TGA Regulation of Autologous Human Cell and Tissue Products

Reading time:
Jayson Nagpiing
Last Modified on 08/05/2024 9:16 pm AEST

In December 2017, the Australian Government decided that regulation of autologous human cell and tissue products including stem cell treatments must be implemented.

Stem cells have been safely and effectively used to treat disorders of the blood and immune systems but some practitioners offer unproven treatments. As a consequence, the level of regulation is being determined by risk posed to patient safety.

Background

Currently, the TGA must approve autologous cells and tissues prior to them being supplied in Australia. In addition, not all products are considered therapeutic goods and therefore may be supplied without approval by the TGA.

Specifically, if they are:

- collected from a patient who is under the clinical care and treatment of a medical practitioner registered under a law of a State or an internal Territory;
- manufactured by that medical practitioner, or by a person or persons under the professional supervision of that medical practitioner; and
- for therapeutic application in the treatment of a single indication and in a single course of treatment of that patient by the same medical practitioner, or by a person or persons under the professional supervision of the same medical practitioner.

Autologous human cell and tissue products were previously not covered by TGA regulation because they were viewed as an extension of medical practice. But as the complexity of the procedure increases, there is growing worldwide concern surrounding risks to patient safety and the ease with which practitioners are advertising directly to consumers.

The new approach will bring Australia into closer alignment with international regulation such as in the United States and the European Union.

These new regulations outline that such procedures can now only be undertaken in an accredited hospital by a medical or dental practitioner.

MIPS members need to be fully compliant in their involvement with any such procedures.

The proposed changes to the regulation of autologous cell and tissue products are to:

1. Prohibit direct advertising to consumersof autologous cell and tissue products, similar to the prohibition in Australia of the advertising of prescription medicines, but noting that services (that do not mention specific products) will still be permitted to be advertised.
2. Exclude from regulation by the TGAonly those autologous cell and tissue products that are manufactured and used in an accredited hospital by a medical or dental practitioner, for a patient in the care of the same practitioner.
3. Introduce regulation by the TGA, with exemptions from some requirements, for autologous cell and tissue products that are:
    1. minimally manipulated
    2. for homologous use only
    3. manufactured and used outside an accredited hospital by a medical or dental practitioner, and
    4. for a patient in the same practitioner's care.
4. Regulate under theBiologicals Regulatory Frameworkautologous human cell and tissue products that are:
5.
    1. manufactured and used outside an accredited hospital, and
    2. more than minimally manipulated, or
    3. for non-homologous use.

When is it changing?

The new regulations will be drafted and submitted to Government for approval in 2018. The timeframe for implementation of the

policy will be confirmed in early 2018. The following timeframe is currently anticipated:

- Changes to the regulation of autologous cell and tissue products will commence in mid-2018.
- The advertising restriction will come in to effect then.
- Transition provisions will be included to allow affected providers time to align with the new regulatory requirements, such as the need to obtain a manufacturing license and/or approval of a clinical trial. The transition period will finish at the end of 2018.
- Detailed guidance on the new regulatory approach will be published early in 2018. This will assist in the interpretation and enforcement of the new requirements.

Further reading

- Regulation of autologous cell and tissue products – including so called 'autologous stem cell' therapies

Should members have any queries related to these issues they are advised to contact MIPS for advice on 1800 061 113.

Related articles