

Chief Executive Officer: Bryan Stevens
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3 July 2009

The Secretary
Senate Community Affairs Legislation Committee
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Mr Humphery,

On behalf of the Pharmaceutical Society of Australia (PSA), I have attached a submission to the Senate Community Affairs Legislation Committee on the *Therapeutic Goods Amendment (2009 measures No. 2) Bill 2009*.

PSA is keen to assist the Committee further by providing evidence at the hearing on 8 July 2009.

PSA looks forward to working with the Committee and is happy to provide further information if required.

Yours sincerely,



Bryan Stevens
Chief Executive Officer

Attached: Submission from the Pharmaceutical Society of Australia

SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE:

THERAPEUTIC GOODS AMENDMENT (2009 MEASURES NO. 2) BILL 2009

BACKGROUND

1. The Pharmaceutical Society of Australia (PSA) is the peak national professional organisation representing approximately 75 per cent of pharmacists in all areas of professional practice across Australia. PSA works to influence attitudes, opinions, policies and practice through representation, networking, consultation, continuing education, practice support, standards, guidelines and a range of publications and health promotion programs and resources.
2. PSA welcomes the opportunity to provide this submission to the Senate Community Affairs Legislation Committee on the *Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009*. This submission provides comments in relation to Schedule 1 of the Bill which covers the scheduling of substances.
3. PSA has also made a submission recently to the Therapeutic Goods Administration on the National Coordinating Committee on Therapeutic Goods' draft *Scheduling Policy Framework for Medicines and Poisons*.¹ Where relevant, comments in our submission on this Bill are made in the context of our understanding of what has been proposed in the Scheduling Policy Framework.

RECOMMENDATIONS

4. **PSA provides the following recommendations on this Bill:**
 - a. **To use the term 'poisons' in place of 'chemicals' to ensure consistency with the proposed *Scheduling Policy Framework for Medicines and Poisons*.**
 - b. **Under subsection 52E(1), paragraph (f), to include additional factors relating to the safety and patterns of use of a substance as well as the need for a substance.**

GENERAL COMMENTS

5. In relation to the proposal to separate the arrangements for the scheduling of medicines and poisons, the draft Scheduling Policy Framework used the terms 'medicines' and 'poisons'. We note, however, that the Bill uses 'chemicals' in place of 'poisons' (eg. section 52C Advisory Committee on Chemicals Scheduling).

¹ Available at: www.tga.gov.au/regreform/drschedule-framework.pdf

6. We have found this to be somewhat confusing, particularly since both terms, 'poisons' and 'chemicals', are used interchangeably throughout the Explanatory Memorandum to the Bill. We are also concerned that the term 'chemicals' is not consistent with the term used in the Scheduling Policy Framework.

SPECIFIC COMMENTS

Subsection 52E(1)

7. We note that section 52E of the existing Act will be repealed and substituted. Subsection (1) in the Bill consists of a revised list of factors which the Secretary must take into account (where relevant). The list broadly corresponds with the factors which are currently considered by the National Drugs and Poisons Schedule Committee (in place of the Secretary).

8. PSA is concerned however, that the Bill does not include the following factors under subsection 52E(1):

- a. the safety of a substance;
- b. the patterns of use of a substance;
- c. the need for (access to) a substance;

9. It might be argued that the proposed paragraph (f) which reads "any other matters that the Secretary considers necessary to protect public health" could capture any or all of the factors listed above. However it is PSA's belief that these three factors, in addition to those already proposed, are all fundamental considerations in the decision-making process for the scheduling of a substance and therefore warrant their explicit inclusion.

10. The three issues referred to above are also mentioned in the Scheduling Policy Framework as factors to be considered in a scheduling decision and therefore their inclusion in the Bill will promote consistency with the Framework.

SUMMARY

11. PSA is committed to the establishment of separate arrangements for the scheduling of medicines and poisons consistent with the relevant recommendations of the Galbally Review and in a manner which promotes the safe and appropriate use of these substances by consumers.

Prepared by:
Pharmaceutical Society of Australia
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