



**Australian Government**  
**Department of Health**

**Deputy Secretary**

Mr Jason Lange  
Executive Director  
Office of Best Practice Regulation  
Department of the Prime Minister and Cabinet  
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BARTON ACT 2600

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Dear Mr Lange

**Addressing prescription opioid use and misuse in Australia**

I am writing to certify that, in determining an appropriate regulatory response to the issue of prescription opioid use and misuse in Australia, TGA has undertaken a similar process and analysis to that required for a Regulatory Impact Statement (RIS), as set out in the *Australian Government Guide to Regulation*.

The attached paper *Addressing prescription opioid use and misuse in Australia* sets out the process TGA has undertaken; and the quantification of the regulatory impact is set out in the attached *Regulatory Burden Costing, Opioid Regulatory Changes – Final Report*.

**Addressing the RIS questions**

*Questions 1 and 2 – What is the policy problem being solved and why is government action needed?*

Opioid use and misuse is having a critical impact on patients, their families and the health system. Every day in Australia, nearly 150 hospitalisations and 14 emergency department admissions involve opioid harm; and three people die from drug-induced deaths involving opioid use.

Government intervention is required to implement a proposal that addresses the issue of opioid misuse to ensure better health and wellbeing for all Australians.

*Questions 3, 4 and 6 – What policy options are you considering, what are the benefits, and what are the best options?*

Eight options were put forward in a public consultation paper issued in early 2018. These options ranged from reviewing the pack size of existing opioid products, their indications of use and warning labels; to consideration of restricting high dose prescription of opioids to specialists, or removing them from the market; as well as increasing health professional awareness of alternatives to opioids in the management of chronic pain.

There was strong and consistent support amongst stakeholders for four of the proposed options – Options 1, 2, 5 and 8 – as follows:

- Option 1: Consider the pack sizes for strong (Schedule 8) opioids.
- Option 2: Consider a review of the indications for strong S8 opioids.
- Option 5: Review of label warnings and revision to Consumer Medicines Information.
- Option 8: Increase health professional awareness of alternatives to opioids (both Schedule 4 and S8 opioids) in the management of chronic pain.

The TGA has completed the reviews associated with these options and, as a result, is implementing the following:

- registration of smaller pack sizes for oral immediate-release prescription opioid products;
- requiring boxed warnings and class statements in the [Product Information \(PI\) documents](#) for all prescription opioids in relation to their potential for harmful and hazardous use;
- ensuring that safety information, including the relevant warnings, is prominently displayed in the [Consumer Medicines Information \(CMI\)](#) to provide consistency of language and information across all classes of prescription opioids;
- restricting the indications (the appropriate circumstances for use of a medicine) within the PI documents for prescription opioids where appropriate to reinforce that opioids should only be used when other analgesics have proven not to be effective;
- restricting the indication for fentanyl patches to state they should only be prescribed to treat pain in patients with cancer, patients in palliative care and those with exceptional circumstances in recognition of the increased potential for harmful and hazardous use; and
- education and communication activities using a range of channels to ensure health professionals follow best prescribing practice and consumers are fully informed on how best to use opioids.

Regulated industry will use existing business processes to submit requests to vary the Australian Register of Therapeutic Goods (ARTG) entries for their products to comply with the above actions.

Smaller pack sizes reduce unused opioids circulating in the community may be used in harmful or hazardous ways, either inadvertently or deliberately, or become targets for theft. The indications (the appropriate circumstances for use of a medicine) in the PI documents for prescription opioids will reinforce that opioids should only be used when other analgesics have proven not to be effective. The various improvements to information for prescribers and patients will encourage best-practice prescribing and help consumers to be better informed about the potential risks and how to mitigate them.

*Question 5 – Who will you consult about these options and how will you consult them?*

The TGA undertook extensive public consultation to reach an informed decision of which regulatory options to pursue. The public consultation was undertaken through a written submission process, which received a total of 98 submissions from a range of stakeholders including health professionals, medical institutions and medical professional bodies; government bodies; consumers and consumer organisations; medicine industry organisations; and industry suppliers/sponsors/manufacturers.

Further consultation on prescription opioid use and misuse in Australia was conducted at a targeted stakeholder workshop on 1 June 2018. Senior staff members from the TGA have also taken part in workshops in Brisbane, Melbourne and Canberra that were organised by peak clinical and pharmacy groups in June and July 2018 on options to manage prescription opioid use and misuse.

*Question 7 - How will you implement and evaluate your chosen option?*

These actions, with the exception of education activities, will be implemented as per the existing regulatory and business processes TGA has for safety-related changes to a product’s registration, with medicine sponsors needing to submit the necessary requests to TGA for review and approval.

Following the introduction of these actions, the prescribing of opioids in Australia is expected to change significantly. The outcomes of these regulatory actions will be evaluated periodically through analysis of key data sources including: PBS prescription volume data and total volume of supply data which is currently procured by the TGA.

**Regulatory Impact**

I also note that the regulatory burden to business, community organisations or individuals has been quantified and offsets identified using the Australian Government’s Regulatory Burden Measurement framework. These have been self-assessed by the Department as they are less than \$2 million per annum and are provided below.

Average annual regulatory costs (from business as usual) (\$million)				
Change in costs	Business - \$	Community Organisation - \$	Individual - \$	Total change in costs
Option A				
<b>Status quo: current regulatory framework is appropriate – no change is required</b>				
Option B				
<b>Amended the regulatory framework for prescription opioids in accordance with the 5 proposed regulatory changes</b>	\$0.108			\$0.108

Accordingly, I am satisfied that the attached report now meets best practice consistent with the *Australian Government Guide to Regulation*.

Yours sincerely



Adj. Professor John Skerritt  
Health Products Regulation Group

11 November 2019