly opposed for devices Class IIb and lower. The Rationale given for this Proposal is fully based on similarity to information supplied for medicines. But this is relevant only for the Class III and higher devices. For the lower classified devices the relevant information is about how to use the device, including Warnings and Cautions in correct operation directed mostly to clinicians and paramedics. This is amply covered in the requirements for Instructions for Use in the Essential Principle 13.4. Instructions for Use are fully under the control of TGA, this is amply sufficient for the lower classified devices.