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Business Improvement and Support Section

Medical Devices Branch

Therapeutic Goods Administration

Email: mmdr.consultation@tga.gov.au

Dear Business Improvement and Support Team,

Re: Designation of Australian conformity assessment bodies for medical devices implementation – version 1.0, November 2016

SAI Global would like to provide the following feedback on the 'Designation of Australian conformity assessment bodies for medical devices implementation – version 1.0, November 2016 consultation paper.

SAI Global is accredited by ANAB to audit against the requirements of ISO13485 – Medical Devices – Quality Management Systems – Requirements for regulatory purposes, and takes the perspective of a potential conformity assessment body. SAI Global is also an organisation Authorised to conduct MDSAP audits.

SAI Global would like to be an interested party to the implementation phase should TGA decide to proceed with process implementation.

Please let me know if any additional information is required.

Kind regards,

Patty Wassenaar

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No.	Issue	Response
1. Scope and Context	Should designated Australian conformity assessment bodies (subject to capability etc.) be able to provide conformity assessment certification for all medical device applications? Should some device types or classes continue to be required to hold TGA conformity assessment certification? Does your organisation market devices to countries relying on 'home market' regulatory approval? How would this proposal impact on this? Are there other key issues which should be considered in developing this proposal?	Although SAI Global agree that Australian Conformity Assessment Bodies should be able to provide conformity assessment certification: • Conformity Assessment Bodies should be formally Accredited by an Internationally Recognised Accreditation Body that are International Accreditation Forum (IAF) members and comply with their requirements (e.g. ANAB, JASANZ); • Conformity Assessment Bodies should be MDSAP approved and accredited to audit to ISO13485.
2. Designating Authority	**Cost recovery** · Should the costs of designation be recovered directly as fees from conformity assessment bodies, or is it appropriate that some or all costs be recovered through other mechanisms such as charge on all medical device sponsors? **Competitive neutrality** · Are there other competitive neutrality concerns for the Designating Authority function that you can identify?	Although Conformity Assessment processes are usually fee based, the risk in allowing costs to be recovered directly from conformity assessment bodies is the 'competition for business' and potential reduction of audit time/duration in order to win business. • Consideration could be given to mandating minimum audit durations in addition to mandating auditor qualification and competence requirements to minimise this risk. With Accreditation of Conformity Assessment Bodies to ISO 17021 (and ISO 17065, this would provide assurance that competitive neutrality requirements are met.
3. Conformity Assessment Bodies	**TGA conformity assessment function** · TGA would continue to offer a full suite of conformity assessment functions. Is this important to you or your organisation? **Possibly interested bodies**	If Conformity Assessment Bodies form part of the TGA approval process, mechanisms for communication of recalls, significant events, risks, complaints and other issues should be established. SAI Global would have an interest in being designated as a conformity assessment body. Issues to be considered would include:

	· Do you or your organisation have an interest in seeking designation as a conformity assessment body? What are the issues which would affect your decision to apply for designation?	• Accreditation requirements; • Auditor competence and training requirements; • Reporting requirements (would reports be mandated by the TGA, could assessment bodies use their own report formats providing they are acceptable to the Accrediting agencies and the TGA); • Audit duration and related cost mandates (e.g. allowing adequate time to conduct thorough assessments and reviews); • Technical expert and competence requirements and access to appropriately qualified and competence technical experts; • Market size. • Availability of technical expertise, particularly in regards to High Risk Medical Devices.
4. Designation process	**Designation framework** · Should the designation framework be aligned to MDSAP requirements, European requirements or a hybrid? · Should particular aspects of each system be adopted for a hybrid approach? · How might alignment to the MDSAP and/or European framework be managed as international regulatory convergence develops? **Designation criteria** · Are the listed criteria appropriate and comprehensive? · Are there particular issues which should be considered in developing these criteria for the regulatory framework?	To ensure a consistent approach that minimises the assessment burden for organisations as well as conformity assessment bodies, the framework should be aligned to MDSAP requirements in addition to any additional requirements mandated under the International Accreditation Framework (IAF). Any additional requirements specified by European or other frameworks could be documented within a Service Specification (or similar) document to ensure a consistent assessment approach is adopted. As organisations (conformity assessment bodies) work Globally, a consistent approach would ensure that requirements continue to be effectively and consistently implemented. Variations can potentially lead to inconsistency across different conformity assessment bodies, both nationally and internationally – an important consideration with the implementation of MDSAP. In addition to the Designation Criteria, Conformity Assessment Bodies should be Accredited by an IAF organisation as outlined above. This would ensure that regular independent assessments of conformity assessment bodies are conducted which would include both management systems and auditor competence.

5. Implementation	**Overall** · In addition to any feedback on specific aspects of the proposed approach to designation of Australian conformity assessment bodies, we are also interested in broader comments on the proposal. · Comments might take into consideration the context for change and issues to consider outlined in the introduction, and consider the risks and benefits of this proposal and how these might be managed.	In addition to the Accreditation requirements suggested above, SAI Global currently provides reports to relevant Government Agencies who utilise third party auditing bodies to conduct assessments against relevant Standards. The TGA may wish to consider how these mechanisms work and adopt a similar approach. For example: • A proactive communication approach ensures that any queries or issues are communicated between the Departments and SAI Global. This includes specific areas the Department may want reviewed during our audits, as well as any potential concerns identified by our audit team members. Queries on audit reports also form part of the review activities. • Meetings between the Government agencies and auditing bodies (generally twice per year) ensure key information is communicated consistently to all the auditing bodies and allows auditing bodies to also gain clarification on any issues that may be impacting on audit activities. (e.g. changed legislation, changes to funding rules etc.). • A 'notifiable issue' process – which mandates immediate communication to the Department of high level risks (e.g. financial impropriety, fraud, client/consumer related risks). The process should also include due consideration to any actual or potential conflict of interest and outline mechanisms for managing this. Given the size of the sector in Australia, and the availability of technical expertise, this could pose a risk to the rigour and impartiality of the assessment process.