June 10, 2016

Business Improvement and Support Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Re: Consultation: Draft Clinical Evidence Guidelines – Medical Devices

The Faculty of Pain Medicine (FPM) and the Australian and New Zealand College of Anaesthetists (ANZCA) thank you for the opportunity to provide feedback on this Consultation Document.

The Faculty and College supports the document in both its intent and content.

The document recognises and discusses the difficulties in defining minimal requirements for evidence and safety that determine the listing by the TGA of new medical devices. Evidence of efficacy and safety of such devices is usually unable to be produced in the form of randomised, double-blind, controlled trials which are the prerequisite gold-standard in the area of pharmaceuticals. A lesser standard is necessarily applied. For this reason, effective, comprehensive, independent, post-marketing monitoring is essential.

The document is explicit that, “Clinical evidence is required not only when a medical device is first included on the register but for the entire period it remains on the register” (page 7). FPM and ANZCA wish to emphasise the important role of device registries in post-marketing surveillance, to ensure demonstration of appropriate levels of safety and performance of devices.

Registries are essential to:
- Inform medical decision-making,
- Promote innovation and evaluation of devices in the clinical environment
- Encourage industry investment,
- Ensure optimal cost-benefit of health expenditure
and most importantly,
- Protect the safety of patients and promote the better health of the Australian public.

In the document, Section 6, “Requirements for specific high-risk devices”, has particular significance for the specialty of Pain Medicine. This section requires comprehensive assessment of the benefit-risk profile of the device to be determined, taking into account the safety, performance and patient health outcomes. Of the six listed dot-points, two are pertinent to FPM and ANZCA: Electrical
impulse generators; and Demonstrating the safety of implantable medical devices in the magnetic resonance environment.

Implantable devices for the treatment of long-standing pain conditions include implantable impulse generators (spinal cord and peripheral nerve stimulators) and implantable, programmable pumps for the delivery of opioids or baclofen into the intrathecal space.

There is currently no independently governed registry in Australia for implantable pain-relieving devices. FPM and ANZCA consider that the establishment of such a registry should not only be a key recommendation arising out of this document but also should be identified as an essential requirement to be achieved in a set time frame.

FPM ANZCA supports the proposed list of potential reportable outcome data to be incorporated in a implantable pain-relieving device registry, including data on performance and on adverse events The proposed requirements for provision of follow up data at thirty days and twelve-months post implant are supported as a minimum.

FPM and ANZCA make the following specific comments and recommendations:

- The TGA should mandate commitment to a device registry as a requirement of device listing and ongoing accreditation
- The TGA should adopt a central role in facilitating post-market surveillance of high risk implantable devices via device registries
- Optimal post-marketing surveillance must address:
  - Efficacy and safety of devices,
  - Judicious health expenditure,
  - Security of industry investment and innovation
  - Information regarding best clinical practice
- Custodianship of the registry should be independent of the device company
- Stewardship of the registry should be by an independent committee, not a single clinician.
- Peak research and educational medical institutions (Faculties, Colleges or Universities) are the most appropriate custodians of device registries to inform the TGA on ongoing safety and efficacy of devices.

The Faculty and College would be happy to develop the point of view put forward in this feedback comment on the Draft Clinical Evidence Guidelines.

Yours sincerely,