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3 March 2015

Biological Science Section  
Office of Scientific Evaluation  
Therapeutic Goods Administration  
Department of Health  
PO Box 100  
WODEN  
ACT 2606

Dear Colleague:

**Re: Regulation of Autologous Stem Cell Therapies**

The Australian and New Zealand Society of Blood Transfusion (ANZSBT) through its Clinical Practice Improvement Committee (CPIC) would make the following points in relation to the *Regulation of Autologous Stem Cell Therapies - discussion paper for consultation*:

- We strongly believe that like blood and blood products, cellular therapies are a biological medicinal with intrinsic impurities or additional substances/elements that may lead to unwanted effects (both short term and long term).
- We therefore believe that careful monitoring for adverse and unexpected effects is essential. Ad hoc reporting of effects in the peer-review literature is not sufficient to obtain comprehensive data on effects and emerging trends.
- As these biological agents are currently unproven and interest is emerging in many different areas careful management of access, quality and safety are important principles.
- One element of safety that is not specifically mentioned in the discussion paper is risk related to mishap such as incorrect labeling, storage and potential for infusion or injection to the wrong patient. This could occur if multiple patient therapies are being undertaken at one time and/or collection is followed by deferred treatment at a later time point. Risks may be greater in a high throughput environment.
- Our membership's clinical training and experience leads to great unease in relation to lack of clinical efficacy data and we are concerned about direct advertising to vulnerable patient groups and high cost of therapies.

In view of these concerns the Society expresses its preference for option 5 as described in the discussion paper but would otherwise be satisfied with option 4 as a minimum.

On behalf of the Society and in particular Dr. Marija Borosak (Chair, CPIC) I would like to thank the TGA for the opportunity to comment on the *Regulation of Autologous Stem Cell Therapies - discussion paper for consultation*. Please do not hesitate to contact the Society if you require clarification on any of the points we have made.

Yours sincerely,



**SIMON BENSON FIBMS**  
President

