

## **Submission to the Therapeutic Goods Administration on Regulation of autologous cell and tissue products**

*6 October 2016*

Arthritis Australia and the Australian Rheumatology Association welcome the opportunity to provide feedback to the TGA's consultation on the regulation of autologous cell and tissue products. Our interest in this area relates in particular to the use of stem cell therapies to treat osteoarthritis, which we believe requires much more stringent regulation by the TGA.

Osteoarthritis is a leading cause of pain and disability in the Australian population. It affects 2 million people and costs the health system at least \$2 billion a year. With an ageing and increasingly obese population, the prevalence of osteoarthritis is expected to increase to 5.5 million people by 2030.

Currently, there are no disease-modifying therapies that have a credible evidence base for osteoarthritis, so we welcome and strongly support research into treatment and prevention strategies to alleviate the burden of this condition.

Autologous stem cell therapies offer great promise as a potential treatment for osteoarthritis, but at present the evidence base is inadequate to support their use for this condition. Current research is still in its early stages and understanding of the efficacy and safety of these therapies is limited. Further research, through properly conducted randomised controlled clinical trials, is essential to determine the therapeutic role of stem cell treatments for osteoarthritis.

Despite limited evidence of their efficacy and safety a number of private clinics offer autologous fat-derived stem cell therapies to patients for osteoarthritis. These unproven therapies are currently marketed directly to vulnerable consumers as innovative therapies, but without the protection of regulation and without needing to meet the TGA's requirements relating to clinical trials.

The current lack of regulation allows medical practitioners to freely administer these unproven therapies to their patients, posing a serious risk to their patients' health, with potential adverse events including infection and ectopic tissue formation, without clear evidence of benefit. They may also displace other, proven therapies for managing a patient's condition. In addition these treatments are provided at substantial financial costs to consumers, including treatment and follow-up costs, as well as the potential cost of emergency medical care in the event of medical complications.

For these reasons, we consider it unethical and unprofessional to market these unproven treatments to consumers and support much tighter regulation of their use by the Therapeutic Goods Administration.

*In order to best protect the interests of consumers, we strongly recommend the adoption of Option 4 for TGA regulation of autologous cell and tissue products.*

**Option 4** – Human cell and tissue products:

a. for autologous use, under the supervision of a medical/dental practitioner, as part of a single course of treatment, would be excluded from TGA regulation only if the product is:

- i. not advertised directly to consumers; and
- ii. not more than minimally manipulated;

b. that do not meet one or more of the exclusion criteria (i.e. not for autologous use, not under the supervision of a medical/dental practitioner, not part of a single course of treatment, more than minimal manipulation or advertised) would be regulated under the TG Act in the same way as other biologicals in the relevant class.

In supporting option 4, we note and fully support the TGA view outlined in the consultation paper, that physical disruption of a tissue such as adipose tissue, as occurs in stem cell treatments for osteoarthritis, constitutes more than minimal manipulation and hence would be regulated under the TG Act in the same way as other biologicals.

We also support the new definition of ‘minimal manipulation’ proposed by the TGA, which more closely aligns with international definitions. We support the consistent use of this new definition across the entire biologicals framework.



Ainslie Cahill  
**CEO**  
Arthritis Australia



Rachelle Buchbinder  
**President**  
Australian Rheumatology Association