

**SUBMISSION ON THE PROPOSED NEW ARRANGEMENTS FOR THE SCHEDULING
OF MEDICINES AND POISONS**

PURPOSE

1. The Pharmaceutical Society of Australia (PSA) makes this submission to the Therapeutic Goods Administration (TGA) in relation to the consultation papers on the Proposed Scheduling Policy Framework and the Proposed Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), released for comment on 17 April 2009.

PSA'S RECOMMENDATIONS

2. PSA makes the following recommendations (which are further articulated in the body of this submission):

- a. **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. **A summary of the outcomes of each scheduling committee meeting should be made public within a week of the meeting.**
- c. **More complete details of each agenda item must be made available in the pre-meeting notice.**
- d. **Scheduling decisions on all new substances must be made public through a process which is separate and additional to their publication in the SUSMP.**
- e. **The TGA should consult further with stakeholders regarding the proposed details and operation of new arrangements which will replace the use of Appendix H.**
- f. **Appendix L should be an inclusive list of substances which can be sold by licensed poisons sellers.**
- g. **A mechanism to record the supply of certain substances through the implementation of Appendix N should be linked to the establishment of a comprehensive national electronic data system to enable the collection of robust data on the quality use and possible misuse of various substances.**
- h. **A set of specific criteria should be developed to enable the determination of exemption from scheduling requirements for a substance.**
- i. **Applications to reschedule human medicines should include information on the likely impact on health professionals and consumers. In particular, it should be mandatory for applications to reschedule a substance from Schedule 4 (S4) to Schedule 3 (S3) or from S3 to Schedule 2 (S2) to include details of programs to assist health professionals and consumers in the implementation of the new schedule.**

KEY ASPECTS OF THE MODEL

3. PSA understands the core responsibility of the NCCTG in dealing with overarching policy principles, guidance and protocols will remain unchanged under the new scheduling policy framework.

Implementation

4. Currently, a major issue of concern for PSA relates to 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.

5. 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 S2 products where self-selection by the consumer is prohibited in two states but allowed elsewhere;
- b. situations such as the availability of large pack sizes (eg. 48 and 72) of codeine-ibuprofen combination analgesics as an S2 product in one state only. This is highly undesirable given the nature of the issues currently under consideration with combination analgesics containing codeine (CACC);
- c. confusion for consumers who travel interstate or reside near state borders. This 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. This issue has been highlighted most recently during the consideration of the scheduling of over-the-counter (OTC) CACC where, as mentioned above, storage requirements and available pack sizes are not consistent nationally;
- 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 S3 supplies. It would appear that, to date, the will and ability to implement an 'S3 recordable' schedule has been variable between jurisdictions. 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. However, 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 is *ad hoc*.

6. 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.

7. PSA would strongly suggest that achieving national uniformity is of the highest and most immediate priority. This includes all matters arising from a scheduling decision such as (but is not limited to) pack sizes, storage requirements, warning statements, labelling, supply, advertising and recording requirements. We believe the NCCTG has a key role in this regard and should take firm leadership in committing to a common outcome.

THE SCHEDULING PROCESS

Public Consultation

8. PSA welcomes the proposal to make all public submissions available through the website. We believe this provides greater transparency and will stimulate debate about scheduling matters outside formal committee deliberations.

9. We also continue to support the public release of recommendations of the appointed committees.

Notification of Decisions

10. The consultation paper indicates that a scheduling decision (together with the reasons for the decision) must be published on the TGA web site "as soon as practicable after a decision is made". Although no other details are available in this section of the paper, it would appear that this statement simply reflects the status quo and that no changes are being proposed.

11. It is PSA's view that the existing timeframe and mechanism through which scheduling meeting outcomes and the reasons for the decisions are made public need to be reconsidered.

12. **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 an 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.

13. **Record of Reasons.** Although the publication of the Record of Reasons after each 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 documents.

14. It is therefore PSA's firm view that these arrangements require modification and improvement and we suggest the following.

- a. **Outcomes summary.** 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. We envisage 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. The publication of the reasons and the gazettal of the outcomes can follow in a timeframe similar to what occurs currently.

- b. **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. 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. 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 the document to provide information for a forthcoming agenda item.

15. With regard to new substances (where the application has not been referred to either committee), we note the consultation paper states that “only the applicant will be advised of the scheduling decision”. We seek clarification on this issue as PSA believes any new decision needs to be communicated separately to pharmacists and other stakeholders rather than simply publishing the outcomes through the SUSMP.

SCHEDULING EXPERT ADVISORY COMMITTEES

16. PSA generally supported the recommendation of the Galbally Review in relation to the administrative arrangements for scheduling. We believe this will result in greater efficiencies and clearer processes.

17. PSA particularly supports 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 the Committee has become unwieldy and somewhat of a burden for its members.

18. **Voting.** PSA has previously expressed concerns about the voting process of the NDPSC not being equitable for all members. We therefore strongly support the proposal to implement equal voting rights for all members of the Scheduling Expert Advisory Committees.

GUIDELINES FOR APPENDICES

Appendix H

19. The consultation paper states that the use of Appendix H will be phased out and replaced by legislation under the *Therapeutic Goods Act 1989*. Given this proposal is of significant interest to pharmacists, PSA would like to be able to consider the details of this plan or options being canvassed by the TGA and to provide comments.

Appendix L

20. The consultation paper proposes that the new Appendix L will list substances which licensed poisons sellers are not allowed to sell. This relates to the implementation of Recommendation 15 of the Galbally Review which stated that S2 poisons licence holders should be permitted to sell all S2 medicines unless that substance is included in an appendix to designate that the risk of diversion, poisoning or medical misadventure is such that the sale of that substance should only be from a pharmacy. PSA notes that criteria for including a substance in this appendix are yet to be developed.

21. PSA recalls that the Galbally Review accepted, for good public benefit and safety reasons, that S2 substances should be available to the public only when supplied from a pharmacy where the advice of a pharmacist who is required to comply with a professional standard of risk assessment and counselling is available. However, for the small proportion of the public remote from pharmacies, it has long been recognised that, for pragmatic reasons, a 'lesser' level of care and responsibility must be accepted.

22. PSA appreciates that licence holders are given special privileges based on strict criteria to meet the need of consumers who are geographically isolated. However, we remain concerned about the extension of these privileges to the full range of S2 medicines as we firmly believe that the potential for inappropriate or sub-optimal use and the risk of medication misadventure are not being appropriately managed.

23. It is PSA's strong preference that Appendix L be an inclusive list of allowable substances rather than a list of substances which are to be excluded. PSA would like to be included in any future consultation on Appendix L.

Appendix N

24. As referred in this submission under sub-paragraph 5.f, PSA strongly believes that the mechanism to record the supply of certain substances on a case-by-case is needed.

25. We note that the creation of this appendix has been flagged as a means to facilitate the listing of substances which have been shown to pose a significant risk of diversion to the illicit market and the public health benefits of recording the supply of these substances has been established. PSA believes these criteria may be too restrictive and would strongly suggest that broader consideration be given to the use of this appendix.

26. For example, we believe this new appendix could be linked to the establishment of a comprehensive national electronic data system to enable the collection of robust data on the quality use and possible misuse of various substances. We believe once such a system is established it will provide useful and necessary information to guide decision-making on scheduling and other associated issues in the future.

27. PSA would like to be included in any future consultation on Appendix N.

CLASSIFICATION OF MEDICINES AND POISONS

28. PSA notes that the model for making scheduling decisions remains unchanged under the new framework in that a 'cascading principle' will continue to be applied. This is disappointing given that we believe the model could be improved if criteria are developed for substances to be exempted from scheduling requirements.

29. PSA believes granting an exemption from scheduling requirements should only occur if a substance meets designated criteria rather than through what is contained in

the current model which is that the substance does not meet the factors for any schedule.

APPLICATIONS FOR RESCHEDULING HUMAN MEDICINES

30. In the current NDPSC guidelines, the guidelines for applications states that “if a program for education of distributors, professionals and users or consumers is proposed then details should be provided”. PSA believes this clause did not adequately facilitate education programs for these audiences because the wording is such that applicants were encouraged to provide details to the Committee, only if they had a proposal. In other words, it would be less onerous to simply state that no such plans existed.

31. However, it is of even greater concern for PSA that the equivalent section in the consultation paper is significantly shorter and more importantly, does not include any statement about the applicant’s requirements for education programs.

32. PSA accepts that applicants (usually sponsor companies) will often, if not always, submit rescheduling applications for commercial reasons. However, from a quality use of medicines perspective PSA is firmly of the view that they must invest in matters beyond the application process particularly in relation to the implementation of any new or revised schedule status.

33. PSA has been involved in many successful initiatives relating to scheduling decisions in partnership with government, industry, consumers and pharmacy organisations.

34. For example, PSA has delivered education, practice support materials and consumer resources through the Pharmacy Self Care (PSC) program. A recent significant initiative was funded through the Australian Government Attorney General’s Department on pseudoephedrine diversion (which related to the rescheduling of pseudoephedrine-containing products). The campaign was extended to all community pharmacies and included an *inPHARMation* magazine with assessment questions for pharmacists and pharmacy assistants, in-store storyboard staff training resource and consumer leaflet tear-off pad.

35. Other PSA initiatives (both within the PSC program and separately) have covered topics such as: generic medicines; rescheduling to S3 of fluconazole, orlistat, levonorgestrel and pantoprazole; and OTC codeine medicines.

36. 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.

37. PSA would be pleased to work with the NCCTG on the development of an appropriate education and practice support framework around scheduling and rescheduling applications.

SUMMARY

38. PSA supports the implementation of a revised scheduling policy framework and the separation of medicines and poisons, consistent with the recommendations of the Galbally Review from 2001. However PSA believes a number of issues (which are outlined in our recommendations) need to be given further consideration.

39. The implementation of a new framework must take into account the necessary changes for each stakeholder and adequate time, information and support for the transition process. In this regard PSA is happy to work in partnership with the TGA to facilitate and communicate relevant requirements for the pharmacy profession.

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

Prepared by:

Pharmaceutical Society of Australia

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