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Pharmaceutical Society of Australia

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House of Representatives Standing Committee on Health and Ageing
Parliament House
CANBERRA ACT 2600

Thank you for the invitation to the Pharmaceutical Society of Australia (PSA) to provide a submission to the House of Representatives Standing Committee on Health and Ageing's inquiry into Impotence Medications. PSA also thanks the Committee for the opportunity to participate in the Roundtable Forum held on 21 August 2009. On behalf of PSA I have attached a submission which addresses the Committee's Terms of Reference together with a sample Pharmacy Self Care kit on men's health issues (including erectile dysfunction) as discussed during the Forum.

Yours sincerely,

Bryan Stevens
Chief Executive Officer



Attached: 1. PSA Pharmacy Self Care Kit

Pharmaceutical Society of Australia

# SUBMISSION BY THE PHARMACEUTICAL SOCIETY OF AUSTRALIA TO THE HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON HEALTH AND AGEING ROUNDTABLE FORUM ON IMPOTENCE MEDICATIONS

## ABOUT PSA

1. The Pharmaceutical Society of Australia (PSA) is the peak national professional pharmacy organisation representing some 75% of pharmacists across Australia. PSA's core functions are: supporting pharmacists' commitment to high standards of patient care; providing continuing professional development, education and practice support; and representing pharmacists' role as frontline health professionals. PSA is the custodian of the *Competency Standards for Pharmacists in Australia* (PSA, 2003), *Professional Practice Standards* (version 3; PSA, 2006) and *Australian Pharmaceutical Formulary and Handbook* (21st edition; PSA, 2009), which is a mandatory resource for all pharmacies and pharmacy departments.

## QUALITY USE OF MEDICINES

2. The underlying principle informing the practice of pharmacy in Australia is the Quality Use of Medicines (QUM), which has three components:

   a. select management options wisely by: considering the place of medicines in treating illness and maintaining health; and recognising that non-drug therapies may be the best option for the management of many disorders;

   b. choose suitable medicines, if a medicine is considered necessary, so that the best available option is selected by taking into account: the individual; the clinical condition; risks and benefits; dosage and length of treatment; any co-existing conditions; other therapies; monitoring considerations; and costs for the individual, the community and the health system as a whole; and

   c. use medicines safely and effectively to achieve the best possible results by: monitoring outcomes; minimising misuse, over-use and under-use; and improving people's ability to solve problems related to medication, such as adverse effects or managing multiple medicines.

3. In the context of the QUM policy, the role of pharmacists relates not only to medicines use and management but also in providing advice on non-drug management where appropriate, providing support and information, and working across the whole spectrum of health from maintenance of good health to management of ill health.

## COMPOUNDING OF MEDICINES

### Definition

4. The APF defines *extemporaneous dispensing (compounding)* as "the preparation and supply of a single 'unit of issue' of product which is intended for immediate use by a specific patient."[1] It is also important to note that the APF clearly distinguishes between compounding (see above) and *extemporaneous manufacturing* which is: "the production of a batch of a product, resulting in a number of units of use intended for supply over a period of time, should not be performed unless in premises approved, certified or exempted for such purposes and where the product has documented stability data."[2]

### Rationale

5. As stated in PSA's *Professional Practice Standards*, the pharmacy profession recognises that commercial products are preferable to compounded products because they are subject to formal quality control procedures. One of the accepted reasons for compounding is that a prescribed formulation or suitable alternative cannot be obtained commercially.

6. There are a number of reasons for compounding medicines, including:

   a. different dosage form required, for example, liquid form required but only tablet form available, or ointment required but only cream available;

   b. sensitivity/allergy to excipients and preservatives;

   c. discontinued or unavailable medicine;

   d. different dose or concentration required;

   e. different route of administration required; or

   f. compliance problems, for example palatability.[3]

### Competencies and Standards

7. The competencies required for registration and the standards of practice expected of pharmacists engaged in the practice of compounding are well articulated through, for example, PSA's Competency Standards, the *Professional Practice Standards* and the APF. PSA is firmly of the view that compounding must remain a recognised activity of pharmacists.

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[1] Pharmaceutical Society of Australia. Australian Pharmaceutical Formulary and handbook. 21st edition. Canberra. PSA, 2009: 31.
[2] *Ibid:* 31.
[3] Feldschuh M. Compounding in community pharmacy. Aust Pres. 31, 2, April 2008: 31.

## Regulation

8. PSA has supported the reviews of the regulation of compounding that are currently underway by the Therapeutic Goods Administration (TGA) and the National Coordinating Committee on Therapeutic Goods (NCCTG). PSA has provided submissions to the reviews and has also participated on the Pharmacy Manufacturing Technical Expert Reference Group convened by the TGA.

9. PSA notes evidence provided by the TGA during the recent Roundtable Forum on Impotence Medication convened by the House of Representatives Standing Committee on Health and Ageing indicating that the NCCTG is considering submissions to its review of compounding and that it is refining amendments to the regulations.[4] PSA requests, through the Committee, that any changes to regulations be made available in draft form for comment by interested parties or, if presented to the Parliament as disallowable instruments, that adequate notification is provided to stakeholders prior to the revision to the regulations taking effect.

10. PSA believes that the revised regulatory framework that is developed must be robust and be able to accommodate potential future expansion and diversification in extemporaneous preparation of medicines which may accompany advances in medical knowledge, biomedical technology and therapeutics. It is likely that in the next decade or two, the development of personalised/genomic medicines will grow and treatments tailored for a specific individual in order to maximise therapeutic benefit may become commonplace.

11. We also believe the regulatory framework must be capable of allowing practitioners to fulfil certain exceptional requirements for compounded medicines. These might be, for example: (a) a one-off requirement of a single formulation in bulk supply for an Australian group deployed overseas; or (b) the provision of an extemporaneously prepared medicine equivalent to a commercial product which is not readily available due to a disruption in the usual supply chain (eg. during a public health emergency or crisis situation). Such cases might require the establishment of a special authorisation system to ensure extemporaneously prepared medicines can be supplied in a timely and lawful manner.

12. Business practices whereby large amounts of a particular compounded medication are manufactured routinely for supply to a range of individual patients with the same diagnosed condition are not supported by PSA. In the development of any revised framework to more adequately regulate this situation, PSA is concerned to ensure that the long standing practice by pharmacists of compounding an individual product for an individual patient is not unduly stifled as this practice continues to be required to meet the specific health needs of individual patients.

13. It is important to note that compounded products are prepared and provided to patients by health professionals other than pharmacists. Therefore, any regulatory framework or set of arrangements that are developed to overcome current shortcomings must apply to all practitioners undertaking this activity and to all

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[4] House of Representatives Standing Committee on Health and Ageing. Roundtable Forum on Impotence Medication. Proof transcript of meeting, 21 August 2009: HA5.

settings where products are compounded or prescribed including, for example, hospitals (public and private), pharmacies and other health facilities.

## PATIENT COUNSELLING

14. Pharmacists are required to provide patient counselling on the appropriate use of all dispensed medicines. Arguably, there is an increased requirement for patient counselling when a pharmacist prepares and dispenses a compounded medicine. Consumer Medicine Information (CMI) leaflets are not readily available for compounded products and therefore prescribers and pharmacists must ensure that the patient is aware of this and advise on correct use, storage, expiry date and possible adverse effects and interactions. This counselling, information and education must be communicated to each individual patient.[5]

15. PSA's *Professional Practice Standards* include a standard on Counselling, which reads: "the pharmacist ensures that the consumer has sufficient knowledge of their medicines and therapeutic devices to facilitate their safe and effective use." The standard includes the following criteria:

a. all consumers are offered counselling by a pharmacist;

b. counselling is provided according to the needs of the consumer;

c. the most appropriately trained person undertakes the counselling;

d. written information is used, when available, to supplement oral counselling;

e. the use of therapeutic devices is adequately explained and/or demonstrated to the consumer;

f. the pharmacist systematically records counselling events that they consider clinically important; and

g. the pharmacist provides counselling that is supported by evidence-based information.[6]

16. In PSA's view, it is important that when a compounded product is supplied to a patient, that the patient understands that the product has been prepared specifically for their individual needs. Consideration could be given to a requirement that each compounded product should carry on the label information or a statement that the product has been specially prepared for the particular patient and that the product has not undergone formal approval by the TGA. This could supplement the counselling provided by the pharmacist.

17. Issues raised at the Roundtable Forum convened by the House of Representatives Standing Committee on Health and Ageing on 21 August 2009 indicate that the treatment of erectile dysfunction may be less than optimal in some

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[5] Feldschuh. *op cit:* 31.

[6] Pharmaceutical Society of Australia. Professional Practice Standards. Version 3. Canberra. PSA, 2006: 59-63.

circumstances. PSA would be concerned if some individual patients may not be receiving appropriate counselling from a pharmacist with regard to medicines compounded for their individual use in the treatment of erectile dysfunction. In PSA's view, the most appropriate means of ensuring effective patient outcomes through the use of compounded medicines is a triad of informed patient, prescriber and compounder.[7]

## PHARMACY SELF CARE PROGRAM

18. As the professional association for pharmacists, PSA has sought to provide a range of appropriate information, education and support for its members on issues around erectile dysfunction. One established means of delivery of this information, education and support is via PSA's Pharmacy Self Care program.

19. PSA's Pharmacy Self Care program[8] is Australia's most established and recognised consumer health information and education program in community pharmacy. This high quality program is designed to increase the professional capacity of pharmacists and pharmacy staff individually, and as a health care team.

20. The program maximises the opportunities for health interventions presented by the community pharmacy setting by uniquely integrating:

a. preventative health information for the public;

b. education for pharmacists and pharmacy staff; and

c. promotion of health and the important role of pharmacy.

21. The program facilitates and enhances the expertise of pharmacists and assists and empowers consumers to integrate self-care into the management of their health. An information pack is attached to this submission for the information of the Committee, which comprises a range of Pharmacy Self Care resources on men's health issues, including erectile dysfunction.

22. At present, the Pharmacy Self Care program is a voluntary subscription-based program with 1,800 member pharmacies. PSA has proposed to the Australian Government that it partner with PSA to implement the program in all 5,000 community pharmacies across Australia. PSA believes that such a measure represents a cost-effective opportunity to provide consumers with access to a consistent base of health promotion and health advice activities across all pharmacies in Australia.

## SUMMARY

23. PSA believes that it is important that regulation is regularly reviewed to ensure that it remains workable, current and appropriate. Where shortcomings can be identified, PSA supports efforts to remedy any deficiencies and improve the regulatory framework through collaboration with all interested stakeholders. PSA

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[7] Feldschuh, *op cit*: 31.

[8] More information is available at: www.psa.org.au/psc

believes that it is important that any regulatory reform in the area of compounding of medicines does not inadvertently compromise aspects of professional pharmacy practice that are working satisfactorily and meeting the needs of individual patients. PSA believes also that any regulatory reform must apply to all settings where compounded products are prepared and provided to patients, that is, not only in community pharmacies.

Prepared by:

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