TGA's New HCT Product Regulations

Reading time:
Jayson Nagpiing
Date created: 08/12/2020

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The Therapeutic Goods Administration's (TGA) updated regulations for autologous human cells and tissue (HCT) products, such as adipose-derived stem cells, came into effect on 1 July 2019. This was the culmination of a year long transition period to allow healthcare practitioners to implement any necessary changes to comply with the new regulatory requirements. The content of the article below is provided courtesy of the TGA and reproduced with permission.

What practitioners need to know

If you do not comply with the new requirements, then you must cease supply of your product from 1 July 2019. In the 'Updates' section below, please also note the clarifications to the exclusion criteria for autologous HCT and classification of conditioned serum.

What are the new requirements that apply to my autologous HCT

Effective from 1 July 2019, supply of autologous HCT (unless excluded or exempt) can only occur where:

- The product is included in the Australian Register of Therapeutic Goods (ARTG); or
- Approval has been granted or the TGA has been notified utilising the 'unapproved' product pathways (eg clinical trials, Special Access schemes), where specific criteria are met; or
- An application has been made for GMP certification, a clinical trial exemption (CTX) or inclusion in the ARTG (where further

transition arrangements may apply); and

- The manufacturing facility satisfies good manufacturing practice (GMP) requirements and is TGA licensed.

All autologous HCT products must also comply with advertising prohibitions/requirements

For clarity, supply of products that are cell fractions isolated from adipose tissue are likely to be subjected to full regulation from 1 July 2019. The process to dissociate the cell-cell contacts and isolate the cellular portion from the adipose tissue is considered to constitute more than minimal manipulation.

What levels of regulation apply to autologous HCT?

Detailed guidance is available on the TGA website, of the different levels of regulation that may apply to your autologous HCT, including interpretation of the provisions.

To determine how your autologous HCT will be regulated by the TGA check whether it is:

- excluded from TGA regulation
- regulated by TGA with exemptions from some requirements
- fully regulated by TGA (as a medicine or biological)

How can I get product-specific advice from the TGA?

If you would like further advice from the TGA, the following options are available:

- Download and complete a Request for advice – Biologicals form, and send to bloodandtissues@tga.gov.au
- Request a pre-submission meeting
- Meet us at your local SME Assist workshop. You can subscribe to the SME Assist email list to stay up to date with the latest SME information from TGA.

If you have questions or feedback please contact us at bloodandtissues@tga.gov.au

Updates

- The TGA have clarified that conditioned serum meets the definition of minimal manipulation and thus will be regulated as a blood component, equivalent to platelet-rich plasma (PRP). Amended guidance on the regulation applicable to platelet-rich plasma (PRP), platelet-rich fibrin (PRF) and conditioned serum is available online.
- A minor amendment was made to clarify that the hospital exclusion criterion for autologous HCT products allows storage and testing to occur under contract with the hospital. See information on the TGA website
- The TGA has made further guidance available on how to ensure your publications on HCT products will comply with the prohibitions on advertising them.

What happens if I continue to advertise or supply my autologous HCT?

There are a range of regulatory tools available to the TGA to address non-compliance with the therapeutic goods regulatory framework. Non-compliance exposes you to risk of enforcement, the tools of which are also set out in the Regulatory Compliance Framework and Complaints handling for the Advertising of therapeutic goods to the Australian public.

Further reading:

TGA Regulation of autologous human cell and tissue products

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