3 March 2015

[redacted]
Biological Science Section
Office of Scientific Evaluation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Via email: bloodandtissues@tga.gov.au

Dear [redacted]

RANZCO Submission - Regulation of autologous stem cell therapies

The Royal Australian and New Zealand College of Ophthalmologists (RANZCO) appreciates the invitation to provide comments in response to the Therapeutics Goods Administration's discussion paper on the regulation of autologous stem cell therapies.

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 RANZCO'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 services for patients.

RANZCO supports Option 4 which would require autologous cells to be regulated under the *Therapeutic Goods Act 1989* (the Act) as Class 1 biologicals.

Many academics in the efforts to raise funds for research have sold the promise that stem cells will deliver astonishing benefits. Patients with severe vision loss, both real and threatened, are desperate and extremely vulnerable to false advertising particularly in the area of stem cell therapy. They are ready to be exploited by unscrupulous entrepreneurs falsely promising benefits in exchange for a lot of money. It is likely that a patient's desire for a miracle will greatly impair their ability to be informed of any risks. Based on contemporary usage autologous stem cells meet the definition of therapeutic goods in the Act. RANZCO believe Option 4 properly addresses these concerns.

RANZCO notes that in many cases, cells will not be used in their original sites of origin. For example in ophthalmology, Ocata's trial Retinal Pigment Epithelium stem cells for age-related macular degeneration patients and Stargardt's disease patients are a differentiated human embryonic stem cell. These will therefore not fit the requirements for regulation as Class 1 biologicals, and will require a greater level of regulation.

RANZCO is willing to provide further advice in regards to the issues raised above. Should you require any further information, please contact [redacted].

Yours sincerely

[redacted]

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