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Reforms in the Medical Devices Regulatory Framework

As a leading supplier of *in-vitro* diagnostics in Australia, Abbott Diagnostics welcomes the opportunity to comment and provide recommendations on the proposals put forward by the TGA in the discussion paper "Reforms in the Medical Devices Regulatory Framework".

Abbott Diagnostics is responding on behalf of all four Abbott diagnostic divisions – Abbott Diagnostics, Abbott Molecular, Abbott Point of Care and Abbott Diabetes Care.

Abbott is strongly supportive of global harmonisation of regulations related to medical devices. Global harmonisation of regulations will be a welcome step in easing the regulatory burden for IVD manufacturers around the world. Industry is hopeful that global harmonisation will result in a reduced number of the essentially equivalent assessments being conducted on manufacturers and their products.

Without compromising either the health or safety, Abbott believes that any reforms undertaken by regulators should be done with a view to global harmonisation.

Any reforms that increase the regulatory burden on manufacturers and/or sponsors must provide significant real benefit to stakeholders.

As more detail is developed on implementation of the proposals TGA decides to proceed with, Abbott looks forward to participating in ongoing consultations.

Response

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.

Abbott has no comment to offer on this Proposal as it is not applicable to Abbott IVD medical devices.

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.

Whilst Abbott is not an Australian manufacturer of IVDs, we support this proposal. Any step towards creation of a level regulatory playing field for all IVD manufacturers is encouraged. The requirement for TGA conformity assessment should be

governed by the risk class of the IVD medical device being placed on the Australian market and not on the location of the manufacturer. It should address demographic differences that may influence the safety and effectiveness of the IVD medical device.

For example, where Australian and EU manufactured products are the same type of IVD medical device and overseas certification is deemed equivalent and acceptable for the EU manufactured IVDs, the same certification should also be acceptable for the Australian manufactured devices.

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.

(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.

Abbott has no comment to offer on this Proposal as it is not applicable to Abbott IVD medical devices.

Abbott understands from the consultation meetings on the discussion paper that the current list of IVD medical devices which require either TGA conformity assessment or mandatory application audits will remain unchanged as part of any reforms being proposed.

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.

IVD medical devices are not currently covered under the Australia-EC MRA and there are no European Notified Bodies designated under the MRA for IVDs. In addition, the majority of IVD medical devices are self-declared in Europe and do not require assessment by a Notified body. Nonetheless, Abbott encourages this proposal where it will contribute to reduce regulatory burden for industry.

The EU commission has commenced a review of the IVD Directive, in particular looking at the possibility of better alignment with the GHTF principles. This review is not anticipated to be complete before 2015 at least. Abbott recommends that any inclusion of IVDs in the MRA not be undertaken until after the EU commission review is complete.

Abbott proposes that the acceptable overseas manufacturers' evidence for IVD medical devices currently agreed upon remain until the EU commission completes the review and until the end of the IVD transition period.

Looking to the future, Abbott does not support the option whereby only certificates issued by MRA Notified Bodies are accepted as Manufacturers Evidence. Nor would Abbott support the option that ALL applications supported by certification issued by non-MRA Notified Bodies undergo mandatory application audits. This does not align with either global harmonisation or with the philosophy that the level of regulatory oversight should be commensurate with the risk associated with the medical device being regulated. This option is essentially designed to force overseas manufacturers to undergo additional conformity assessment and obtain an MRA certificate for ALL medical devices because the regulatory burden for entry into the Australian market is too high without it.

Whether additional regulatory review is conducted as conformity assessment on the manufacturer or technical review of the medical device upon application by the sponsor, there is an increase in regulatory burden. The cost of this is born by the Australian sponsor, and ultimately all stakeholders, either directly (by paying for the additional cost of an MRA certificate or for the application audits) or indirectly (additional cost of the medical device).

TGA has stated it has concerns about the consistency of evaluation by European Notified Bodies in relation to medical devices. The EC commission has recognised these shortcomings and both they and the competent authorities are taking steps to rectify these shortcomings.[1] To make permanent reforms within the Australian regulations based on these potentially short term issues would be considered short-sighted.

(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.

The proposal to designate Australian third party assessment bodies is encouraged as it will provide flexibility for Australian manufacturers and has the potential to reduce regulatory burden. Abbott questions the requirement for these assessment bodies to be based in Australia.

The true benefit to IVD manufacturers, both Australian and overseas, in the use of third party assessment bodies lies in the ability to potentially use a single

[1] The Notified Bodies Operations Group (NBOG) are putting in place Best Practice Guides, eg Role of Notified Bodies in the Medical Device Vigilance System.

assessment body to obtain certification against, and meet the requirements of, regulations around the world.

In the absence of the ideal world, Abbott recommends TGA put in place a process whereby any suitable authority or body can be designated by the TGA to undertake conformity assessment to the Australian regulations so long as they meet TGA requirements. In this way, third party assessment bodies do not have to be tied to the EU-Australian MRA or be Australian-based. This would open up the opportunity, for example, of Canadian CMDCAS registrars or other suitable bodies being designated to perform conformity assessment to Australian Regulations.

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

Abbott recognises the limitations of the current regulatory system in relation to TGA's ability to specifically identify medical devices supplied in Australia and accepts that TGA be provided with these details.

Abbott does have the following concerns:

- the possible mechanisms being proposed to achieve this,
- the additional regulatory burden this may impose on sponsors,
- the real benefit of the TGA published information to stakeholders, and
- the possibility of creating a perception in end users minds that all IVD medical devices have been fully 'assessed' as part of the TGA approval to supply.

Underpinning the medical device regulations is that inclusion on the ARTG is by a 'kind of medical device'. As such not all medical devices are assessed. The risk v benefit to the public has been considered when determining which medical devices require assessment.

(i) amend the way in which a kind of device is included on the ARTG; and

Should the TGA wish to pursue this option, a list of the IVD devices supplied under the same ARTG entry could be supplied in such a way as to allow identification of these products. Inclusion of model numbers and variants (ie kit size) should be optional.

For low and medium risk devices not requiring assessment, Abbott recommends sponsors be able to update/vary their entries to add new models as an automatic update to the ARTG entry through eBS. There should be no pre-market oversight by the TGA or fees associated with the update.

Higher risk IVD devices which currently require a mandatory application audit would continue to require an assessment, including new products being added.

Abbott does not support any proposal for further IVD devices to undergo an assessment to allow the addition of a new model/product to an existing inclusion within the ARTG. This would be a significant change to the level of assessment currently required for these IVD devices and would add significantly to regulatory overheads.

While Abbott is willing to provide the TGA with the Declaration of Conformity (DoC) for all classes of IVD medical devices, we do not recommend the inclusion of the DoC on the TGA website as a public document.

- Some of the manufacturers' information contained in the DoC could be deemed confidential;
- The DoC information would mean little to the general public.
- Manufacturers may choose a variety of formats to prepare the DoCs and this could make it very difficult to provide the information in an easily accessible way.

The only information of value to stakeholders in the DoC would be the names of the medical devices, which would be more easily provided as a simple table under the inclusion.

(ii) enhance the ability to identify devices that have been approved by the TGA for supply in Australia.

Abbott does not support the proposal to add the ARTG Id to labelling in order to enhance the ability to identify devices that have been approved by the TGA for supply in Australia. The benefit of this proposal does not outweigh the regulatory overhead.

If proposal 3 (i) proceeds, the details of individual medical devices or types of devices will be equally accessible. Other major medical device regulated markets like EU, USA & Canada do not require device specific approval number identifiers to be displayed on the device. For a consumer or healthcare professional to use a specific ARTG Id number on a device as a pathway to the latest information on the device is not feasible as this information generally resides with the manufacturer or sponsor (see Proposal 4 comments).

It is doubtful in this day and age if the use of a specific ARTG Id number on a medical device would enhance the ability to identify TGA approved devices, particularly if greater detail is provided on the TGA public website regarding which products are covered by an inclusion. A quick search of on-line trading sites illustrates that unscrupulous suppliers will readily 'mock up' an ARTG Id number on medical devices they sell. The presence of the ARTG Id on the device could make it less likely for the end user to check the ARTG entry to ensure the device is actually approved for supply.

The statement that this change "should not adversely impact on regulatory costs" is not correct. Provision of a single consistent piece of information like sponsor name and address is quite different to the provision of product specific information.

Given its regulatory importance, labelling is a tightly controlled process. Whether the ARTG Id number is supplied on the IVD device itself, on it's labelling, through local over-labelling or through documentation provided with the IVD medical device, additional labelling approvals and tightly controlled labelling processing steps are required.

Most IVD medical devices currently use global labelling that is finalised prior to approval of the IVD device for supply in Australia. Addition of product specific information would require local labelling approval and control processes are put in place. As evidenced in the pharmaceutical industry this is a resource intense process.

Provision of the information through the inventory management system, eg invoicing, requires additional design, programming and ongoing controls to ensure accuracy and currency of information.

Abbott recommends that an enhancement to the TGA website to allow searching by MANUFACTURER of the public ARTG domain coupled with implementation of Proposal 3(i) would satisfy both TGA requirements and provide stakeholders with the information they want.

4. Publication of device product information on the TGA Website

Beyond the information suggested in Proposal 3, Abbott does not believe that there is a need for additional information to be provided publicly on the TGA website.

Under Proposal 4 the TGA has explained the process for provision of information regarding medicines but not the benefits that accrue from this process. It is not clear to Abbott how application of a similar process would benefit IVD industry end users who already have ready access to all the information that would be essentially duplicated on a TGA website.

Detailed information, including safety and performance data, is required to be provided to users for all IVD medical devices. In addition, IVD information can be lot specific with multiple lots available on the market at any one time.

All relevant IVD information (manuals, instructions for use, product bulletins, etc.) is freely available either with the IVD medical device, through our distribution network, through our extensive customer support network, or online at Abbott's internet portal. This information is managed at a global level and can be updated for currency as required by Abbott through our information channels in a way that TGA published information could not.

For example, the FDA Office of Vaccines, Blood and Blood Products approved the Abbott ARCHITECT HIV Combo assay in June 2010. The FDA published on their website the instructions for use, the Summary of Safety and Effectiveness and the FDA approval letter. The Instructions for Use provide much of the Safety and Effectiveness data but are not version specific. They represent a snapshot in time and are not intended to act as current reference material. Also, a Summary of Safety and Effectiveness is not a requirement as part of a Class 4 Design Examination submission under the Australian Regulations. The information is provided in detail. An additional document would need to be created adding further burden on both the IVD manufacturer and sponsor.

Proposal 4 would completely change the effective inclusion process for devices not currently requiring mandatory pre-market assessment as it would act as a default assessment and approval process for each new model of device.

The suggested information for publication to stakeholders like the Instructions for Use and the Summary of Safety and Effectiveness data are specific to individual IVDs that are nevertheless the same kind of IVD medical device, and therefore the same ARTG inclusion. Requiring this information for IVD devices that currently do not require an application audit or TGA conformity assessment will act as a default assessment process, significantly changing the currently accepted balance of device risk/regulatory requirements.

For those IVD medical devices requiring application audit, the TGA samples an IVD from the 'kind of device' to be included. Publication of safety and performance data only on the assessed product is of little benefit to stakeholders and singles out specific medical devices.