Please find important information about the potential impact to your operations of changes to the regulation of autologous human cells and tissues (HCT) products that came in force on 1 July 2018. The one year transition period for implementation of these changes is due to end on 30 June 2019.

We encourage you to commence action to address the upcoming changes to the new regulatory requirements sooner rather than later.

The information below provides detailed guidance on the changes and highlights opportunities for you to seek further advice from TGA, where necessary.

What levels of TGA regulatory requirements apply to different autologous HCT products?

To determine how your autologous product 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)

What immediate action do you need to take as a provider of autologous HCT products?

You are reminded that from 1 July 2018 all autologous HCT products must comply with advertising prohibitions/requirements. Most autologous HCT products must also comply with the following requirements:

- reporting adverse events to the TGA
- compliance with all applicable standards

What TGA regulatory requirements should you prepare for during transition period?

Effective from 1 July 2019, supply can only occur where:

- The product has been included in to the Australian Register for Therapeutic Goods (ARTG);
- Approval has been granted or the TGA has been notified utilising the 'unapproved' product pathways (e.g. clinical trials, Special Access schemes), where specific criteria are met;
- The manufacturing facility satisfies good manufacturing practice (GMP) requirements and is TGA licenced.
- An application has been made for GMP certification, a clinical trial exemption (CTX) or inclusion in the ARTG (where further transition arrangements may apply)

For further information refer to our website on Transition arrangements for autologous HCT products.

Where can I find further information?

Please refer to our detailed guidance on the regulation of autologous cells and tissues for further information.
A recent public webinar that we gave providing an overview of the changes to the regulation of autologous HCT products is available on TGA website.

How can you get further specific advice?

If you would like further advice from us, 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. The next SME Assist workshop is to be held in Melbourne on Wednesday 21 November 2018. Please register your interest by **Wednesday 7 November 2018**. Alternatively you can subscribe to the SME Assist email list to stay up to date with the latest SME information from TGA.

Please forward this information to other interested parties or providers those are likely to be affected by these changes.
If you have questions or feedback please contact us at bloodandtissues@tga.gov.au.

Regards
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