Submission to Therapeutic Goods Administration

Discussion Paper
Regulation of autologous stem cell therapies

Thank you for inviting a submission on the discussion paper on "Regulation of autologous stem cell therapies" from the Australian Rheumatology Association

The ARA has had an interest in this area as it now impacts on the treatment of osteoarthritis which is both an extremely prevalent condition which is devoid of disease modifying treatment. Accordingly we have published on our website a "Position paper on stem cell therapy"[1].

Our concerns lay specifically in the procedure for harvesting adipose tissue derived stem cells which are being advocated and provided for patients with osteoarthritis of the knee. We are pleased to see that this procedure has been thoroughly examined in attachment 2. of your "Discussion paper".

Our position as promulgated in the position paper is summarized as follows:-

Osteoarthritis is a leading cause of pain and disability for the Australian population and it is likely to increase as a cause of morbidity with the ageing of the population, therefore research into methods of alleviating this burden is to be encouraged and supported.

There is no currently accepted disease modifying therapy that has a credible evidence base for efficacy for the treatment of osteoarthritis. Stem cell based therapies hold promise to redress this deficiency and research into their efficacy needs to be pursued as a matter of priority.

Of equal importance is that research needs to be conducted along scientific lines so that any result will stand up to scrutiny. For a clinical question such as the efficacy of autologous stem cell therapy this means properly conducted randomized controlled trials.

We have drawn attention to the fact that the use of fat derived stem cells involve multiple steps (harvesting, purifying cell culture, stimulating and re-injecting). Therefore this cannot be regarded as minimal manipulation and thus is not in the same category as vein harvesting for coronary artery bypass grafting or skin flaps.

As stated in our position statement and in line with the opinion of the International Society for Stem Cell Research[2], we regard it as unethical and unprofessional to market such treatments directly to patients.

We note the high cost of the process and thus the high cost to patients and which we see this as yet another disincentive to use an unproven therapy outside a trial setting.

Given the above and given the options put forward in the discussion paper we favour a regulatory system that involves

- No advertising directly to patients
- Adverse effect reporting
- Safety and quality standards
- Requirement for the demonstration of efficacy
- Appropriate manufacturing standards

It would therefore appear that option 5 in the Discussion paper is the only option that satisfies these requirements. We believe that autologous fat derived stem cells should be treated by the TGA as a class 2, 3 or 4 biologic.

Yours sincerely

Julian McNeil
Associate Professor in Medicine
Chair, Therapeutics Committee
Australian Rheumatology Association
JM:FA

1. http://www.rheumatology.org.au/downloads/ARA%20Position%20Statement%20042014.pdf

2. http://www.isscr.org/home/about-us/news-press-releases/2013/2013/09/12/isscr-statement-of-delivery-of-unproven-autologous-cell-based-interventions-to-patients