Questions for states and territories

Introduction

Section 52EC of the *Therapeutic Goods Act 1989* (the Act) requires that an independent review of the operation of Part 6-3 of the Act be conducted, with particular reference to the amendments to that Part made by the *Therapeutic Goods Amendment (2009 Measures no. 2) Act* (the amendments).

The review must report on:

a) the system of access controls for goods containing scheduled substances established by that Part;
b) the outcomes of the administration of scheduled substances by the Secretary and by the committees established by that Part;
c) the effect of the amendments on the therapeutic goods industry and on individual parties within the industry;
d) whether there are adequate avenues for review of decisions made by the Secretary and by the committees established by that Part;

and may make recommendations for further changes to the scheduling regime.

This questionnaire is for State and Territory members of the Advisory Committee for Medicines Scheduling (ACMS) and/or the Advisory Committee for Chemicals Scheduling (ACCS) and will help inform the Scheduling Review Panel's report. Questions relate to seven meeting cycles prior to the amendments and seven meeting cycles after the amendments (June 2008 to October 2012).

A public call for submissions to the review is expected to be made in mid-March. Documents provided in response to this questionnaire will not be treated as public submissions. Information provided, or parts thereof, that are confidential or not for quotation should be clearly marked as such and justifications provided. Please be aware that documents and information supplied may still be subject to public access under freedom of information law.

Please email your responses to scheduling.review@health.gov.au. In order to meet Commonwealth accessibility requirements, responses are required in a Word or RTF format (*not* as a .pdf).

Principal contact:			
Position:			
Phone:		**Fax:**	
Mobile:			
Email address:			
Postal address:			
Suburb/City:		**State:**	**P'code:**

System of access controls for goods containing scheduled substances

Section 52A: Definitions

1. Does the definition of 'substance' contained in the Act meet the needs of your jurisdiction? If not, how could the definition be changed to meet those needs?
2. Are there any inconsistencies between definitions contained in the *Poisons Standard* and those in the Act that have a material impact on your jurisdiction? What are these and what are the impacts?

Changes to advice provided by ACCS/ACMS and decisions made by the Secretary

3. Did your jurisdiction seek any editorial changes or errata of decisions during the period June 2008 to October 2012?
4. If yes, what was the nature of the changes sought?
5. Was the original advice / decision changed as a result of the request?

Section 52B and 52C: Membership of ACCS and ACMS

6. Do the membership categories and current appointees meet the needs of your jurisdiction?
7. If not, what changes to the membership categories facilitate better meeting the needs of your jurisdiction?
8. Has the exclusion of New Zealand from the membership of ACCS and/or ACMS had any material impact on your jurisdiction? If yes, please describe that impact.
9. Has the replacement of the National Drugs and Poisons Schedule Committee with the ACCS and ACMS had a material impact on the *financial cost* of your jurisdiction's participation in the process of the scheduling of substances? Please provide details, specifically in relation to the period June 2008 to October 2012.

Section 52E(2)(b): matters Secretary must have regard to

10. Does the *Scheduling Policy Framework* meet the needs of your jurisdiction in relation to the application and review processes?
11. Has your jurisdiction experienced any positive outcomes as a result of the Secretary amending the Poisons Standard on her own initiative? If so, please briefly describe the amendment and how it impacted on your jurisdiction.
12. Has your jurisdiction experienced any adverse outcomes as a result of the Secretary amending the Poisons Standard on her own initiative? If so, please briefly describe the amendment and how it impacted on your jurisdiction.
13. Does the *Scheduling Policy Framework* require amendment in order to meet the needs of your jurisdiction better? If yes, please briefly explain the unmet need of your jurisdiction and the section of the *Scheduling Policy Framework* that requires amendment to meet that need.

Outcomes of administration

Section 52E Application to amend the Poisons Standard

14. Is the template *Application to amend the Poisons Standard* sufficiently comprehensive to support the provision of the required advice? If not, what amendments do you suggest? What would be the impact on your jurisdiction if it were amended in this way?
15. Has there been any positive or negative impacts on your jurisdiction of the Secretary amending the *Poisons Standard* based on advice from a committee or person/s other than the ACCS and/or ACMS? Please briefly describe the relevant amendment and the impact on your jurisdiction.
16. Has your jurisdiction been able to make faster decisions as a result of the amendments? If so, please give an example.

Matters relating to the Regulations

17. Other than those already mentioned, have there been any adverse outcomes for your jurisdiction as a result of the changes to Part 6 Divisions 3A- 3D of the *Therapeutic Goods Regulations 1990*, which established the current advisory committees and their operations and the procedure for

amending the Poisons Standard? If yes, please describe the adverse outcome, how it affected your jurisdiction and the specific regulation that it relates to.

Other issues

18. In addition to the above, have you had any other benefits as a result of the amendments? If so, what were they and how did they impact on your organisation?
19. What metrics do you think are important for monitoring the system for the scheduling of substances? How would the relevant data be collected? How often?