



The Royal Australasian
College of Physicians

[REDACTED]

20 February 2015

[REDACTED]

Via Email: bloodandtissues@tga.gov.au

Dear [REDACTED]

Therapeutic Goods Administration - Consultation on the regulation of autologous stem cell therapies

Thank you for the opportunity to provide The Royal Australasian College of Physicians' (RACP) input into the Therapeutic Goods Administration's (TGA) consultation on the regulation of autologous stem cell therapies.

The RACP has consulted with a number of RACP Fellows working in this area to produce its response to this consultation. The general consensus amongst these experts is that the current regulation of autologous stem cell therapies is insufficient and presents a number of significant risks to public health including:

- Potential adverse effects on patients' health, such as potential risks of injury, transmissible infectious disease, tumours, bleeding and death. These risks cannot be appropriately assessed in the current regulatory environment given that the reporting of adverse effects is not mandatory
- False hope from dishonest or misleading advertising (both online and television including through television programs)
- The possibility of diminished patient access to proven therapies due to the high costs and lack of reimbursement of fees for unproven therapies
- Lack of proven efficacy and increasing commercial use of a variety of stem cells sources for unproven indications including osteoarthritis, multiple sclerosis, autism and neurological disorders by practitioners with limited or no expertise in the field.

Autologous stem cell therapies have the potential to improve health outcomes for a range of conditions for which their efficacy and safety have not yet been proven. However, until the efficacy of these therapies is proven for a given condition, it is too premature and risky to offer them for routine clinical use due to the range of potential risks previously mentioned.

Where appropriate and available, the RACP supports eligible patients having access to these therapies via properly conducted, well designed clinical trials approved by a Human Research Ethics Committee and carried out by experts in the relevant diseases. All therapies available to patients should be evidence-based, safe and have proven efficacy.

Although the expert Fellows we consulted expressed a range of views about alternative options for regulating stem cells, the overwhelming majority agreed that the current regulation requires significant strengthening to ensure the range of risks identified are addressed and patient safety is safeguarded. In addition, the RACP's view is that the option chosen should incorporate the following:

- Stem cells therapies should be regulated under the Act
- All autologous stem cell therapies made available should have proven their efficacy and safety in properly conducted clinical trials before being made available for routine clinical treatment
- Once their efficacy and safety is adequately assessed and proven, these therapies should be dispensed by expert practitioners only
- The reporting of adverse effects should be made mandatory
- Advertising should be limited to health practitioners only.

The RACP would like to be kept informed of progress with the outcomes of the consultation. Should you require any further information about this submission, please contact [REDACTED]

Yours sincerely

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