From: [redacted]
To: [redacted]
Cc: Regulatory Impact Analysis
Subject: Draft Preliminary Assessment - Up-scheduling codeine [SEC=UNCLASSIFIED]
Date: Thursday, 15 October 2015 5:17:44 PM
Attachments: IS A RIS REQUIRED Up Scheduling Codeine.tr5

Hi [redacted]

Could you please distribute the attached document for comment and input to the people that attended today's meeting. I would appreciate people's feedback so we can finalise the document early next week.

Kind regards, [redacted]

[redacted], Regulatory Impact Analysis
Regulatory Practice Unit
Regulatory Practice and Support Division

Phone: [redacted]
Email: [redacted]@tga.gov.au

Australian Government Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

AUSTRALIAN GOVERNMENT REGULATION IMPACT STATEMENT PRELIMINARY ASSESSMENT FORM: IS A RIS REQUIRED?

July 2014

The Government has introduced the *Australian Government Guide to Regulation*, which outlines the process for developing a regulatory proposal, including a Regulation Impact Statement (RIS).

All Cabinet submissions require a RIS. RISs are also required for all decisions made by the Australian Government and its agencies that are likely to have a regulatory impact on businesses, community organisations or individuals, unless the proposed change is a minor or machinery change.

It is your responsibility to contact OBPR for advice on whether a RIS is required for your proposal. OBPR conducts a Preliminary Assessment to determine whether one is needed, based on the information that you provide in the form discussed in this guidance note.

Contacting OBPR early during policy development will help you to:

- progress the proposal through decision making forums, such as Cabinet, in a timely manner
- ensure full compliance with the Government's requirements.

Early advice to your Deregulation Unit will also allow you to take into account any portfolio or agency specific requirements.

The Preliminary Assessment form

When you have a rudimentary set of answers to the seven RIS questions listed in the *Guide to Regulation*, give a written summary to OBPR in the form shown on the following page. If you provide enough information to help OBPR understand the nature of the proposal, you should receive a response within five working days confirming whether or not a RIS is required and, if so, what type. This is known as a Preliminary Assessment.

While filling in this form is not compulsory, it will help you identify the key features of your regulatory proposal. This will allow OBPR to quickly assess whether a RIS is required.

If you have any questions about completing the form, contact the OBPR at helpdesk-OBPR@pmc.gov.au or call (02) 6271 6270.

A different Preliminary Assessment form is required for COAG regulatory proposals.

Preliminary Assessment Form

Overview

Name of department/agency

Department of Health, Therapeutic Goods Administration (TGA)

Name of proposal

Rescheduling of products containing codeine on the Poisons Standard

Background

Scheduling is a national classification system that allows restrictions to be placed on how medicines and poisons are made available to the public. This is aimed at minimising the risks of poisoning from, and the misuse and abuse of scheduled substances.

Medicines and poisons are classified into Schedules within the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard) according to the level of regulatory control over the availability of the medicine or poison.

The Schedules are published in the Poisons Standard and are given legal effect through state and territory legislation.

Scheduling decisions are made according to subsection 52D(2) of the Therapeutic Goods Act 1989 and take into account relevant matters of public health as set out under section 52E of the Act. These matters include the risks and benefits of the use of a substance, the purposes for which a substance is to be used, the substance's toxicity, dosage, formulation, labelling, packaging, presentation and any potential for abuse.

The Scheduling Policy Framework (SPF) was developed by the Australian Health Ministers' Advisory Council (AHMAC), and sets out the scheduling process, guidance for amending the Poisons Standard, the classification system for medicines and chemicals, as well as guidelines for applications, public consultation and confidential information as these relate to scheduling applications. Relevant factors from the SPF are also considered.

The framework therefore allows the decision maker a measure of discretion particularly in relation to the implementation timeframe.

Codeine is currently listed in Schedules 8, 4, 3 and 2 of the Poisons Standard.

On 1 October 2015 the TGA published an interim decision on a proposal to up-schedule codeine. This interim decision recommends that all over-the-counter medicines containing codeine be rescheduled to become prescription-only medicines, that is from S2 and S3 to S4.

The interim decision is based on the assessment of many issues including risk of dependence and adverse events compared to safer products also available over-the-counter. The decision was made after an application, public submissions and advice from the Advisory Committee on Medicines Scheduling

(ACMS). Stakeholders were then provided 10 days to make any further submissions (closed 15 October 2015). 127 submissions were received.

Following a review of these submissions, a final decision by the delegate will be made (at the earliest) in mid November 2015.

If the delegate determines that a change is required the earliest possible implementation for any final decision is 1 June 2016 so the availability of any over-the-counter products containing codeine will not change before then. The delegate will announce an implementation date that will allow time for industry, consumers, pharmacists and doctors to manage any change.

No changes to the current S4 and S8 listing of codeine is being considered.

Background to the problem

The TGA continually monitors therapeutic goods supplied in Australia to ensure their ongoing safety, efficacy and quality. As part of this process, the TGA routinely undertakes safety reviews of therapeutic goods.

The TGA completed a review of codeine safety in the context of ultra-rapid metabolism of codeine to morphine by children and breastfeeding mothers. The main conclusions of the review were that the risks associated with ultra-rapid metabolism of codeine are not consistently and adequately addressed across all codeine-containing products.

Morphine (the active metabolite of codeine) can also be ingested by infants through breast milk, leading to a risk of respiratory depression in infants of ultra-rapid metaboliser mothers who take codeine whilst breastfeeding. Deaths have been reported internationally in some infants, and warnings regarding this risk have been issued by overseas regulators. Administration of codeine to children of any age for analgesia is not in keeping with current World Health Organization (WHO) guidelines for paediatric analgesia.

Codeine shares the properties of other opioid analgesics and is potentially capable of producing dependence and, in overdose, respiratory depression and reduced level of consciousness.

Description of the problem

There is significant health risks associated with the misuse of S2 and S3 medications that contain codeine.

The potential for severe adverse effects at "usual" doses in ultra-rapid metabolisers is such that codeine is an unsuitable candidate for OTC availability, with either S2 or S3 scheduling. This conclusion applies equally well to the products intended for treating coughs and colds, and those intended for the treatment of pain.

Changing the labelling and decreasing the pack size has not adequately addressed the problem of misuse and dependence.

The rescheduling, in 2011, to Schedule 3 (from Schedule 2) did not achieve the required reduction in harm to affected individuals. Although inclusion in Schedule 3 may have initially decreased abuse of codeine-containing combination analgesics, numbers of patients presenting for codeine detoxification have continued to grow since 2011.

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Current labelling and packaging include insufficient warnings, and access to codeine in Australia is inconsistent, in that the total amount of codeine available in packs varies with potential for abuse or addiction. There is increasing evidence for harm from abuse.

Misuse of OTC codeine products includes deaths resulting from hepatic injury, gastrointestinal perforations, hypokalaemia and respiratory depression.

The matters that are relevant to the delegate making a decision are prescribed under subsection 52E (1) of the *Therapeutic Goods Act 1989:*

(1) In exercising a power under subsection 52D(2), the Secretary must take the following matters into account (where relevant):

(a) the risks and benefits of the use of a substance;

(b) the purposes for which a substance is to be used and the extent of use of a substance;

(c) the toxicity of a substance;

(d) the dosage, formulation, labelling, packaging and presentation of a substance;

(e) the potential for abuse of a substance;

(f) any other matters that the Secretary considers necessary to protect public health.

The reasons for the recommendation to up-schedule codeine comprised the following:

- Risks of medication misadventure through polymorphic metabolism, deliberate misuse/abuse combined with the relative lack of efficacy compared to safer products.
- OTC intended for management of acute self-limiting pain, however, there is inappropriate use for chronic pain.
- Codeine shares the properties of other opioid analgesics and is potentially capable of producing dependence and, in overdose, respiratory depression and reduced level of consciousness.
- Changing the labelling and decreasing the pack size will not adequately address the problem of misuse and dependence.
- Increasing amount of evidence for harm from abuse.
- Misuse of OTC codeine products including deaths resulting from hepatic injury, gastrointestinal perforations, hypokalaemia and respiratory depression.
- Genetic influence on codeine's action complicates risk and benefit decisions, and leads to questions regarding the role of codeine in clinical practice.

The following factors for a Schedule 3 medicine in the Scheduling Policy Framework (SPF) are not met:

Codeine does not meet the SPF scheduling factors for inclusion in Schedule 3. In particular, criterion 2 is not satisfied - i.e. "The use of the medicine at established therapeutic dosages is not expected to produce

dependency. Where there is a risk of misuse, abuse or illicit use identified, the risk can be minimised through monitoring by a pharmacist."

Codeine containing analgesics should be included in Schedule 4 because codeine meets the factors in the Scheduling Policy Framework required for Schedule 4, and particularly the following factors:

In particular, use at established therapeutic dosage levels may produce dependency (criterion 3).

Codeine also meets SPF Schedule 4 criterion 1 (diagnosis, management or monitoring of chronic pain conditions requires medical or dental intervention before use and, although OTC codeine products are intended for short-term use, many consumers use them for chronic pain without medical intervention) and criterion 7 (its use has contributed to, or is likely to contribute to, communal harm).

Outline of the objectives of government action

To ensure that medicines containing codeine are controlled and monitored at an appropriate level that will limit the occurrence of morbidity, toxicity and dependence that is related to the misuse of the medicine.

The current scheduling of codeine on the Poisons Standard has been reviewed a number of times by the National Drugs and Poisons Schedule Committee (NDPSC). The reviews were undertaken to follow up on concerns that have been raised regarding the abuse of codeine and the availability of all OTC combination analgesics containing codeine (i.e. paracetamol and ibuprofen products containing codeine).

One review agreed to foreshadow a proposal (for consultation) to reschedule all over-the-counter (OTC) codeine to Schedule 3 (with suggestions to limit the maximum daily dose to 100 mg codeine, limit the maximum pack size to 5 days' supply, restrict divided preparations to 12 mg of codeine per dosage unit and restrict undivided preparations to 0.25% codeine). In addition, it proposed to maintain a Schedule 2 entry for codeine + phenylephrine, if all other OTC codeine was included in Schedule 3 and foreshadowed a proposal to include all OTC codeine (and not just analgesics).

Another agreed that the current scheduling of OTC codeine combinations for coughs and colds remained appropriate (but with a pack size limit of 5 days' supply), and that all OTC combination analgesics containing codeine should be rescheduled from Schedule 2 to Schedule 3 (with the maximum daily dose limited to 100 mg, the duration of treatment limited to 5 days, divided preparations restricted to 12 mg of codeine per dosage unit and undivided preparations restricted to 0.25% codeine) and that Schedule 3 codeine should not be included in Appendix H of the Schedule. The implementation date was to be 1 May 2010.

After further review the NDPSC agreed to amend the pack size limit for Schedule 2 cough and cold preparations to a maximum of 6 days' supply. The NDPSC also confirmed the resolution regarding the Schedule 3 entry for all OTC combination analgesics containing codeine. The implementation date remained as 1 May 2010. An editorial amendment was made to the Schedule 3 entry at the February 2010 NDPSC meeting.

Outline of the options available – note that the delegate may consider other options prior to any announcement.

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Option 1: Final decision is not to up-schedule - status quo. Make no changes to the scheduling of medicines containing codeine. Option 2: Proposal to delete the Schedule 2 and/or 3 entry for codeine, and reschedule all to Schedule 4. An implementation date to be set by the delegate at the time of the decision announcement. Option 3: Defer the decision, monitor the number of patients presenting for codeine detoxification (and any other relevant measures as required by the delegate) to determine if instances are reducing. Review in 12 months if there is no improvement. Option 4. Defer the decision to allow an electronic monitoring system to be developed and trialed. The finding will determine if a new review is required.
Other elements of your proposal (including consultation undertaken or proposed) 60 submissions were received in response to the earlier consultation on the proposed changes. Of these 29 submissions supported the up-scheduling , 25 were opposed and 6 did not state whether they supported the proposal or not.
Will Cabinet be the decision maker? ☐ Yes ☑ No
Likely impact on businesses, community organisations
Have you considered whether small businesses should have different obligations from larger businesses in relation to the operation of the possible regulation? ☑ Yes ☐ No
How has this been incorporated? N/A. The size of the business is not a factor. It was considered that there would be no different regulatory obligations.
Is your proposal likely to have any regulatory impacts? If so, please specify. The proposal will have a minor regulatory impact. There is an expectation that these products comply with the current regulations but the sponsor is not required to demonstrate compliance (demonstration of compliance would be required if a product is up-scheduled to S4). 31 sponsors currently supply medicines containing codeine in Australia. As of 1 September 2015 there are 313 entries on the Australian Register for Therapeutic Goods that have codeine as an active ingredient in them. • 73 S2 entries - 20 are exempt from the annual charges (not supplied on the Australian market) and 53 are not exempt • 214 S3 entries - 55 are exempt from the annual charges (not supplied on the Australian market) and 159 are not exempt • 18 S4 entries - 8 are exempt from the annual charges (not supplied on the Australian market) and 10 are not exempt • 4 S8 entries - 1 is exempt from the annual charges (not supplied on the Australian market) and 3 are

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not exempt • 4 listed export only entries Of these 212 are likely to be affected by changes (this figure does not include S4, S8 entries, those listed for export only and those exempt from annual charges). It should be noted that if the scheduling delegate decides to amend the scheduling of codeine, sponsors/manufacturers of products have several options including: • Apply for their product to be available under Schedule 4 • Modify their product to an alternative product that falls under Schedule 3 or 2 through: o Reformulation to remove the codeine o Reformulation to remove the codeine and substitute another active ingredient Ultimately while this will be a marketing decision for the sponsor.
Is your proposal likely to affect regulatory costs (including administrative, substantive compliance costs and delay costs)? If so, how? Any changes are likely to increase the regulatory costs for affected stakeholders (this includes both business and individuals).
Timing
The Delegate is currently considering the scheduling proposal. An instrument made under the Act will be drafted if the Delegate determines that it is necessary to reschedule medicines containing codeine. A decision can be made any time after mid November 2015. The delegate has discretion as to the implementation date.
Contact information
Please enter your contact information below.
Name: [redacted]
Email: [redacted]@tga.gov.au
Phone: [redacted]
Date: October 2015
Please forward the completed form to OBPR at helpdesk-OBPR@pmc.gov.au or call (02) 6271 6270 to discuss your proposal with an OBPR officer.

Overview

Description of the problem

Describe the problem that the proposed regulation is intended to solve:

- Do not confuse the problem with a 'symptom' of the problem. Identify the underlying cause of the problem. Is the problem the consequence or the cause?
- What is the nature of the problem? What loss, harm or other adverse consequences are being experienced, and by whom?
- How significant is the problem? What is its magnitude? If your proposal is intended to mitigate risk of an adverse event, what is the likelihood of that event occurring? What evidence do you have to support that assessment?
- How is the problem currently regulated by Australian Government, state, territory or local government regulations, or by governments overseas? Are there deficiencies in the existing regulatory system?
- Is there a case for government intervention or is the problem of purely private interest?
- Why does current regulation not properly address the problem?
- If the problem relates to existing legislation or regulation, is it caused by faulty design, implementation, or both?
- What are the consequences of not taking any action?
- Could relying on the market in conjunction with the general application of existing laws and regulations solve the problem? If not, why not?
- Will the problem self-correct within a reasonable timeframe?

Outline of the policy objectives

Clearly identify why there is a legitimate reason for the Government to intervene. Demonstrate that the Government has the capacity to intervene successfully, and identify alternatives to government action. List objectives, outcomes, goals or targets that are sought in relation to the problem, and constraints or barriers to achieving them.

A common error is to confuse the desired final outcome of a proposal with the outputs, or means of obtaining it. The aim is not to pre-justify a preferred solution, but to specify the objective broadly enough so that all relevant alternative solutions can be considered.

Outline of the options

Outline a range of genuine and viable alternative policy options available to address the problem and achieve the policy objectives. Identify a minimum of three options, of which at least one option must always be non-regulatory.

Other elements of your proposal

Include any additional information that is relevant to the proposal. For example: have there been recent proposed regulations similar or related to this proposal, or is it a new regulation, an amendment to an existing regulation, or a replacement for sunsetting regulation.

State whether any consultation has already been undertaken, and what consultation is proposed.

Likely impact on businesses, community organisations and individuals

Impacts can be thought of as either regulatory impacts or compliance costs.

Regulatory impacts

Regulatory impacts may include:

- changes to the number or type of products that businesses can offer, such as:
  - banning products or industry practices
  - changing the way products can be offered
- impacts on consumer demand for certain products, such as:
  - increasing prices through the regulation's requirements
  - changing the information available to consumers
- impacts on the ability of businesses to compete in the market or on their incentives to compete, such as:
  - creating a self-regulatory or co-regulatory regime
  - changing the requirements for a licence, permit or other authorisation
  - influencing the price or quantity of goods that are sold
  - setting standards for product or service quality
  - changing the prices or types of inputs available to businesses.

Regulatory Compliance costs

All RISs must quantify the regulatory costs of new regulations to businesses, community organisations and individuals and identify (in dollar terms) measures that offset the cost impost of the new regulation.

Regulatory costs include:

- compliance costs:
  - administrative costs
    - costs incurred by regulated entities mainly to demonstrate compliance with the regulation (usually record keeping and reporting costs)

    - costs incurred through complying with government taxes, fees, charges and levies, beyond the amount paid (for example, the time taken to pay a licence fee).
  - substantive compliance costs
    - costs that lead directly to the regulated outcomes being sought (usually purchase and maintenance costs for plant and equipment to meet regulatory requirements, fees paid to training providers, costs of providing information to third parties, and costs of operation—for example, energy costs).
- delay costs:
  - expenses and loss of income incurred by a regulated entity through one or both of:
    - an application delay—the time taken to complete an administrative application requirement that prevents the party from beginning its intended operations
    - an approval delay—the time taken by the regulator to communicate a decision on the administrative application that prevents the party from beginning its intended operations (this includes the time taken to asses and consider an application).

Timing

Outline key dates and give an indicative timeline.

More information on the RIS process

More information on the RIS process is in the *Australian Government Guide to Regulation* (http://www.cuttingredtape.gov.au).