AUSTRALIAN
AND
NEW ZEALAND
COLLEGE
OF
ANAESTHETISTS
A.B.N. 82 055 042 852

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

Designation of Australian conformity assessment bodies for medical devices

Thank you for the opportunity to provide comment on the public consultation document, *Designation of Australian conformity assessment bodies for medical devices*.

The Australian and New Zealand College of Anaesthetists (ANZCA), including the Faculty of Pain Medicine (FPM), is committed to high standards of clinical practice in the fields of anaesthesia, perioperative medicine and pain medicine. As the education and training body responsible for the postgraduate training programs of anaesthesia and pain medicine for Australia, New Zealand and parts of Asia, we believe in ongoing continuous improvement and strive to ensure our programs represent best practice and contribute to a high quality health system.

The medical specialty of anaesthesia is critical to the provision of safe, effective anaesthesia and perioperative care for patients. ANZCA is involved in anaesthesia mortality reviews, collecting patient outcome data, publishing information relevant to the safe practice of anaesthesia, preparing evidence based guidelines and improving communication about quality and safety in anaesthesia, perioperative medicine and pain medicine. Its Faculty of Pain Medicine is the first multidisciplinary medical academy in the world to be devoted to education, training and standards in pain medicine.

ANZCA has reviewed the consultation paper and the responses that are set out below reflect the position of anaesthetists and pain medicine specialists as end-users of medical devices, including a number of high-risk implantable devices.

ANZCA regards the recommendations made in this consultation to be generally sound. These recognise the complexity of the assessment of medical devices, especially high-risk implantable devices.

ANZCA is aware that the vast proportion of medical devices included on the Australian Register of Therapeutic Goods (ARTG) have relied on European certification (CE mark) and that concerns about performance of "notified bodies" in Europe has led to a significant reduction in the number of such organisations and a longer assessment time frame. As the TGA indicates, the industry expertise required to undertake conformity assessment of medical devices is significant and this may be in limited supply in Australia until capability is developed. Due process regarding the ongoing maintenance of standards and audit must be both explicit and assured during this transition in capability. The availability of guaranteed and ongoing funding to achieve this capability is also of significant concern.

The College considers that the risk to patients or clinicians from unsuitable devices being approved is likely to be small as the designation process for certification of conformity assessment bodies appears to be robust and the requirements for such bodies well defined. Of greater concern is the delay in suitable devices being included on the ARTG due to the limited availability of suitably qualified experts able to provide conformity assessment.

The TGA is to be commended for emphasising the importance of public health protection when proposing these regulatory changes and acknowledges the balance that the TGA has struck between reacting to the implications of such changes globally and mitigating any risk to the Australian public.

Thank you for the opportunity to provide feedback. Should you require any further information, please contact Karen Gordon-Clark, Safety and Quality Coordinator via email sq@anzca.edu.au or telephone (03) 8517 5394.

Yours sincerely

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Chair, Safety and Quality Committee