RANZCO The Royal Australian and New Zealand College of Ophthalmologists
THE LEADERS IN COLLABORATIVE EYE CARE

25 August 2017

Business Improvement and Support Section
Medical Devices and Product Quality Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Via online submission platform.

RANZCO submission to: Consultation: Alignment with European medical device regulatory framework – Up-classification of surgical mesh & Patient implant cards

The Royal Australian and New Zealand College of Ophthalmologists welcomes the opportunity to provide feedback on the Authorised Prescribers process review.

RANZCO's mission is to drive improvements in eye health care in Australia, New Zealand and the Asia Pacific Region through continuing exceptional training, education, research and advocacy. Underpinning all of the College's work is a commitment to best patient outcomes, providing contemporary education, training, and continuing professional development, evidence based decision making, collaboration and collegiality.

Surgical meshes are used in a number of different ophthalmology surgeries, including different types of ophthalmic implants or ptosis surgery.

In general, RANZCO supports ensuring that patients are fully informed about their implants, and strengthening the regulation regarding handing out implant cards to patients is appropriate. Furthermore, RANZCO supports in principle aligning Australian regulatory frameworks with appropriate and relevant overseas frameworks.

Based on the experience of RANZCO Fellows, patients often ask their doctors to keep the implant cards in their records. We also note that the TGA anticipates that "information on implantable medical devices would increasingly be entered into a patient's Myhealth record in coming years". It may therefore be appropriate to ensure that both the patient and the surgeon keep a record of the information covered in an implant card. This may also aide with any future safety audits.

It should be noted however that the full implication of re-classification on ophthalmic procedures is not entirely clear. In particular, it is not clear whether Intra-Ocular Lenses applications would also be impacted by these changes. Therefore, it may be appropriate to re-evaluate the impact of these changes after they come into effect.

If you require any further information, please contact RANZCO Policy Manager, Guy Gillor, at ggillor@ranzc.edu , in this regard.

Your sincerely,

Andrew Symons
Chair, RANZCO Therapeutics Committee

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