Medical Council
OF*NEW*SOUTH*WALES

PO Box 104 | Gladesville NSW 1675
DX: 22808 Gladesville
Telephone: (02) 9879 2200
Facsimile: (02) 9816 5307
www.mcnsw.org.au

Our Ref: C15/200-01 : DD15/06713

3 March 2015

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

CONFIDENTIAL

Dear [redacted]

**Regulation of autologous stem cell therapies –
Discussion paper for consultation**

Thank you for the opportunity to provide a response to the Regulation of autologous stem cell therapies – Discussion paper for consultation (Version 1.0 January 2015).

The Medical Council of NSW (the Council) is a statutory authority established under the Health Practitioner Regulation National Law (NSW). The Law is designed to provide for the protection of the public by ensuring that medical practitioners are fit to practise medicine, and that all registered doctors maintain proper standards of conduct and competence. The Council expects registered medical practitioners to comply with its published policies, as well as those standards and codes published by The Medical Board of Australia.

Regardless of the regulation arrangements for autologous stem cells themselves, the Council will maintain responsibility for managing any complaints about the conduct, performance or health of registered medical practitioners providing autologous stem cell therapies in NSW.

The Council supports the maintenance of the current arrangements with regard to those other autologous human cells and tissues currently captured by the Therapeutic Foods (Excluded Goods) Order No. 1 of 2011 (the Order) Item 4 (q), and the comments in this submission refer only to autologous stem cell therapies as defined in the Discussion Paper.

The Council has identified several concerns with the current arrangements for the use of autologous stem cells, including the current lack of standards and regulation with regard to the manufacture of stem cells, and the absence of any organised widespread data collection regarding efficacy or adverse events.

The Discussion Paper highlights reports of infrequent significant adverse events which have occurred following the use of autologous stem cells, and it is this risk to patient safety which the Council considers paramount. It is considered that there may be significant potential and possibly as yet unidentified risks to patients in an unregulated environment, such as have been outlined in the Discussion paper. These include risks related to the manufacturing process; risks inherent to the product or the way it is administered, which may manifest during or after the procedure; potential financial risks to patients; and the current lack of ability for true informed consent for such procedures where the efficacy and level of risk has not been conclusively established.

With these patient safety considerations in mind, the Council considers that Option 5 is the only option which will adequately reduce the risks to patients, specifically in regard to the ability to ensure the licensing and safety of the manufacturing process. Of equal priority is the opportunity for the widespread organised collection of data regarding adverse events and efficacy. The Council considers such a formal system to be vital in informing current practice and future developments in this area. Option 5 includes all of these safeguards and is therefore strongly supported by the Council. Provision should be made, however, to ensure that despite a lack of data regarding efficacy, the product would still be made available in the circumstance of a properly conducted clinical trial of an experimental therapy.

Of lower priority, but significance nonetheless, is the advertising of autologous stem cell therapies directly to patients. With regard to advertising, registered medical practitioners are currently required to comply with the provisions of the Health Practitioner Regulation National Law (NSW), as outlined in the *Guidelines for advertising regulated health services* published by the Medical Board of Australia. Given the current paucity of evidence on the efficacy and safety of many autologous stem cell therapies, the Council considers that additional advertising restrictions, such as are suggested under Option 5, would be of further benefit in public protection.

The selection of any of the other suggested options (1 – 4) would not be supported by the Council, as the regulation of the manufacturing process is considered imperative.

The Council recognises the importance of ongoing evidence-based development in this area, and the need to facilitate properly conducted research whilst the ensuring standards of practice and requirements of patient safety are met.

Yours sincerely

Stuart Dorney