



Australian Government

Department of Health and Aged Care

Ms Joanna Abhayaratna
Executive Director
Office of Impact Analysis
Department of the Prime Minister and Cabinet
PO Box 6500
CANBERRA ACT 2600
Australia

Dear Ms Abhayaratna

Therapeutic Goods Order No.70C - Standards for Export Only Medicine

I am writing to the Office of Impact Analysis (OIA) regarding the Therapeutic Goods Order No.70C - Standards for Export Only Medicine, which, as per the Legislation Act 2003, had been scheduled to sunset on 1 October 2024. However, it has been decided that the instrument is to be remade without significant amendment.

The Therapeutic Goods Administration certifies that Therapeutic Goods Order No.70C - Standards for Export Only Medicine is operating effectively and efficiently, and that therefore Impact Analysis is not required for this legislation to be remade.

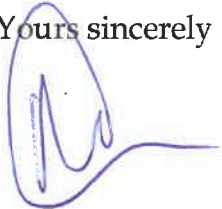
The assessment that the legislation is operating effectively and efficiently has been informed by a consultation process which involved medicine sponsor/manufacturers and industry associations, over the period 15 July 2024 - 26 August 2024.

I also note that the regulatory burden of the remade instrument to people, business, or community organisations will have minimal to no financial impact (i.e. there will be no difference in cost to industry between the existing instrument vs. the remade instrument).

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

If you have any queries about this advice, please contact Andrew Simpson at andrew.simpson@health.gov.au.

Yours sincerely



Nick Henderson
First Assistant Secretary, Medicines Regulation Division
Therapeutic Goods Administration, Department of Health and Aged Care

9 October 2024