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Matt Pitt
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Dear Therapeutic Goods Administration

Thankyou for the opportunity to provide comments on the consultation paper for Designation of Australian conformity assessment bodies for medical devices (November 2016).

The Joint Accreditation System of Australia and New Zealand (JAS-ANZ) was established in 1991 by the Australian and New Zealand governments to support national markets and trading relationships between Australia and New Zealand, and each of these countries with the world at large. JAS-ANZ operate a joint accreditation system to deliver on four goals relating to: Integrity and confidence; Trade support; Linkages; And international acceptance. JAS-ANZ adheres to ISO/IEC 17011:2004 (Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies), and this is verified through peer assessment by other members of the International Accreditation Forum[1].

JAS-ANZ recognises 138 public and proprietary schemes, including in Management systems certification; Product certification; Personnel certification; Inspection; Validation and verification. The schemes provide a level of confidence to support exchange of products and services across a wide range of industry sectors. As the Governing Board is appointed directly by the governments of Australia and New Zealand, JAS-ANZ meets authority criteria in clause 3.2 of ISO/IEC 17011:2004 (definition of 'Accreditation Body'), that the: 'authority of an accreditation body is generally derived from government'.

One scheme of particular relevance to the context of this submission is the International Accreditation Forum scheme: '*Application of ISO/IEC 17011:2004 in the Field of Medical Device Quality Management Systems (ISO 13485*)' ('IAF MD 8:2015), and: '*Application of ISO/IEC 17021 in the Field of Medical Device Quality Management Systems (ISO 13485)*' (IAF MD 9:2015). The scheme is currently in transition from the certification standard ISO 13485:2003, to ISO 13485:2016. The latter greatly strengthens obligations on manufacturers to determine acceptability criteria, and document clinical evidence, monitor and report post-market findings, and other such aspects of safety and performance, to ensure devices continue to meet requirements of the regulatory jurisdictions that they are intended to be supplied within.

JAS-ANZ has confined its submission to those aspects relating to the oversight of third party accreditation systems for medical device quality management systems.

[1] www.iaf.nu

Performance of 3rd party conformity assessment systems

The consultation paper depicts a somewhat sceptical view of the veracity of third party accreditation systems. For example, page 7 states that: 'The use of third party conformity assessment bodies can result in different regulatory outcomes increasing risk for consumers in some jurisdictions. For example: Thomas J Hwang et al'. Page 6 states that: 'In recent years a number of concerns emerged about the performance of notified bodies in regards to medical device assessment'. Similar doubts are raised in 'Issues to Consider'.

As stated in an Overview Report by the European Commission[2], the suboptimal performance was in part attributable to 'planning, scope and depth of surveillance activities' by Designating Authorities; the National authority with responsibility for the designation, monitoring and control of national Notified Bodies. Given its transnational aspect and associated regulatory complexity, the European conformity assessment system for medical devices is not a directly analogous comparator for any third party medical devices conformity assessment system in Australia. If it becomes the designator for bodies (accreditor for conformity assessment bodies, in the nomenclature of ISO/IEC 17011:2004), TGA may exert very close control and requirements over the bodies' conduct, including in the areas of human resources, impartiality safeguards, reporting obligations, and sanctions.

If third party accreditation systems are adopted, the TGA will be able to more flexibly control conformity assessment workloads, and promote competition in assessment quality and responsiveness of accredited bodies.

It is premature to assume that third party conformity assessment bodies – many of which have extensive international operations – would be unable to adapt and cope *per se* with the technical complexity and workload requirements involved in medical device conformity assessment of high risk medical devices. Several bodies that would be attracted to enter such a scheme would be well-placed to undertake conformity assessment of active implantable medical devices and other high risk medical devices. The designation of other bodies could be confined to lower risk devices, and adjusted as appropriate. All pre-market approval systems – whether overseen by public service administrators or by third parties on their behalf – are susceptible to releasing goods that ultimately prove to be harmful to the public.

Structure of a third party conformity assessment system for medical devices in Australia

It is noted that the consultation paper states the TGA: Will be the 'accreditor/designator'; Will comply with 'relevant sector standards and guidance for accreditation bodies (such as ISO/IEC 17011:2004)'; And, retain the legislated monopoly over conformity assessment of high-risk medical devices specified in Regulation 4.1 of the Therapeutic Goods (Medical Devices) Regulations 2002.

Page 12 of the consultation paper invites input into whether 'there are other competitive neutrality concerns' from this dual function. In this respect, JAS-ANZ notes that clause 4.3.7 in ISO/IEC 17011:2004 specifically states certain criteria that must be met for an accreditation body that also undertake conformity assessment, e.g., 'different top management' overseeing the functions, and 'distinctly different name, logos and symbols'. If the TGA were to undertake both conformity assessment and accreditation activities as the "Therapeutic Goods Administration", it would not be meeting requirements of clause 4.3.7 in ISO/IEC 17011:2004. Additionally, clause 4.3.6 of ISO/IEC 17011:2004 states that an accreditation body

[2] DG(SANTE)/2014-7666– MR Final

shall not offer or provide any service that affects its impartiality, such as: 'those conformity assessment services that CABs perform". JAS-ANZ agrees that impartiality aspects of any cross-over between conformity assessment activities of TGA and its accredited bodies require careful consideration.

The discussion paper states that requirements of accredited bodies will be as per the EU legislation and/or MDSAP. In particular, page 17 proposes an approach that is a hybrid between the two. The discussion paper then asks: 'are the listed criteria appropriate and comprehensive'? In the view of JAS-ANZ, the listed criteria is missing reference to ISO/IEC 17021-1 (or 17021), which is accepted as the underlying basis for Notifying Bodies (CABs) in the EU under NBOG, and for which JAS-ANZ has extensive experience in accrediting to. An example of the influence of ISO/IEC 17021-1 is that requirements against subcontracting out certification decision from the 'NBOG Designating Authorities Handbook' (page 8), is itself derived (as acknowledged by NBOG) from the requirement in ISO/IEC 17021-1 (and the superseded version, ISO/IEC 17021). Similarly, the listed criteria omits another international standard of relevance, ISO 19011:2011, which specifies principles for the competence and evaluation of management system auditors.

The IAF MD9 technical areas and product categories may serve as a starting point for consideration for the scope of accreditation (or designation) of a body. Alternatively, the use of NBOG (EU) accreditation scopes would also be pragmatic and facilitate the international recognition of certifications within the scheme. The TGA could also incorporate the existing medical device classifications (or GHTF medical device classifications A to D, latter being high) into a bodies' designation. The experience of JAS-ANZ with the IAF medical devices scheme is that such information would be beneficial in a bodies accreditation record (its permitted range of activities), and in the scope of certifications issued to manufacturers.

The discussion paper states that TGA assessors would need to have 'Expertise in third party oversight including audit skills', and that 'some contracting for particular expertise may be required on occasion to balance workloads and expertise requirements.' With over 25 years of experience in Australia, New Zealand, and overseas, JAS-ANZ is well placed to offer ongoing advice and assistance on these matters to the TGA. In time, a reasonable aim would be cooperating in the training and use of contract assessors for both the TGA Medical Devices programme and the IAF MD9 programme, and potentially progressing to joint assessments.

It is noted that an accreditation body well-placed to discuss the merits of both the IAF Medical Devices Scheme (IAF MD8), and the European Medical Device Directives is UKAS, which operates as an accrediting body in both systems.

Please do not hesitate to contact JAS-ANZ for further discussion of any of the above information.

Yours Sincerely

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