TGA Consultation

Designation of Australian Conformity Assessment Bodies for Medical Devices

MTAA Submission - December 2016

Medical technology for a healthier Australia

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Contents

1. Executive Summary 3
2. MTAA recommendations 3

1. Executive Summary

The Medical Technology Association of Australia (MTAA) welcomes the opportunity to comment on the TGA consultation: *Designation of Australian conformity assessment bodies for medical devices – Implementation* which was opened on November 16, 2016. We would like to commend the TGA for providing clarity and focus on matters related to implementing a system for designating conformity assessment bodies (CABs) within Australia, in response to Recommendations 15(2) and 16 of the March 2015 report of the Medicine and Medical Devices Review (MDDR).

The MTAA supports the option of using CABs designated within Australia as an alternative to conformity assessments performed by the TGA to ensure the applications workload is managed efficiently.

The MTAA is committed to ensure that the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

2. MTAA recommendations

Recommendation 1

Designated Australian conformity assessment bodies (CABs) should be able to provide conformity assessment certification for all medical device applications according to their capability and scope of designation, irrespective of the medical device risk classification.

The same designation criteria that are applied for auditing the TGA CAB function should be applied for auditing the Australian designated CABs to ensure that Australian designated CABs have a level of competency that is comparable to that of the TGA.

Recommendation 2

Certain markets require regulatory approval from the country of origin hence a locally issued regulatory approval, from the TGA or a locally designated CAB, will continue to be needed for Australian manufacturers. Therefore Australia should retain the capability of providing conformity assessments locally. It should be up to the applicant to decide whether they wish to apply for conformity assessment from the TGA or an Australian designated CAB.

Recommendation 3

As long as there is an efficient and effective process for regulatory approvals, the industry does not have a preference whether approvals are issued by the TGA or other Australian designated bodies. The MTAA and its members do not have an interest in seeking designation as a CAB.

Recommendation 4

Regardless of whether the applicant chooses the TGA or another Australian designated CAB to perform the conformity assessment, there should be no difference in how an application is treated. I.e., an approval from an Australian designated CAB should be equivalent to a TGA approval and it should not require an application audit.

Also, applications for inclusion into the ARTG that rely on CE Marking obtained in the EU should be treated the same, regardless of whether they are going through the TGA (in its role as CAB) or through an Australian designated CAB.

Recommendation 5

The costs of designation should be recovered directly as fees from the CABs, as it is done in the EU with the Notified Bodies. It is not appropriate to impose a charge on all medical device sponsors to support the operations of Australian designated CABs.

Recommendation 6

We acknowledge TGA's awareness of competitive neutrality requirements. In order for a separation between designating and conformity assessment activities to be effective, an appropriate monitoring mechanism will have to be put in place.

Recommendation 7

The Australian CAB designation framework should be aligned with the EU requirements, because the great majority of medical devices marketed in Australia come with a CE Marking approval. As regulatory agencies move towards convergence and harmonization, the MDSAP may well become the harmonized framework and the transition should be managed in a gradual manner. Details of the designation requirements should be worked out through dedicated consultation process.

The MTAA agrees with the designation criteria provided in the consultation document. The designation criteria should not be in conflict with:

- the IMDRF guidance IMDRF/MDSAP WG/N3FINAL:2013 *Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition* or
- the ISO/IEC 1702X series of standards *Conformity assessment - Requirements for bodies providing audit and certification of management systems*

Recommendation 8

The MTAA is supportive of TGA's proposal to use MDSAP reports to provide evidence of compliance with the QMS requirements of the relevant conformity assessment procedures.