DISCUSSION PAPER :
REFORMS IN THE MEDICAL DEVICES REGULATORY FRAMEWORK

Response from :
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Comments are provided for the following proposals:

Proposal 2	**2B (i) (ii)**	**Increasing pre-market scrutiny for implantable medical devices TGA issued CAC for Class III and AIMD implantables Application audit for Class IIb implantables**
	2C (i)	**Recognition of third party assessment bodies Confidence building for EU Notified bodies designated under the MRA**
Proposal 3	**3**	**Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices**

2 B(i) TGA issued CAC for Class III and AIMD implantables
2 B(ii) Application audit for Class IIb implantables
The TGA have stated that TGA issued conformity assessment certification will be required for all Class III/AIMDs implantables, and an Application audit for all Class II b implantables so as to address Recommendation 8 of the Health Technology Assessment Review (HTA).

Lack of lead- in time and cost details
The delays to the release of the HTA review and the TGA response to the HTA review were adequately explained at the Information session in Melbourne. However, this does not justify why sponsors who have had no forewarning or any consultation whatsoever prior to the release of the Discussion paper on the TGA website November 2nd, 2010 must now be expected to be ready and compliant for all new products in mid 2011 (mid 2011 being the date that was given at the Melbourne Information session as to when implementation is likely to occur for Proposal 2). Although Proposal 2A has been in discussion and consultation for some time now with stakeholders, Proposals 2B and 2 C have not. .

Planning for regulatory submissions is not a simple matter of getting documentation together - which in itself will increase exponentially with this "increased pre-market scrutiny". Not enough time has been allocated for new products (2011) for which increased documentation requirements will mean planning over a longer period of time. Planning a regulatory budget is not a month to month exercise, but a long term exercise over a number of years. This is especially true for sponsors who are part of larger corporations, who may also be located overseas. The increase in regulatory costs cannot be suddenly acquired within the next few months for an implementation date for all new products of 2011. In addition, other factors such as budgetary constraints, especially for low turnover products, have to be taken into account and how this may affect supply in Australia. Although the TGA allows exemptions for Annual charges, it does not as a cost recovery agency , do so for application or assessment fees.

Manufacturers located overseas will need sufficient time to be informed and educated about how this change will conceivably affect them. A conformity assessment, now being proposed for all ClassIII/AIMD implantables may include an on-site audit. Squeezing this into a busy manufacturing plant's schedule with 6 months notice is difficult to justify for the small market we are in.

No possible regulatory costs have been detailed as yet as the TGA do not have any detail of how the concept of a TGA conformity assessment certificate could change with these proposals. It appears the TGA have not themselves been provided with sufficient time to flesh out any details or give any guidance to sponsors.

The increase to sponsors costs is not just going to be increased assessment fees but also increased staff costs. A conformity assessment is complex and collating all the information, especially from overseas sites is not a simple and quick exercise, nor is it always clearly defined due to the nature of the breadth of differences in medical devices and the type of assessment that is a conformity assessment. Even collating documentation for an Application Audit, as defined as these requirements are, takes time and a different skill set, and this will also increase staff costs.

Whether this increased pre-market scrutiny will actually provide a "*sound evidence basis for Commonwealth HTA processes*" (HTA Report- Recommendation 8) as far as those involved in the Commonwealth HTA processes has not been determined, nor communicated with sponsors. To increase this regulatory burden by the TGA, and then for the Commonwealth HTA processes to still work in isolation from the TGA, as they do now, seems a pointless exercise.

If the TGA propose to require all ClassIII/AIMD implantables be subject to a conformity assessment instead of an Application audit as is currently required, and for all ClassIIb implantables to be subject to an Application audit instead of a simple Inclusion, then :

- far more than 6 months notice of an implementation date for all new ClasssIII/AIMD implantables is required; at a minimum, a 2 year implementation date for any new products is suggested as this gives sponsors sufficient time for firstly the TGA to provide detail and for sponsors to then inform manufacturers of the increased regulatory requirements and also plan for increased regulatory budget costs
- more consultation, and discussion papers such as option papers, are needed from the TGA with actual detail, that allow sponsors to be able to understand firstly the increased documentation requirements and then secondly, the corresponding regulatory costs so that sponsors can adequately plan
- the TGA, in any regulatory impact exercise, need to include not only the increased regulatory assessment fees but also the increased staff costs due to the increased complexity of submission requirements
- Both the TGA and the Commonwealth HTA processes need to provide evidence that this proposed increase to pre-market scrutiny by the TGA will actually "*provide a sound evidence basis for Commonwealth HTA processes*", and not merely increase the regulatory burden on sponsors. If there is no clear reduction in the requirements after TGA approval, or if the time to reimbursement ends up being longer, then Proposals 2A and 2b will not meet Recommendation 8 of the HTA review.

2 C(i) Confidence building for EU Notified bodies designated under the MRA

The TGA stated during the Information session in Melbourne that the reforms in Proposal 2 are proposed as a package. There was also a statement that confidence building exercises with EU notified bodies designated under the MRA are not going to occur prior to implementation of Proposal 2B.

It is difficult to see how any of this increase of pre-market scrutiny is conducted in the "*....context of international harmonisation*" (HTA Recommendation 8, Line 1) if the possibilities for using certificates issued by EU notified bodies designated under the MRA are not taken into account. There is no point in the TGA proceeding with implementing conformity assessment of ClassIII/AIMD implantables and Class IIb implantables if the TGA does not *firstly* establish how this will be conducted in the '*context of international harmonisation*' and does not look at mechanisms of utilising these MRA certificates to simplify the process.

The TGA should strongly consider that ***prior*** to any increase in pre-market scrutiny (for both ClassIII/AIMD implantables and ClassII implantables), they conduct these confidence building exercises. The TGA should also consider that there are other regulatory jurisdictions who issue certificates that may be able to be used by the TGA in the "context of international harmonisation". For example, Class 4 and 4 Product Licences issued by Health Canada may also be able to be utilised by the TGA along with consideration of CMDCAS certificates for quality systems.

- Unless this occurs, the transition time for those ClassIII/AIMD implantable devices where approval is dependent on an MRA certificate may actually only be 2 years, and not 4 years, if the TGA's estimate of how long it will take (2 years) to conduct any EU-Australia MRA confidence building exercise is accurate.
- Similarly, for ClassIIb implantables, the mechanisms for use of MRA certificates needs to be established prior to implementing legislation that all new such devices must undergo a mandatory Application audit
- The possible use of CMDCAS QS certificates and Health Canada Product Licences where the device classification is equivalent for those devices not manufactured in Europe or Canada. There is a significant proportion of imported devices that are not manufactured in the EU (or Canada) and thus cannot utilise the EU-Australia MRA.
- Consideration that certification issued by MRA designated notified bodies be acceptable for Application audits whether the device has been manufactured in the EU or not.

Proposal 3 Enhance the ability to identify devices that have been approved by the TGA for supply in Australia

It is a level of complexity greater for an ARTG number to be added to the label of a device compared to the name and address of a sponsor. A name and address is the same for all devices being supplied by one sponsor, but to match up the device to the correct ARTG number requires greater IT and logistics resources. A 12 month transition time to prepare after implementation is not enough time for a sponsor to prepare.

Depletion of stock considerations

The TGA stated at the consultation session in Melbourne that if product could not comply with the requirement to label with the ARTG number within the 12 months, that a sponsor could submit an application for a Reg 10.2 exemption to the TGA . To do so, a sponsor needs to be able to estimate when stock that does not comply will be depleted. Estimating this for a therapeutic that has an expiration date is not as difficult as there will be a definite time after which that therapeutic cannot be used. This is the case for medicines, but not all devices. There are many devices that do not an expiration date, so estimating stock depletion is not as easy, or sometimes not even possible.

The TGA needs to consider whether sufficient time is proposed for transition especially since the TGA also proposes that all Models/Trade names are proposed to be itemised under an ARTG entry. Not all these products under the one ARTG entry will all have the same expiration date or the same turnover; so will an application need to be submitted for each Model in each ARTG entry affected?

- At the least, if the TGA continue with this proposal, a longer transition time is needed than 12 months. Simple GMP changes, or application of a new edition of a Standard can sometimes have a 2 year transition time.