IVD AUSTRALIA

Wednesday, January 11, 2017

Director
Business Improvement and Support Section
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Director

IVD Australia Response to the Consultation: Designation of Australian Conformity Assessment Bodies for Medical Devices

IVD Australia welcomes the opportunity to comment as part of the TGA consultation on the Designation of Australian Conformity Assessment Bodies for Medical Devices.

IVD Australia fully supports the proposal to designate third parties and Australian Conformity Assessment Bodies. While TGA does an excellent job of managing and reviewing medical devices, and IVD medical devices, that are placed on the Australian market, due in part to the 100% cost recovery model, it cannot achieve this without considerable burden being passed on to industry in terms of cost and time to market.

The implementation of Australian designated Conformity Assessment bodies must deliver the same high standard of review of the quality and safety of medical devices and IVDs but it must also deliver this within timeframes acceptable to industry and without overall increase in the cost burden to industry. By becoming a full Designating Authority, TGA would ensure the safety and quality of medical devices and IVDs by reinforcing the work being done in Europe to provide greater oversight of third party designated Conformity Assessment Bodies, ie, notified bodies. TGA still retains overall responsibility and authority over which products may be included on the ARTG and will have the right at any time to instigate non-mandatory assessments of applications were it feels there is some doubt about the quality of the assessment undertaken.

Conformity Assessment is a pre-market process which looks at a 'snapshot in time' when it reviews the design and performance of a medical device or IVD. By relinquishing Conformity Assessment reviews, and focusing more on post-market performance the TGA also increases its oversight on the real time, on-market performance of these devices to ensure their ongoing safety and performance. Please find attached further comments.

Yours sincerely

Wendy-Jane Morrow

CEO
IVD Australia

PO Box 298, Parramatta CBD BC, NSW 2124
Phone: 1300 IVD AUS (483 287) Fax: 02 8004 8103 E-Mail: info@ivd.org.au

Page	Para	IVD Australia Comment
Relevant MMDR Recommendations		
4	Recommendation Fifteen Recommendation Sixteen	IVD Australia strongly supports the implementation of Recommendations fifteen and sixteen. We also understand the requirement for any third party designated body to have a presence in Australia from a regulatory and legal perspective. However, IVD Australia does not see a need for these third party bodies to hold expertise within Australia for all kinds of medical devices. Given the size of both the Australian market and the population this would be unrealistic. IVD Australia anticipates that the majority of designated authorities would be local affiliates of global organisations that are also designated as EU notified bodies. These organisations would then be able to pull expertise from a global pool in order to undertake the required technical assessments of Medical Devices, including IVDs. Just as manufacturers now concurrently apply for Quality Management System certification for ISO13485, CMDCAS ISO13485 and, for example, EU 98/79/EC Annex IV certification, the expectation is manufacturers would apply for Australian Conformity assessment certification also with those notified bodies designated to undertake certification. With the implementation of the Medical Device Single Audit Program (MDSAP) this alignment is even more applicable. With the introduction of third party designated bodies to undertake Australian Conformity Assessment, IVD Australia sees no need for the TGA to retain the ability to undertake these types of assessments. The additional administrative burden this would entail would be passed on to industry and potentially make the whole program unviable, regardless of the mechanism of charging. IVD Australia fully supports third party designated Australian conformity assessment bodies being able to assess ALL medical devices, including Class 4 IVDs, subject to competency assessments. With the introduction of the IVD Medical Device Regulations in Europe there will be much greater harmonisation between the Australian Regulations and the European Regulations. This also opens the way for concurrent assessment by suitably qualified and designated bodies. The concern is that with the implementation of the IVD Medical Device Regulations, notified bodies will not have the capacity to take on additional certification work in the next five years.

Page	Para	IVD Australia Comment
9	Scope	IVD Australia fully supports third party designated Australian conformity assessment bodies being able to assess ALL medical devices, including Class 4 IVDs, subject to competency assessments. This is subject to the assumption that most designated bodies will be a branch of a larger global organisation that will be able to access relevant expertise in order to have the capability to undertake these assessments. Given that the majority of high risk devices, particularly IVDs, are already assessed by competent notified bodies in Europe this capability is already established. While some local manufacturers will rely on 'home market' regulatory approval, IVD Australia has always assumed TGA would retain the overall responsibility for regulatory approval for inclusion on the Australian Register of Therapeutic Goods (ARTG). While the TGA would not undertake conformity assessments, IVD Australia expects that TGA oversight as a Designating Authority would be stringent enough to avoid any of the problems seen in Europe historically.
9	Context	IVD Australia supports parallel review by bodies designated across multiple jurisdictions such as occurs now for QMS certification. This is the only way to achieve a sustainable designation process from both a cost recovery and timeliness to market perspective. IVD Australia does not want to see a similar process to today, whereby European certification is needed to support assessment by an Australian designated authority. This avenue would continue to foster the duplication of assessment and the high local workload which is already criticised by industry and leads to long lead times to market for high risk devices.
Designating Authority		
12	Cost Recovery	There should be a set fee for designation for all conformity assessment bodies dependent on scope. This should be transparent and equal for all bodies so that there is no likelihood of disadvantaging any one body. This fee should purely cover the cost of designation of the body. The costs for the requisite changes within TGA, eg, reorganisation and retraining to become a Designation Authority, should be covered by annual fees, in the same way that other operating and post-market costs are covered. This retains a level of equity for all sponsors and manufacturers. Costs for auditing of overseas facilities of the designated body should also be included in a annual fees as this now potentially becomes a cost to all industry. However, depending on the implementation of the program, should lower risk devices continue to rely on other overseas certification, the cost of overseas audits may have to be born by those who use the Australian designated bodies.
12	Competitive Neutrality	As stated below, TGA should cease to offer TGA Conformity Assessments and become a Designating Authority only for the purposes of conformity assessment. Only in exceptional circumstances, eg, Class 4 In-house IVDs should it undertake any form of TGA conformity assessment itself.

Page	Para	IVD Australia Comment
Conformity Assessment Bodies		
15	TGA Conformity Assessment Function	TGA should cease to undertake Conformity Assessment certification activities and focus on re-training as a Designation Authority, similar to the MHRA in the United Kingdom. This will potentially reduce the likelihood of costs increasing and making the whole process untenable in the long term. The duplication of administrative oversight and costs if the TGA is both a Designating Authority and Conformity Assessment reviewer is unlikely to be sustainable given Australia already is one, if not the, most expensive regulatory jurisdiction in the world. Even if cost-neutral, industry is unlikely to select TGA as the Conformity Assessment body if the third party alternative leads to significantly shorter timelines to market and/or review of changes. Particularly if this can be done in conjunction with assessment for other jurisdictions.
15	Possibly Interested Bodies	IVD Australia is not in a position to become an Australian designated conformity assessment body and nor are any of it's members. IVD Australia sees the current EU Notified Bodies, CMDCAS Registrars etc being the organisations best equipped to undertake designation as an Australian conformity assessment body.
Designation Process		
19	Designation Framework	The aim of regulatory authorities and industry involved with IMDRF, and previously GHTF, has always been global harmonisation. The ultimate aim is to reduce regulatory burden for manufacturers and distributors/sponsors whilst maintaining high levels of safety and quality for all medical devices, including IVDs. Designation of Australian conformity assessment bodies and the processes that surround this must be aimed at global harmonisation. To that end, alignment with the European designation framework is the preferred option for the majority of industry given the size of the market in Europe. For most medical devices and IVDs, this also overcomes the fact that MDSAP is limited to QMS assessment and does not cover the assessment of medical device compliance with the essential principles and hence does not cover any of the following: • Design examination for high risk medical devices (Regulations, Schedule 3, Part 1.6) • Type examination procedures (Regulations, Schedule 3, Part 2) • Verification procedures (Regulations, Schedule 3, Part 3) • Clinical evaluation procedures (Regulations, Schedule 3, Part 8) Adoption of the European Regulations/Directives will immediately provide a mechanism for the above assessment criteria to be available as the European notified bodies already undertake equivalent assessment. Some additional criteria will be required at least initially while the MDD and IVDD still exist. However, as the European Regulations develop and MDSAP is, hopefully, adopted into the European framework, the logical framework for Australia should incorporate a hybrid of the European framework and MDSAP to cover off the limitations of

Page	Para	IVD Australia Comment
		MDSAP. Given that it would presumably take some time for the Australian framework to be implemented, it is foreseen that both the European regulations and MDSAP would be well advanced in full implementation by the time the Australian framework came into effect. In order to align to the MDSAP and European framework simultaneously, TGA should engage with European authorities, industry and notified bodies as soon as the new European Regulatory framework is finalised and, through IMDRF and the MDSAP program ensure the finalised MDSAP program meets the European needs. In parallel, TGA should align to the European regulations as implemented. The issue of Australian Conformity Assessment Certificates being reciprocally accepted in Europe is probably of minimal importance as long as European and Australian (and possibly other) certification can be reviewed and issued concurrently. The majority of medical device manufacturers/distributors, even Australian ones, focus on the European market ahead of the Australian market due to their relative sizes.
19	Designation Criteria	The Designation Criteria are appropriate and comprehensive and IVD Australia has no issue with these. The structure and legal status would be equivalent to the use of a sponsor or an authorised representative as the legal entity that is responsible for the kinds of devices registered on the ARTG. The designation body would, however, have a contractual obligation with the manufacturer but would be held accountable to the TGA for the issuance of certification. Designation criteria would rightly include the right for TGA to inspect the facilities of the certification body regardless of location, just as they can now inspect a manufacturers facility. It is critical that, as stated, the Australian designated conformity assessment body be able to access expertise for assessment outside Australia. Expertise within Australia will be limited and, possibly, unlikely to have the requisite impartiality to conduct assessments. In addition, when TGA looked at using local external experts to assist with Design Examination of IVDs during the development of the IVD framework, the pool of suitable experts was limited and presumably cost-prohibitive as this path was never utilised.
Implementation		
20		IVD Australia fully supports the proposal to designate third parties and Australian Conformity Assessment Bodies. While TGA does an excellent job of managing and reviewing medical devices, and IVD medical devices, that are placed on the Australian market, due in part to the 100% cost recovery model, it cannot achieve this without considerable burden being passed on to industry in terms of cost and time to market. The implementation of Australian designated Conformity Assessment bodies must deliver the same high standard of review of the quality and safety of medical devices and IVDs but it must also deliver this within timeframes acceptable to industry and without overall increase in the cost burden to industry.

Page	Para	IVD Australia Comment
		This can be achieved through key aspects of the program: • Alignment to the European conformity assessment program and the European regulations along with adoption by both Europe and Australia of the MDSAP program. True harmonisation should be the aim. • Concurrent assessment of medical devices and IVDs for the European, Australian, and possibly other markets. This should include assessment of compliance with Essential Principles and, for example, Design Examination requirements (Schedule 3, Part 1.6). • Allowance of the use of global expertise in assessment of medical devices and IVDs, in particular, for technical and clinical review of IVDs • TGA should become a Designating Authority exclusively for the purposes of Conformity Assessment Certification. It should no longer undertake to do assessments itself. (Note: the TGA may need to retain this ability for a very small sector, eg in-house Class 4 IVDs but this would be undertaken by the Designating Authority personnel). By becoming a full Designating Authority, TGA would ensure the safety and quality of medical devices and IVDs by reinforcing the work being done in Europe to provide greater oversight of third party designated Conformity Assessment Bodies, ie, notified bodies. TGA still retains overall responsibility and authority over which products may be included on the ARTG and will have the right at any time to instigate non-mandatory assessments of applications were it feels there is some doubt about the quality of the assessment undertaken. It should also be noted that the use of third parties instead of a regulatory authority to undertake assessments does not inherently mean there will be a degradation of quality and safety within medical devices, IVDs and indeed therapeutic goods in general. In most instances of major safety concerns, eg PIP, neither a regulator or a notified body is likely to discover truly fraudulent behaviour on behalf of a manufacturer. Conformity Assessment is a pre-market process which looks at a 'snapshot in time' when it reviews the design and performance of a medical device or IVD. By relinquishing Conformity Assessment reviews, and focusing more on post-market performance the TGA also increases its oversight on the real time, on-market performance of these devices to ensure their ongoing safety and performance.