

## Australia and New Zealand Legal and Regulatory Affairs

### Watchdog Update



### Australia

The Therapeutic Goods Administration (TGA) recently sought comments on the following consultation paper: Changes to accessing unapproved therapeutic goods through the Authorized Prescriber and Special Access Schemes (closing date 29<sup>th</sup> March 2017).

There are currently a number of mechanisms that allow individuals to gain limited access to therapeutic goods that are not listed on the Australian Register of Therapeutic Goods (ARTG):

1. The Special Access Scheme (SAS). This scheme has two pathways depending on patient categorisation: Category A includes persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment; and category B includes all other patients.

Category A patients have the right, in consultation with their medical practitioner, to use any therapeutic good (other than listed exceptions). The treating registered medical practitioner can prescribe the unapproved therapy and notify the TGA.

For category B patients, the treating medical practitioner needs to seek approval from the TGA.

2. Authorised Prescriber (AP) Scheme whereby the TGA gives medical practitioners authority to prescribe a specified unapproved therapeutic good or class of unapproved therapeutic goods to patients with a specified medical condition. The medical practitioner becomes an 'Authorised Prescriber' and can prescribe that product for that condition to individual patients in their immediate care without further approval from the TGA. Human research ethics committee (HREC) approval is also required.
3. The personal importation scheme which allows restricted and short-term importation of some unapproved therapeutic goods for personal use.
4. Via Clinical Trials

The consultation paper proposes the following changes:

- a) SAS Category B: Change from approval by the TGA to notification of the TGA for defined products.

- b) For the AP Scheme, the TGA has proposed a reduction in duplication of approval by allowing the HREC or specialist college to approve the clinical justification.
- c) Change to an online system for SAS and Authorised Prescriber Scheme notifications and approvals.

A response was submitted on by the ISCT ANZ LRA ISCT indicating that the group broadly endorses the proposals specified in this paper, but notes that these proposals should be considered in conjunction with the medical exemption in the Excluded Goods Order Item 4(q) for autologous human cells and tissues, as well as the relatively permissive scheme for clinical trials available under the Clinical Trials Notification (CTN) pathway. The rapid and broad exemption available to patients and clinicians under SAS and AP schemes may be associated with relatively low risks when used for pharmaceuticals such as “established pharmaceuticals in other regulated jurisdictions” but this is not necessarily the case when applied to cells and tissues.

Our comments relate specifically to cells and tissues, whether autologous or not. These are sometimes available under conditional access or expedited access schemes in other jurisdictions, where there is little if any evidence of efficacy and it is absolutely critical that these approvals are not seen as a *de facto* justification for availability under SAS or AP in this market.

The reduction of regulatory burden in relation to HREC or specialist college approval of AP and the extension for length of approvals for AP for devices and medicines is supported. However we would recommend that products considered as Category 3 or 4 products in the Biological Framework should **not** become available via either the SAS Category B scheme or the AP scheme. We do not endorse automated acceptance of cell-based products with an established pattern of treatment in another market without any evidence of efficacy.