



## Australian Government

### Department of the Prime Minister and Cabinet Office of Best Practice Regulation

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Adj. Professor John Skerritt  
Deputy Secretary, Aged Care  
Health Products Regulation Group  
Department of Health

Dear Professor Skerritt

#### **Certification of Independent Review: Addressing prescription opioid misuse in Australia**

Thank you for your letter of 11 November 2019 certifying that, in determining an appropriate regulatory response to the issue of prescription opioid use and misuse in Australia, the Therapeutic Goods Administration (TGA) has undertaken a similar process and analysis to that required for a Regulation Impact Statement (RIS).

The Office of Best Practice Regulation (OBPR) acknowledges the certification. Under the Government's best practice regulation requirements, the OBPR does not assess the adequacy of independent reviews.

I note the Department of Health has estimated the proposed changes to opioid regulation will result in a net increase in regulatory burden of \$108,000 per year.

The OBPR maintains an online RIS register. I ask that the Department of Health notify the OBPR when a final decision has been announced with regard to the matter being published on the RIS register.

Our reference number for this matter is **25436**.

Yours sincerely



Jason Lange  
Executive Director  
26 November 2019