3rd March 2015

Australian Government
Department of Health
Therapeutic Goods Administration

via email: bloodandtissues@tga.gov.au

UNSW AUSTRALIA

To whom it may concern

Re: UNSW submission to the TGA Discussion paper for consultation on *Regulation of autologous stem cell therapies*

UNSW welcomes the opportunity to contribute to the issues raised in the Therapeutic Goods Administration (TGA) Discussion paper, *Regulation of autologous stem cell therapies* released in January 2015 (Discussion Paper).

UNSW was established in 1949 as the only research-intensive university in Australia with scientific and technological focus. The Faculty of Medicine was added in 1960 with five foundation chairs – anatomy, medicine, pathology, physiology and surgery, and Prince Henry Hospital as the University's first teaching hospital. Since that time, UNSW Medicine has evolved to become one of the world's top 30 medical faculties with leading educators, researchers and clinicians translating discoveries into breakthrough cures, therapies and treatment strategies. Each year, UNSW Medicine graduates high achieving students into caring healthcare professionals with globally recognised qualifications. Currently, UNSW Medicine is comprised of eight schools in Sydney, a Rural Clinical School with country campuses across NSW, and close affiliations with some of Australia's finest hospitals and healthcare organisations.

Introduction

UNSW is well placed to make a contribution to this consultation as a leading research-intensive university with valuable affiliations with leading medical research institutes and flourishing research, teaching and clinical programs for both undergraduate and graduate students. UNSW is a bastion of evidence-based medicine and patient safety.

UNSW recognises stem cell therapy as heralding a new age of clinical medicine with unprecedented potential for the treatment of disease and injury. Being at the frontier of medical innovation, research and practice, stem cell therapy, however, raises significant public policy issues and challenges which must be considered and effectively managed for wider social and health benefits to accrue. The area is, however, still relatively nascent and autologous stem cell treatments specifically are still experimental and this leaves significant issues and challenges unresolved. In the interim, the potential for risk and harm to patients is significant and could lead to exploitation and other unintended consequences.

UNSW preferred option for regulation of autologous cells – Option 5

UNSW observes a weakness in the current regulations under the TGA; namely, the TGA regulations currently sanction doctors to administer cells extracted directly from a patient for a single condition in a single course of treatment, evading all the usual legal and regulatory constraints on manufacture, manipulation, efficacy and safety reporting. This loophole has seen the development and acceleration of a new, international market for unfounded, unproven and potentially unsafe stem cell treatments.

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Demand for such treatments is especially high among patients who are very ill, desperate and vulnerable. While **'doctor-shopping'** for such unfounded, unproven and potentially unsafe treatments is not new, a recent complicating factor for the profession is the proliferation of **'Dr Google'** which connects patients to unscrupulous practitioners around the world. There is potential, therefore, for Australia to become a destination for stem cell tourism.

Further, once therapy is commenced, there is **no requirement for verification of treatment efficacy against reliable or independent protocols or standards**, and frequently **multiple courses of treatment** are required of the patient by the practitioner. This type of autologous stem cell therapy is contrary to evidence-based medicine and patient safety.

At present, action by the **Australian Health Practitioners' Regulation Agency (AHPRA)** is only triggered when patients report an unsatisfactory experience or when a patient lodges an advertising complaint to the **Australian Competition and Consumer Commission (ACCC)**.

In light of the above, **UNSW advocates for adoption of Option 5** outlined in the TGA Discussion Paper. Option 5 is regulation of autologous stem cells under the *Therapeutic Goods Act* proper (i.e. not in the regulations) in the same manner as biologicals are regulated *i.e.* according to applicable class 2, 3 or 4. The corollaries of this include:

- **Advertising of autologous stem cell treatment will be limited to health practitioners**. This will remove advertising from the public domain so that GPs and other health care practitioners become the holders of this information regarding such treatments.

This is especially important as there is lack of understanding of the difference between 'experimental medicine' and 'approved therapeutic procedures' in some sectors of the community and acceptance of the risks associated with unproven therapies. This is especially concerning for the vulnerable and ill patients most likely to embark on autologous stem cell treatment.

- The **standards of the TGA will apply to autologous stem cell treatment and reporting of any adverse patient effects will be mandated**. The TGA standards set a very high benchmark for evidence-based medicine and patient safety, and encompass safety requirements in administration of the treatment.

- the **Revised code for Good Manufacturing Practice (GMP) for human blood and blood components, human tissues and human cellular therapy products**, will apply to autologous stem cell treatment.

Adoption of this regulatory regime will give the TGA,. as well as the ancillary regulatory authorities, AHPRA and ACCC, the correct levers to regulate and manage autologous stem cell treatment in Australia, as well as curb the expansion of further unproven therapies becoming available in Australia. This will ensure that evidence-based medicine and patient safety remain the paramount drivers for Australian health care. It will also mitigate potential unintended consequences such as unproven and unregulated treatments such as autologous stem cell treatment being marketed to vulnerable and desperate patients and/or development of the perception that Australia is a destination for stem cell tourism.

UNSW welcomes the opportunity to discuss these issues further, and consults to publication of this submission in part and in full.

Yours faithfully

Professor Les Field
Vice-President and Deputy Vice-Chancellor (Research)