Australian Government

Department of Health
Therapeutic Goods Administration

Mr Jason Lange
Executive Director
Office of Best Practice Regulation
Department of Prime Minister and Cabinet

Dear Mr Lange

Sunsetting of standards and legislative instruments for human cell and tissue (HCT) products, blood and blood components

I am writing to the Office of Best Practice Regulation (OBPR) regarding the standards and legislative instruments for human cell and tissue (HCT) products, blood and blood components that, in accordance with the *Legislation Act 2003*, are scheduled to sunset on 1 October 2021.

The relevant Therapeutic Goods Orders (TGOs), that were reviewed, can be broadly categorised into three groups:

1. Product-specific standards:
    - TGO 83: Standards for human musculoskeletal tissue
    - TGO 84: Standards for human cardiovascular tissue
    - TGO 85: Standards for human ocular tissue
    - TGO 86: Standards for human skin
2. Labelling requirements:
    - TGO 87: General requirements for the labelling of biologicals
3. General donor selection and testing requirements:
    - TGO 88: Standards for donor selection, testing, and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products

Additionally, two other legislative instruments, were also reviewed:

- Therapeutic Goods (Things that are not Biologicals) Determination No. 1 of 2011
- Therapeutic Goods (Things that are Biologicals) Specification 2019

Although TGO 88 does not sunset until 1 October 2023, this Order cross-references TGOs 83-87 and so it was reviewed at the same time to provide clarity across these HCT-relevant TGOs, which, as per the *Legislation Act 2003*, are scheduled to sunset on 1 October 2021.

The Australian Government Department of Health certifies that the review of the performance of standards and legislative instruments for human cell and tissue (HCT) products, blood and blood components found that they are fit for purpose and have operated effectively and efficiently since they came into force. Therefore, a Regulation Impact Statement is not required for the instruments to be remade.

The self-assessment was informed by a public consultation process. The proposal to remake the standards and legislative instruments for human cell and tissue (HCT) products, blood and blood components without substantially altering the current arrangements was available on the TGA website for public comment from 27 May 2021 to 11 July 2021. 33 submissions were received during this consultation period. Most considered the standards and legislative instrument to be efficient and effective, with only minor amendments requested.

Minor amendments will be made, to reflect this feedback and to ensure that the standards remain fit for purpose and broadly aligned with international best practice. These amendments also include exemptions from most labelling requirements for biologicals that are exported from Australia, to reflect that the labelling requirements are only designed for biologicals supplied in Australia.

A 12 month transition period applies for all standards, and an extended three year transition period for certain additional testing requirements for 'cornea only' ocular tissue products, have been negotiated with affected stakeholders.

I acknowledge that OBPR will publish this letter for transparency purposes.

If you have any queries about this advice, please contact Dr Jane Cook on 02 6289 4210 or via email, jane.cook@health.gov.au.

Yours sincerely

Adj. Professor John Skerritt

Health Products Regulation Group

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