RANZCO submission re: Draft clinical evidence guidelines - Medical devices

The Royal Australian and New Zealand College of Ophthalmologists (RANZCO) welcomes the opportunity to comment on the TGA’s Draft clinical evidence guidelines – Medical devices consultation.

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. RANZCO also seeks to educate the general public in all matters relating to vision and the health of the human eye and advocates for accessible ophthalmology cost effective services for patients.

From the information presented in the draft clinical evidence guidelines, as released for consultation, it is difficult to discern the impact it will have on the current approval process for ophthalmic devices as compared to existing arrangements. However, RANZCO wishes to express its concern that the draft guidelines do not seem to relieve some of the biggest burdens on the process as it stands, and may in practice add to the burden of the process.

A longstanding problematic aspect of the TGA process is the existing ‘user pays’ principle, whereby applicants are covering the cost of the TGA processes. These costs may often increase costs to both Government and consumers in the long term, as they may stifle innovation and competition. Furthermore, the ‘user pays’ system puts the TGA in a conflicted state where the applicants are also the source of revenue. The proposed draft clinical evidence guidelines do not seem to alleviate these problems.

One aspect of the draft guidelines that particularly concerns RANZCO is that they may increase the existing burden on applicants (and therefore the efficient introduction of breakthrough medical devices for Australian patients) due to the apparent lack of a specific pathway for devices approved in accepted overseas processes. These may include specific, relevant approval processes of the United States’ Food and Drug Administration (FDA) or the European Economic Area’s Conformité Européenne (CE).

RANZCO is concerned that this may lead to delays in the adoption of acceptable devices for use in Australia. If the burden of regulation is too great, reputable manufacturers may not deem it
commercially viable to apply for TGA approval, concentrating their efforts on larger, more lucrative markets. This problem is exacerbated by the small size of the Australian market.

Current approval practice, whereby CE approval for example is considered adequate for ophthalmic device approval in Australia, appears to have worked well. This is in contrast to the FDA approval process in the United States, which has proved to be lengthy and expensive. In the United States, some manufacturers of ophthalmic devices have stopped applying for FDA approvals as their potential revenue is impacted by the increasing costs associated with applications for FDA approval. This has resulted in a number of ophthalmic and other therapeutic devices which are widely accepted as being effective and safe being denied to patients in the United States due to the cumbersome FDA approval process.

The existing TGA process for approval of medical devices can already be too cumbersome and expensive for devices with limited domestic market revenue potential. This has pushed some Australian medical scientists to develop devices overseas rather than in Australia. In ophthalmology, for example, two breakthrough devices related to Microinvasive Glaucoma Surgery, created by Australian ophthalmologists Professor Minas Coroneo (Cypass) and Professor William Morgan (Aquesys), were developed overseas.

RANZCO supports the draft’s concept that evidence gathered to support a company’s application need not be generated anew in Australia if it has been collected elsewhere. This may allow for more rapid introduction of devices than in the US even if the current automatic TGA approval extended to CE approved devices were ceased.

To further illustrate the importance of reducing the burden on medical devices innovation, please see the attached Tale of Surgical Scissors with a Twist, kindly provided by RANZCO Fellow Dr Nigel Morlet, in the Appendix. The tale is based on the actual process of registering a new medical device, and is an example of how the current process may stifle medical innovations. While it is absolutely crucial to have proper regulation mechanisms for medical devices, there is a real danger of such mechanisms acting as barrier for innovation and may demotivate entrepreneurship. Finding the right balance is crucial.

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

Kind regards,

David Andrews
RANZCO ECO
Appendix: A Tale of Surgical Scissors with a Twist / Dr Nigel Morlet

- An experienced lacrimal surgeon finds existing scissors to not be accurate enough. He finds that a specific twist of the tips improves the scissors’ application.
- The surgeon asks a medical instruments maker to produce scissors with the specific twist on the tip.
- The surgeon is then told that he is not allowed to use the scissors in surgery, because they haven’t been registered with the TGA’s list of therapeutics goods and devices, and any use of the scissors would need to be endorsed by an Ethics Committee (given its surgical nature it would be classified ‘IIb’).
- The HREC meets monthly and requires a highly detailed submission, which should include a research protocol, and because it is an “experimental” device, a Clinical Trials Notification Scheme approval from the TGA as well as sponsoring organisation also required.
- In addition, an insurance certificate is required for the Ethics Committee application. There is only one insurer for clinical trials in Australia, with costs starting at $10,000 (or starting at $20,000 if the “trial” is in NSW).
- Manufacturing the twisted scissors in Australia requires a TGA registered company. To obtain a compliance certificate, a basic manufacturing ‘system’ can cost well over $100,000.
- Given the complicated nature of such applications, it can then take 9-18 months to complete the review.
- The HREC is then likely to decide that a simple evaluation is insufficient, and may require a controlled trial.
- After many months of the above process, the surgeon can finally use the twisted scissors. The surgeon finds that the twist was useful 80% of the time, but surmised that a slightly different twist might improve that to 95% plus. However, this would require going through the entire process once again, which may decide that a larger trial is needed, with all expenses involved.
- The lengthy and expensive process may then suppress innovation by demotivating clinicians to innovate and further develop existing technologies, which may ultimately impact on patients. And even if the surgeon in this example does go through the entire process, the eventual cost of the instrument may be very high, to somewhat compensate for its process. Even if it’s a seemingly simple pair of twisted scissors.