Australian Government
Department of Health

Deputy Secretary

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

Email -
helpdesk-OBPR@pmc.gov.au

Dear Mr Lange

Sunsetting of Therapeutic Goods Order No. 89 Standard for water for injections for parenteral medicines, Therapeutic Goods Order No. 90 Standard for human albumin and Therapeutic Goods (Exempting monographs of pharmacopoeias) Determination No. 1 of 2011 – OBPR21-01205

I am writing to the Office of Best Practice Regulation (OBPR) regarding Therapeutic Goods Order No. 89 Standard for water for injections for parenteral medicines (TGO 89), Therapeutic Goods Order No. 90 Standard for human albumin (TGO 90) and Therapeutic Goods (Exempting monographs of pharmacopoeias) Determination No. 1 of 2011 (the Determination), which, as per the *Legislative Instruments Act 2003*, are all scheduled to sunset on 1 April 2022.

The Department of Health has decided TGO 89 will be allowed to sunset as it is no longer needed due to alignment between the United States Pharmacopeia-National Formulary (USP) and European Pharmacopoeia/ British Pharmacopoeia water for injection monographs. However, TGO 90 and the Determination are required. TGO 90 will be remade without significant amendment. The Determination will be repealed and the content of the Determination will be included, without significant amendment, in the Therapeutic Goods (Exempt Monographs) Determination 2021. The Australian Government Department of Health certifies that the Therapeutic Goods Order No. 90 Standard for human albumin and Therapeutic Goods (Exempting monographs of pharmacopoeias) Determination No. 1 of 2011 are

operating effectively and efficiently, and that therefore a Regulation Impact Statement is not required for these instruments to be remade or for the requirements to be included within another instrument.

The Department's decision has been informed by a self-assessment on the performance of the legislative instruments. The sunsetting review found that Therapeutic Goods Order No. 90 Standard for human albumin and Therapeutic Goods (Exempting monographs of pharmacopoeias) Determination No. 1 of 2011 are fit for purpose and have operated effectively and efficiently since they came into force on 26 October 2011. However, many monographs listed in the Determination are no longer official and have been omitted from the USP since 2011 and can therefore be removed from the instrument.

For the remaining monographs in the Determination that are official, reasons for exempting these monographs continue. The following will continue to be exempted by being included in the Therapeutic Goods (Exempt Monographs) Determination 2021:

- Antithrombin III Human
- Factor IX Complex
- Pancreatin
- Pancrelipase
- Plasma Protein Fraction.

The assessment that the regulations are operating effectively and efficiently was informed by a targeted consultation process which involved peak industry stakeholders and selected medicine sponsors that may be directly impacted by the sunsetting of these instruments, over the period 22 October to 19 November 2021. Two submissions were received during this consultation period. Both supported the proposal to remake the instruments without significant amendments, with one recommending the Therapeutic Goods Administration continues to monitor the need for the instruments. Additionally, both respondents also supported the proposal that TGO 89 was no longer required.

I also note that as the instruments are either being remade or combined with another instrument without significant amendment, the regulatory burden to business, community organisations or individuals is not expected to change.

Average annual regulatory costs (from business as usual)				
Change in costs ($ million)	Business	Community organisations	Individuals	Total change in costs
Total, by sector	$0	$0	$0	$0

I acknowledge that OBPR will publish this letter for transparency purposes. If you have any queries about this advice, please contact Tony Manderson on 02 6289 3275, or Tony.Manderson@health.gov.au.

Yours sincerely

Adj Professor John Skerritt
Health Products Regulation Group

25 March 2022