Australian Government
Department of Health

DEPUTY SECRETARY

29 November 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@pmc.gov.au

Dear Mr Simovski

Second Pass Final Assessment – Regulation Impact Statement – Codeine Rescheduling

Thank you for your first pass final assessment of the Regulation Impact Statement (RIS) which examined how to address the problem of misuse and abuse of codeine-containing products available over the counter (OTC) to consumers.

I am satisfied that the second formal version of the RIS addresses the concerns raised in your letter of 22 November 2016. Specifically, I note that the following issues have been considered and addressed:

1. Clearly articulate the current problems, including behaviours that contribute to the misuse and abuse of codeine-containing products available OTC.

   Response: Additional text has been provided under the section title, '*What is the problem*' which more clearly and concisely articulates the problem in lay terms.

2. Further discuss and clarify the costs and benefits of each option, including the assumptions and justifications underlying the preferred option.

   Response: Additional text has been added beneath each option to address this concern (refer to Attachment A for further details).

3. Identify more clearly how issues raised by stakeholders in the consultation process have been addressed.

Response: Issues raised by industry and peak bodies have been outlined under '*Targeted consultations with industry and peak bodies*'. These consultations were structured around product strategy, market response, labelling, packaging, updated listing and regulatory approvals, including implementation (additionally see '*Implementation timeframe*'). As indicated at the beginning of the section, information obtained from these consultations was used to support the economic, social and regulatory modelling, for example product rationalisation, the number of GP visits and the implementation date of any scheduling decision.

Further, the RIS has explicitly noted that issues identified in the three public consultation periods will be taken into consideration in any final decision or implementation date (see '*Introduction*', '*Formal consultation periods regarding the rescheduling of codeine*', '*interim decision public consultation*', *'What is the preferred scenario?'*, and *'Appendix A'*).

4. Explain the status of the RIS at major decision points through the policy development process.

   Response: This RIS was drafted to provide further information on the regulatory and economic impacts associated with a proposed regulatory decision regarding the re-scheduling of codeine, and not related to the development of policy.

   The RIS contains an overview of the legislative process provided for by the *Therapeutic Goods Act, 1989* (see Figure 6). Within this flow chart, additional text has been included to illustrate at what stage of the process the development of a RIS has been completed.

In addition, a full list of responses individually addressing the 17 comments provided in OBPR's first pass review assessment letter is outlined in '*Attachment A –Responses to First Pass Final Assessment.*'

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

The intention is to have the RIS completed in the current reporting period (1 July to 31 December 2016). Any potential change to the scheduling of codeine will be implemented at a date to be announced by the delegate, noting the implementation timeframe feedback as published in the RIS, once a scheduling decision is made.

At this time, the estimated regulatory burden is expected to be less than $12.5 million per annum. Depending on the implementation timeframe, the regulatory burden will be offset in the ensuing couple of years. These have been agreed with your office.

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

Yours sincerely

Adj. Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
30 November 2016

Problem

	OBPR Advice	TGA response
1.	Overall, the problem section is not a clear guide to the problem, particularly to lay readers. This would be addressed by including a new summary at the start of the section that is concise and non-technical (unlike the current summary).	The section "What is the problem?" (refer p14) has been re-written for simplicity and restructured to provide greater clarity.
2.	Why do consumers currently choose codeine-containing products over the alternatives? There should be a distinction made between those making informed choices and those consumers that may be misinformed.	Additional text has been inserted under the heading of 'how is codeine used? (refer p16).
3.	The RIS should clarify the efficacy of codeine in combination codeine analgesics, as it appears some of the studies referenced appear to suggest some benefit for some people. This is in contrast to the TGA's summary that there is essentially no benefit. In addition, the conclusions of the studies on the effectiveness of codeine as an antitussive should be reported.	Additional text is provided on p20. There is limited data on the incremental effectiveness of the codeine component in codeine containing medicines when compared to simple analgesics Codeine-based medicines have been shown to reduce cough severity, but not frequency; however the evidence for this is very low quality.
4.	At the end of the discussion on international regulation of codeine, the RIS could provide a short overall summary of what happens overseas and note any implications for Australia.	A summary titled, '*Summary of international regulation of codeine and implications for Australia'* has been added, along with a new figure to illustrate the consumption of codeine world-wide.

Impact analysis

	OBPR Advice	TGA response
5.	The impact analysis would benefit from giving the qualitative analysis greater primacy and using the health economics modelling to support this, rather than using the modelling as the centrepiece of the analysis.	Additional text placed on p38-39 under the heading '*Why are regulatory options being considered*?' Further information is provided on how a change in regulatory access to codeine will assist in the protection of public health and safety. Each option now has the health benefits qualified by the insertion of additional text.

OBPR Advice	TGA response
6. The potential health gains identified in the RIS appear to be based on the current arrangements providing the wrong treatment to a fairly large number of people. The discussion on the status quo could better outline this and how this situation has developed. This should include an explanation of why there is not currently the opportunity or incentive for people using codeine-containing analgesics to get the alternative pain treatments (as anticipated to occur under the rescheduling option).	The additional text provided under the heading '*Option 1: Status quo*' outlines the reasons how the low-dose problem has developed (refer p63). Any explanation of why there is a lack of opportunity or incentive (under the status quo) for people using codeine-containing analgesics to get the alternative pain treatments would be purely speculative as only anecdotal information was provided to this question during the consultation process.
7. Alternative options are dismissed as offering no benefits based on not driving GP visits, but this appears to ignore the possibility of some level of effectiveness in addressing the health costs of the misuse of products under the status quo. Greater justification is needed if no benefit is claimed.	Additional paragraphs inserted for all options being considered at p64, p65, p69 and p76 to provide further information on the expected limited health benefits to particular subsets of consumers.
8. The challenges/limitations of the preferred option, such as dependent/addicted consumers undertaking drug substitution (legal or illegal) or doctor shopping, should be further explored.	Additional paragraphs inserted under Scenario 4 to address the limitations associated with the preferred option.
9. A pragmatic description of how consumers behave and how they will respond to the changes would help justify the assumptions (specifically, the RIS should advise how consumers currently buy drugs for colds and pain and what they would do under the change).	Further information has been provided under the various options (similar to point 7).
10. The analysis assumes all users of codeine cough and cold products are deliberately seeking codeine. This may be unrealistic and it is possible that a fair proportion of consumers are not even cognisant that the product contains codeine, for instance, they are choosing a 'trusted' brand. The analysis could consider this possibility and the effect it has on consumer responses to up scheduling.	Additional text has been included under the heading '*impacts to consumers*' that suggests that consumers have significant gaps in their knowledge relating to cough and cold medicines. Consumers appeared to be poorly informed of the appropriate use, efficacy and safety of OTC medicines for respiratory symptoms despite the risks. Most consumers believe that cough and cold medicines can cure or shorten the duration of an illness, rather than simply provide symptomatic relief.

OBPR Advice	TGA response
11. The analysis appears to assume there are close to perfect substitute products available which are cheaper. This assertion could be supported by evidence.	Citation included.
12. The increase in GP visits appears a major driver of the results, increasing the health benefits, but also increasing regulatory costs" The RIS should include sensitivity analysis of the increase in GP visits, and discuss the results.	Additional table and text has been inserted under the heading *'sensitivity analysis associated with GP visits.* The TGA notes that up-scheduling to s4 will produce additional GP visits, but this increase is not as significant as other previous reports have indicated. Indeed the outcome of the sensitivity analysis for the economic modelling has indicated that the increase in the number of GP visits does not significantly alter the net health benefit to society.
13. As the RIS contains only a partial cost-benefit analysis, the RIS should caveat any claim of net benefit for an option.	An extensive cost benefit analysis has been completed on the basis of the limited data available to support the assumptions used. Target consultations were used to validate assumptions where possible, and robust sensitivity analysis was completed to determine the robustness of the model. A footnote has been included to indicate that assumptions have been made on the basis of the information available.

Consultation

OBPR Advice	TGA response
14. The RIS should identify more clearly how issues raised by stakeholders in the consultation process have been addressed, including why it may not be possible or appropriate to accommodate the issue. It also appears there should be more discussion of the feedback provided by pharmacists.	Throughout the RIS additional text has been included to specify specific feedback from stakeholders from the targeted stakeholder consultations. For example under regulatory cost assumptions 4 dot point. p62 – additional text '*Most stakeholders indicated that additional face-to-face education.....*
15. We note that stakeholder feedback identified the cough and cold product lines containing codeine would effectively be discontinued in the event of rescheduling to Schedule 4. The RIS should address this	Our targeted stakeholder consultations have indicated that product rationalisation is a likely consequence of this regulatory option. Therefore less choice of cough and cold preparations may result from this

OBPR Advice	TGA response
comment.	regulatory option. However, noting that consumers appear to be misinformed of the risks, benefits and proper use of these preparations, consumers are likely to make an informed choice on how to use such preparations when this information is conveyed to patients at the time of consultation. On this basis, great awareness of the risks posed by codeine containing cough and cold medicines may also encourage conversations about the use of such medicines in relieving symptoms.

General

OBPR Advice	TGA response
16. The RIS needs to explain the status of the RIS at major decision points through the policy development process.	An important distinction between this RIS and those RISs that are often associated with policy decisions is that the scheduling delegate must consider the factors prescribed by subsection 52E of the Therapeutic Goods Act, and the scheduling policy framework when making a scheduling decisions, and not necessarily the economic or social impacts of that decision. Figure 6 was updated to include that no RIS was undertaken at interim decision stage.
17. There are a number of technical terms used in the RIS that are likely unclear to a lay person reader, particularly in the introductory sections. The RIS would be improved by clarifying these, possibly in footnotes or a glossary.	Definitions to technical terms have been provided where necessary as footnotes.