

From: [REDACTED]
To: Dereg@health.gov.au; [REDACTED]
Cc: [REDACTED]; [Helpdesk-OBPR](#); [REDACTED]
Subject: RE: TGA - Preliminary Assessment - up-scheduling codeine [DLM=For-Official-Use-Only]
Date: Wednesday, 28 October 2015 10:42:45 AM

For Official Use Only

Dear [REDACTED]

Re: Rescheduling of products containing codeine on the Poisons Standard

Thank you for consulting with the Office of Best Practice Regulation on this matter.

The OBPR considers that this proposal is likely to have more than minor impacts on businesses, community organisations or individuals, so it would be appropriate to prepare a standard-form Regulation Impact Statement (RIS) to inform the Delegate of the impacts when making the final decision.

To comply with the Government's RIS requirements the RIS should be assessed by the OBPR in accordance with the final assessment process set out in the Australian Government Guide to Regulation before the Delegate's final decision (however, there is some flexibility on timing in the system if a relevant later decision-making point can be identified).

Regulatory costs will need to be estimated in accordance with the Regulatory Burden Measurement Framework and agreed with the OBPR as part of the RIS process. If there is a net cost a regulatory offset will also need to be identified.

The OBPR is happy to meet or teleconference with you and/or relevant persons from the TGA to discuss how to address the RIS requirements.

Please note for future correspondence on this matter that the OBPR reference number is 19826.

Kind regards

[REDACTED] | [REDACTED]
RIA Team 1
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From: Dereg [<mailto:Dereg@health.gov.au>]

Sent: Tuesday, 27 October 2015 12:19 PM

To: Helpdesk-OBPR; [REDACTED]

Cc: Dereg

Subject: FW: TGA - Preliminary Assessment - up-scheduling codeine [DLM=For-Official-Use-Only]

Please find attached a Preliminary Assessment for the proposal, *Rescheduling of products containing codeine on the Poisons Standard*, for your consideration. The contact for further information is [REDACTED], Regulatory Practice, Education and Compliance Branch on [REDACTED].

[REDACTED]
Regards

[REDACTED]

Regulatory Reform Section | Best Practice Regulation Branch

Health Systems Policy Division | Department of Health

MDP 67, GPO Box 9848, Canberra ACT 2601

T: [REDACTED]

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