Australian Government

Department of Health and Aged Care

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 Information (Database of Adverse Event Notifications) Specification 2012*

I am writing to the Office of Best Practice Regulation (OBPR) regarding the *Therapeutic Goods Information (Database of Adverse Event Notifications) Specification 2012*, which, as per the *Legislative Instruments Act 2003*, was scheduled to sunset on 1 October 2022. It has been decided that the instrument is to be remade with minor amendments to clarify that adverse events associated with biological therapies as well as medicines may be published in the Database of Adverse Event Notifications (DAEN) for medicines.

The sunsetting instrument authorises the Therapeutic Goods Administration (TGA) in the Australian Government Department of Health and Aged Care to publish de-identified information about adverse event reports associated with medicines on the TGA website. The TGA acknowledges the importance of maintaining transparency and certifies that the *Therapeutic Goods Information (Database of Adverse Event Notifications) Specification 2012* is operating effectively and efficiently, and that therefore a Regulation Impact Statement is not required for this instrument to be remade. There is no additional regulatory burden associated with the remaking of this sunsetting instrument, amended to include the publication of biological adverse event data.

Regulatory burden estimate table **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

Phone: (02) 6289 4200 **Email:** John.Skerritt@health.gov.au
PO Box 100 Woden ACT 2606 - **www.health.gov.au**

This self-assessment was informed by two targeted consultations:

- In March 2022, the TGA invited consumer, medicine sponsor and health professional representative groups to comment on the proposal to remake the instrument without substantially altering the current arrangements. We received 23 responses, almost all supporting the proposed remake and confirming that there is a need for continued transparency of medicine adverse event data in Australia.
- In August 2022, we invited sponsors of biological therapies to comment on the continued publication of adverse event information in relation to these products in the DAEN – medicines. Biological therapies are cell and tissue therapies such as faecal microbiota transplants, skin grafts and products made from genetically modified cells. We received 6 responses, all either actively supporting the proposal or not objecting to it. Several noted that the DAEN – medicines is a good resource for the Tissue Banking Sector and access to this data can be useful and valuable for health professionals.

The importance of maintaining transparency of medicine and biological adverse event information is further highlighted by the number of people accessing this data through the DAEN - medicines on the TGA website (accessed more than 688,000 times in the 12 months until April 2022).

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

If you have any queries about this advice, please contact Medicine Safety Projects team via email on medsafetyprojects@health.gov.au.

Yours sincerely

Tracey Duffy
Acting Deputy Secretary
Health Products Regulation Group

21 September 2022