Chief Executive Officer: Bryan Stevens
ABN 49 008 532 072

Pharmaceutical Society of Australia

13 July 2009

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

Dear Mr Humphery,

RE: *Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009*

Please find attached a supplementary submission from the Pharmaceutical Society of Australia (PSA) in response to the questions raised by the Senate Community Affairs Legislation Committee at the hearing held on 8 July 2009.

Please do not hesitate to contact me if the Committee requires further information or clarification.

Yours sincerely,

Grant Martin
Acting Chief Executive Officer

Attached: Supplementary submission from the Pharmaceutical Society of Australia

PO BOX 42, DEAKIN WEST ACT 2600
(44 Thesiger Court, DEAKIN ACT 2600)
E-mail: grant.martin@psa.org.au
Telephone: 02 6283 4777
Facsimile: 02 6285 2869

Pharmaceutical Society of Australia

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

SUPPLEMENTARY SUBMISSION TO THE SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE

BACKGROUND

1. The Pharmaceutical Society of Australia (PSA) made a submission to the Senate Community Affairs Legislation Committee on 3 July 2009 in relation to the *Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009*.

2. On 8 July 2009, PSA provided evidence to the Committee in relation to this Bill. At the hearing the Committee requested additional information on a number of matters. PSA takes the opportunity to provide comments on these matters through this supplementary submission.

SUMMARY OF PSA'S COMMENTS

3. PSA's comments articulated in this submission are summarised below:

a. In the interests of national uniformity, the National Coordinating Committee on Therapeutic Goods (NCCTG) should demonstrate leadership to ensure all decisions on scheduling and associated matters are adopted by all states and territories.

b. More timely and detailed feedback should be provided on the outcomes of consultation processes.

c. More comprehensive detail on each item of the scheduling committee meeting agenda should be made available in the pre-meeting notice.

d. A summary of the outcomes of each scheduling committee meeting should be made public within one week of the meeting.

e. Where a scheduling change or related matter is likely to have a significant impact on professional pharmacy practice, PSA seeks support for the pharmacy profession in the transition and implementation stages.

f. It is anticipated that additional detail on the proposed *Scheduling Policy Framework* and amendments to the Regulations will be released. PSA seeks the opportunity to consider these and provide further comment.

SPECIFIC COMMENTS

4. A number of issues of particular interest to PSA and importance to the pharmacy profession are detailed below. Most of these comments were also provided in our submission to the Therapeutic Goods Administration (TGA) on the *Scheduling Policy Framework* in May 2009.

National Uniformity

5. A major and ongoing issue of concern for PSA is the variability in the implementation of scheduling and other related matters in the states and territories following a decision or recommendation made at a national level. Decisions of the National Drugs and Poisons

Schedule Committee (NDPSC) are one example where they are simply 'recommendations' which may or may not be adopted unchanged in each jurisdiction.

6. PSA is firmly of the view that inconsistencies across jurisdictions contribute to situations which are not conducive for the promotion of quality use of medicines principles. For example, the inconsistencies result in or contribute to:

a. different storage requirements for Schedule 2 (S2) products where self-selection by the consumer is prohibited in two states but allowed elsewhere;

b. the availability of different pack sizes of medicines which varies between jurisdictions;

c. confusion for consumers who travel interstate or reside near state borders, which in turn creates a burden on pharmacists and pharmacy staff who need to provide explanations to consumers, some of whom believe the pharmacy is not practising consistently;

d. an inability to obtain nationally robust data on medicines use;

e. difficulties for organisations such as PSA to provide a single set of nationally consistent professional guidance to pharmacists and pharmacy staff; and

f. different arrangements for the implementation (if any) of a mechanism to record Schedule 3 (S3) supplies. Although PSA believes the recording of S3 supplies is appropriate best practice in assisting good medication management and may also be used as a tool to identify inappropriate use, in the absence of a consistent legislative basis for S3 recording, even if pharmacists were to engage in best practice the delivery of any real benefits to consumers would be *ad hoc*.

7. We understand that the application of state and territory laws resides with each jurisdiction and that perhaps historically there was a need to be flexible in order to accommodate local circumstances. However, PSA believes that continuing to allow such flexibility has the potential to significantly undermine the principles of quality use of medicines across Australia. In addition, this is clearly inconsistent with Recommendation 4 of the Galbally Review which promoted the adoption of all scheduling decisions by all states and territories.

8. PSA strongly suggests that achieving national uniformity on scheduling and related matters is of the highest and most immediate priority. We believe the NCCTG has a key role in this regard and should take firm leadership in committing to a common and consistent outcome.

Outcomes of Consultations

9. PSA has contributed its views and suggestions on most, if not all, consultation papers and proposals in the last decade relating to scheduling, advertising, labelling, packaging and other related issues.

10. We have experienced some difficulty in tracking progress and outcomes of the various consultations. This has been due to lack of feedback on our submissions, long periods where there appears to be low level (or no) activity, 'low-key' announcements of outcomes, or follow-up consultations where the outcomes are more or less determined with little or no scope for change.

NDPSC

11. Specifically in relation to the NDPSC, PSA has on previous occasions commented on a number of issues including:

a. the lack of detail in pre-meeting notices;

b. the inefficient and delayed reporting of outcomes; and

c. the short timeframe available for the profession to implement changes.

12. PSA firmly believes these aspects require modification and we have suggested the following to the TGA.

13. **Pre-meeting notices.** PSA believes more complete details must be published for each agenda item in the pre-meeting notices. If an issue/item is subject to public consultation, we believe it is inappropriate for the onus to be on the person or organisation making a submission to make enquiries about the exact detail of a proposal or to guess what it may entail.

14. We understand there may be reservation by applicants regarding the possible release of any commercial-in-confidence material. However, we believe it is reasonable and possible for additional details to be listed without revealing truly commercial-in-confidence information such as formulation details or manufacturing methods.

15. Further, while we have no objections to cross-referencing an agenda item to the Record of Reasons from a previous meeting, we do not believe it is appropriate to totally rely on this document to provide information for a forthcoming agenda item.

16. **Outcomes summary.** Although the publication of the Record of Reasons after each NDPSC meeting can provide important information for the basis of a scheduling decision, in recent years the document has become unwieldy in length and detail. It also appears that the document is used as a tool by the NDPSC Secretariat to help inform agenda items for subsequent meetings and we find this unhelpful in that there is a need to keep referring to past voluminous documents.

17. PSA strongly advocates for a summary of the outcomes of a scheduling meeting to be published on the TGA web site within a week of the meeting. This could be similar to the type of summary report published by the Pharmaceutical Benefits Advisory Committee after their meetings. This will facilitate communication to all stakeholders including pharmacists and assist PSA (and other relevant stakeholders) to commence preparation of professional practice support materials for implementation in a timely manner.

18. **Timeframe.** It is our experience that the timeframe to implement the required changes as a result of a scheduling decision is not always adequate. We refer, in particular, to decisions which significantly impact on the professional practice of pharmacists such as a decision to reschedule a Schedule 4 (S4) item to S3. In these cases, while pharmacists are already familiar with the product through supply as an S4 item, the new arrangement to supply as an S3 item can have different implications. This may include more detailed consideration of the person's health status, making appropriate assessments prior to supply, responding to consumer requests in an appropriate manner, and providing education and training to pharmacy staff for appropriate referral.

19. The adequacy of the implementation timeframe is also influenced by the level of support provided to PSA and the pharmacy profession as outlined in the following section.

Support for the Pharmacy Profession

20. PSA accepts that changes to scheduling policies or the classification of medicines will occur regularly, whether they are due to policy changes initiated by Government or sponsor companies submitting rescheduling applications for commercial reasons.

21. Where the outcome of any change has a significant impact on professional pharmacy practice, PSA is firmly of the view that the 'initiator' of such change should invest in supporting the profession through the transition and implementation stages.

22. Currently some companies do offer support, for example, in the delivery of education and practice support tools when a medicine has been rescheduled from S4 to S3. However, generally this type of support is ad hoc and as the current NDPSC guidelines for applicants do not adequately facilitate this to occur, it is usually non-existent particularly for other rescheduling outcomes.

23. The appropriate level and type of support will depend on the substance as well as reason for change but may include one or more of the following:

a. communication to all pharmacists regarding the background to the change (eg. whether it is a policy change or a recommendation based on new evidence), timelines, administrative requirements;

b. new or revised guidelines relating to professional practice;

c. education articles and practice support tools (eg. protocols);

d. in-pharmacy education for pharmacy support staff;

e. information materials for consumers.

24. Where a scheduling change has been initiated by a sponsor company for commercial reasons, PSA believes it should be mandatory for applicants to:

a. include information in their application about the likely impact the new schedule will have on health professionals and consumers;

b. propose an education program for health professionals and consumers to facilitate appropriate use, quality use and minimise any possible misuse of the product; and

c. demonstrate an ongoing commitment to work with relevant stakeholders.

25. The development and delivery of any resources should occur in partnership with PSA in order to ensure the appropriate level of information and guidance is provided and in an unbiased manner.

26. PSA has expressed in its submission to the TGA that it would be pleased to work with the NCCTG on the development of an appropriate education and practice support framework around scheduling and rescheduling applications.

Need for Additional Detail

27. In relation to the proposed *Scheduling Policy Framework*, PSA has indicated it would wish to consider further details when they are made available whether they are through additional consultation papers, the Regulations or other means.

SUMMARY

28. PSA continues to support the separation of medicines and poisons through the implementation of a revised scheduling policy framework, consistent with the recommendations of the Galbally Review from 2001. We particularly support the establishment of separate expert advisory committees to provide advice on the scheduling of medicines and poisons in place of the existing NDPSC. With the increase in the number and complexity of issues being considered by the NDPSC, we believe its operation has become unwieldy and somewhat of a burden for its members. However as outlined in our submission to the TGA on the *Scheduling Policy Framework*, some of which are summarised here, PSA believes a number of issues require further consideration and consultation.

29. The implementation of any new framework must take into account the specific changes necessary for each stakeholder and adequate time, information and support for the transition process. In this regard PSA has communicated to the TGA that we are happy to work in partnership to facilitate and communicate relevant requirements for the pharmacy profession.

30. PSA has no comments in relation to the status of the Regulations. However, we do seek the opportunity to provide comments when the proposed amendments are released.

31. PSA seeks to remain an active participant in the reform consultation processes and activities.

Prepared by:

Pharmaceutical Society of Australia

13 July 2009