Australian Government
Department of Health

DEPUTY SECRETARY

July 2016

Mr Tony Simovski
Acting Deputy Executive
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet
1 National Circuit
BARTON ACT 2600

Email: helpdesk@obpr.gov.au

Dear Mr Simovski

Regulation Impact Statement –final assessment second pass

I am writing in relation to the attached Regulation Impact Statement (RIS) prepared for the Therapeutic Goods Administration's (TGA) proposed reforms to general requirements for medicine labels. The regulatory burden to businesses, community organisations and/or individuals has been quantified and offsets have been identified and quantified using the Regulatory Burden Measurement framework. These have previously been agreed by your office.

I am satisfied that the RIS addresses the concerns raised in your letter of 7 June 2016. Specifically, I note the following issues have been considered:

Question	OBPR Comment	TGA response
Problem/Why Government action is needed?		
1.	Option 1 identifies as an issue 'being out of step with international labelling requirements.' It is not clear whether this is arguing that Australian requirements fall short of best practice of that there are costs or other issues that result from inconsistency with international standards.	The problem section of the RIS now includes a new section that clarifies that Australian requirements fall short of international best-practice for medicine labelling.
2.	The clarity of the problem identification could be	The problem identified in

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	improved by including a summary statement of the problem and its significance.	the RIS has been further clarified by including a summary statement with information about the problem and its significance. Further detail on the problems reported by Australian consumers has also been provided. Additionally, closing remarks in the problem section now summarise the projected impact of the new labelling requirements.
Options		
3.	The identification of the status quo option includes a listing of 'limitations' associated with the option, which includes 'wasted effort from consultations with external stakeholders that has occurred over the last 5 years.' This is not a valid argument for rejecting the status quo option, so should be deleted. Similarly, for 'lack of recognition of the outcomes of extensive consultation.'	The status quo policy option (option 1) in the RIS has been clarified. The quoted arguments have been deleted.
Impacts		
4.	The impact analysis section needs further depth and should include a more comprehensive assessment of the range of impacts on all affected groups.	The likely benefits presented in the RIS now provide further depth and a more comprehensive assessment of the range of impacts on all affected groups including industry, consumers and healthcare professionals. For clarity, impacts have been separately addressed under 'benefit' and 'risk' headings.
5.	The RIS currently asserts benefits for option 3. Information should be included in the RIS on the effectiveness of overseas labelling changes in support of the claimed benefits.	The concluding remarks in the problem section and information in the conclusion section now consider the complexities of analysing the effectiveness overseas labelling changes in support of the claimed benefits for option 3.
6.	The impact analysis focuses on compliance costs for business. The analysis also needs to assess other impacts, such as market impacts associated with brand recognition.	The analysis, particularly for option 3, has assessed other impacts such as potential benefits to consumers from increased market competition due to prominence of active ingredients.

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7.	The RIS should include a clearer assessment of any benefits for option 2. At present, it is not clear whether the RIS is suggesting no benefit or a small benefit, relative to the status quo.	The analysis for option 2 has been revised to more clearly identify both possible benefits and risks. This provides a more balanced summary that supports the assessment that the perceived benefits associated with this option are negligible. This includes potential changes to the marketplace and impacts on consumers in both the medium and longer term.
7a.	The discussion in the RIS infers that industry could voluntarily comply with the updated guidance for option 2, without significant costs, if it is undertaken in the long run. This may result in potential benefits over the longer run. This possibility should be discussed.	
8.	We understand that the regulatory costs of option 2 are argued to be zero. The RIS needs to make this position clearer, as at present it suggests that there could be a small cost. In addition, the analysis should be further developed to address matters such as whether there might be a variation in take up between prescription and non-prescription medicines.	The regulatory burden cost has been clarified for option 2; this was a drafting oversight. Table 5 has been updated to confirm an average annual regulatory cost of $0.032M for option 2. This figure was in the Regulatory burden measure calculator.
8a.	Where there is no actual cost estimate, the listing of costing assumptions under option 2 appears confusing. In the event the RIS concludes there are no costs for Option 2, the assumptions might have greater relevance if listed with the regulatory burden estimates.	
9.	We note that there appears to be some confusion about direct and indirect costs of regulation in the RIS. It appears the RIS is referring only to direct financial costs, that is, to government fees and charges, as a direct cost.	The incorrect categorisation of direct and indirect costs has been removed from the introductory sentences in the Impact section of the RIS. Options 2 and 3 have been amended to include further clarification of the direct and indirect regulatory compliance costs. This includes any impact on prices for consumers and cost to businesses who voluntarily comply with best-practice guidance.
Regulatory Burden		
10.	The RIS identifies a labelling cost estimate for the prescription and non-prescription medicine industry of around $100 million, but it is not clear what this cost represents (given that it is very different to the later regulatory burden costings summarised in Table 5) and how it is made up. Further explanation would likely avoid any confusion.	To avoid any confusion, this paragraph has been deleted. The previous labelling cost estimate of $100 million represented all labels being changed at once, including those done as business as usual circumstances. However, the regulation impact costs

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		are for those activities that are outside business as usual circumstances.
Conclusion and recommended option		
11.	The conclusion needs to recognise the uncertainty in the assessment of net benefits for option 3 and also include an assessment of relative net benefits of option 2.	The conclusion now recognises the uncertainties presented by option 3 and includes an assessment of relative net benefits for option 2.
One-page RIS summary		
12.	The one-page summary document will likely need to be updated to reflect any changes to the RIS	Relevant updates have been made to the one-page summary.

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

I submit the RIS to the Office of Best Practice Regulation for formal final assessment.

Yours sincerely

Adj. Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
7 July 2016