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Pharmaceutical Society of Australia

31 March 2010

Ms Naomi Bleeser
Secretary
Senate Community Affairs References Committee
Parliament House
CANBERRA ACT 2600

Dear Ms Bleeser

On behalf of the Pharmaceutical Society of Australia (PSA), I have attached a submission to the Committee's Inquiry into Consumer Access to the PBS.

Please contact me if PSA can further assist the Committee's Inquiry.

Yours sincerely,

Bryan Stevens
Chief Executive Officer

Attached:
1. Submission by the Pharmaceutical Society of Australia

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SUBMISSION BY THE PHARMACEUTICAL SOCIETY OF AUSTRALIA TO THE SENATE COMMUNITY AFFAIRS REFERENCES COMMITTEE'S INQUIRY INTO CONSUMER ACCESS TO PHARMACEUTICAL BENEFITS

PURPOSE

1. The purpose of this document is to inform the Inquiry by the Senate Community Affairs References Committee into Consumer Access to Pharmaceutical Benefits.

2. This submission primarily canvasses issues relevant to the Inquiry's Term of Reference (h) "any other related matters".

ABOUT PSA

3. The Pharmaceutical Society of Australia (PSA) is the peak national professional pharmacy organisation representing some 75 per cent of pharmacists across Australia. PSA's core functions are: supporting pharmacists' commitment to high standards of patient care; providing continuing professional development (CPD), education and practice support; and representing their role as frontline health professionals.

NATIONAL MEDICINES POLICY

4. Consumer access to pharmaceutical benefits occurs within the framework established by Australia's National Medicines Policy, which has four central objectives:

a. timely access to the medicines that Australians need, at a cost individuals and the community can afford;

b. medicines meeting appropriate standards of quality, safety and efficacy;

c. quality use of medicines; and

d. maintaining a responsible and viable medicines industry.[1]

Quality Use of Medicines

5. Pharmacy practice in Australia is firmly underpinned by Australia's policy on the Quality Use of Medicines (QUM).[2] The key elements of this policy are to:

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;

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[1] Department of Health and Ageing. National Medicines Policy. Canberra. DoHA, 1999: 1.

[2] Department of Health and Ageing. The national strategy for quality use of medicines: Executive summary. Canberra: Commonwealth of Australia, 2002.

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.

6. In the context of this 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.

IMPROVING PATIENT OUTCOMES AND THE EFFICIENCY OF THE PBS

Therapeutic Groups Policy

7. The apparent rationale of the Therapeutic Groups policy is to produce savings to the Pharmaceutical Benefits Scheme (PBS). This is clear both from the introduction of the policy by the former Howard Government in 1997: "the Therapeutic Group Premiums scheme introduces greater competition into the pricing of medicines which are judged by independent clinical and scientific experts to have an equivalent therapeutic effect"[3] and from the 2009 decision of the current Government to extend the reach of the policy: "the new therapeutic groups, being created on the advice of the independent Pharmaceutical Benefits Advisory Committee (PBAC), will result in a saving to the PBS of $48.2 million over the next four years."[4]

8. While the creation of therapeutic groups may engineer savings to the PBS, there is no evidence available to PSA that indicates the measure necessarily works to improve patient outcomes. The need for policy measures to focus on patient outcomes has been a consistent message arising from recent reports[5] to the Federal Government and is a stated objective also of the Government.[6]

9. Therefore, PSA believes that consideration should be given to initiatives that can both improve patient outcomes and also provide savings to the PBS and other parts of the health system. One such initiative advocated by PSA is the introduction of a system of clinical interventions by pharmacists (see discussion at paragraphs 16-22).

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[3] Wooldridge. Hon Dr M. Therapeutic group premiums a win for consumers and taxpayers: Media Release 20 November 1997.
[4] Roxon, Hon N. MYEFO points to rising health costs: Media Release. 2 November 2009.
[5] See for example, National Health and Hospitals Reform Commission. A healthier future for all Australians: final report. Canberra, NHHRC, 2009.
[6] See for example, A National Health and Hospitals Network for Australia's Future. Canberra, 2010: 72.

Professional Pharmacy Services

10. Successive Community Pharmacy Agreements have been negotiated between the Federal Government and the Pharmacy Guild of Australia since 1990. The scope of the Third Community Pharmacy Agreement (2000-2005) and the Fourth Community Pharmacy Agreement (2005-2010) was expanded to include funding for a range of patient-focussed professional pharmacy programs and services. These comprise programs and services that:

a. target particular diseases and conditions such as diabetes and asthma;

b. are designed to identify and improve medication management for high-risk patients (Home Medication Reviews and Residential Medication Management Reviews); and

c. focus on areas of health disadvantage including Aboriginal and Torres Strait Islander patients and people living in rural and remote areas.

11. Disappointingly, the development and implementation of several important programs and services have been unduly delayed during the Fourth Agreement and PSA understands that a considerable proportion of allocated funding may remain unspent when the Agreement ceases on 30 June 2010. PSA believes that this situation is due, at least in part, to the failure of the administrative arrangements to provide a workable and efficient mechanism for the development and delivery of these programs.

12. The Fifth Community Pharmacy Agreement (2010-2015) is currently under negotiation between the Federal Government and the Pharmacy Guild of Australia. PSA believes that the Fifth Agreement should be underpinned by the following five key principles:

a. deliver quality professional pharmacy services;

b. integrate professional pharmacy services within the health system to meet the changing health care needs of the Australian population;

c. deliver cost effective health care solutions;

d. maintain a viable community pharmacy network; and

e. negotiate and manage the CPA through a collaborative framework.

13. PSA is the guardian of the professional and ethical cornerstones of the pharmacy profession, the Professional Practice Standards and the Code of Professional Conduct. PSA has a long history in the successful design, development and delivery of quality professional development programs for pharmacists and pharmacy assistants and has a well-established national practice support network that assists pharmacists with the implementation of new professional services for patients. As such, PSA believes that it has much to contribute to the development and consideration of professional programs and services that are based on robust evidence, provide value for scarce health funds, have the capacity to improve the

health of the population and assist in delivering on the Government's health reform agenda.

14. PSA would welcome a review of the current arrangements for negotiating the Community Pharmacy Agreements to ensure that:

a. proposals for professional programs and services that are considered for funding under these Agreements are formulated on behalf of the pharmacy profession and its patients;

b. these programs and services are developed in a timely fashion; and

c. all programs and services are implemented efficiently and effectively.

Adverse Drug Reactions

15. The financial and personal impact of adverse medication events has been well documented[7] and is a high priority of the Australian Commission on Safety and Quality in Health Care[8]. For example, it is estimated that over 1.5 million people suffer an adverse event from medicines each year in Australia,[9] resulting in some 180,000 hospital admissions, of which 30%-50% are preventable.[10] The cost of these medication-related hospital admissions has been estimated at some $380 million annually.[11]

Clinical Interventions by Pharmacists

16. PSA believes that a program of Clinical Interventions by Pharmacists should be included in the Fifth Community Pharmacy Agreement. This evidence-based professional pharmacy program has the potential to make a genuine difference to patient outcomes while also delivering savings to the PBS and the broader health system.

17. The capacity of community pharmacy to alleviate the burdens of adverse drug reactions and reduce the use of unnecessary medicines (thereby delivering savings to the PBS) through the provision of clinical interventions has been the subject of recent research funded under the Fourth Community Pharmacy Agreement.[12]

18. Estimates arising from the PROMISe III project indicate that 2 clinical interventions are currently performed on average by pharmacists for every 1000 prescriptions dispensed. The project found that the intervention rate among participating pharmacies increased on average to 3.1 interventions per 1000 prescriptions following implementation of the PROMISe system. Interventions

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[7] National Prescribing Service. Medication safety in the community: a review of the literature. Sydney. NPS, 2009.

[8] See for example http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/PriorityProgram-06 accessed 3/3/2010

[9] Roughead EE and Lexchin J. Adverse drug events: counting is not enough, action is needed. Medical Journal of Australia 2006: 184(7):315-6.

[10] National Prescribing Service. Medication safety in Australia: status at November 2007. Discussion paper. Sydney. NPS. 2008.

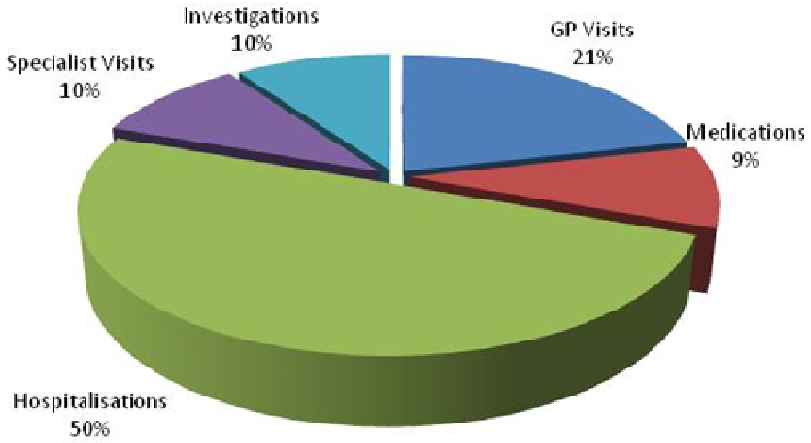
[11] Roughead EE and Bedford G. Medication safety: will adverse drug events be reduced? Windows into safety and quality in health care 2008. Australian Commission on Safety and Quality in Health Care.

[12] Tenni P et al. The value of clinical interventions in Australian community pharmacies (the PROMISe III project), unpublished.

observed among participating pharmacies ranged from 0 to 23.4 per 1000 prescriptions dispensed.

19. Research arising from this project indicates that direct, realisable savings are achievable as a result of the provision of interventions by pharmacists. For example, the project estimated that implementation of the program would realise some $26 million in direct savings against the PBS over the life of the Fifth Community Pharmacy Agreement which is currently under negotiation between the Federal Government and the Pharmacy Guild of Australia. Total savings could be as high as $288 million over five years.

20. Each intervention performed by a pharmacist was estimated to result in $220 of direct cost savings. The chart below indicates the distribution of these savings across the health system.



21. The objective of this proposal is to develop a framework that supports the performance of clinical interventions as part of the pharmacist's usual activities within the dispensing process. In this way, consumers will benefit through improved health outcomes and through the receipt of higher quality and more consistent pharmacy services.

22. **Articulation into Other Initiatives.** An ancillary benefit of PSA's proposal on clinical interventions by pharmacists is its capacity to articulate into other Government initiatives, thereby adding value both to this proposal and to the other initiatives. For example, the clinical interventions program can:

a. be used to build a profile of all prescriptions that are dispensed, not only those dispensed against the PBS;

b. be used as an early trial of Individual Healthcare Identifiers in the primary care setting, involving community pharmacists; patients with chronic conditions and multiple medications; and general practitioners; and

c. readily link e-prescribing models.

IMPROVING QUALITY AND SAFETY

Pharmacovigilance

23. Pharmacovigilance is a vital element of medication safety. It encompasses the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.[13]

24. The Royal Pharmaceutical Society of Great Britain reports that a recent UK Department of Health White Paper has identified pharmacovigilance "as an area in which pharmacists should be making further contributions."[14] PSA agrees that there is much potential for pharmacists to play a more systematic and consistent role in pharmacovigilance. For example:

a. by promoting the safe use of medicines; and

b. by gathering and reporting post-marketing surveillance information on adverse effects to the Adverse Drug Reactions Advisory Committee (ADRAC).[15] (Note that this Committee is now known as the Advisory Committee on the Safety of Medicines or ACSOM)

25. The importance of establishing a system of pharmacovigilance was also canvassed in evidence to the Senate Community Affairs References Committee's inquiry into the National Health Amendment (Pharmaceutical and Other Benefits–Cost Recovery) Bill 2008.[16]

26. PSA is concerned that in the absence of a coordinated approach overseen by the Therapeutic Goods Administration (TGA), these important activities are currently undertaken by pharmacists in an ad hoc manner. PSA supports the World Health Organisation's contention that the "management of the risks associated with the use of medicines demands close and effective collaboration between the key players in the field of pharmacovigilance".[17] PSA has recommended previously that the TGA be required to adopt a comprehensive primary care-based pharmacovigilance regime that capitalises on the knowledge and skills of frontline pharmacists.

27. PSA believes that a systematic, organised process of post-marketing pharmacovigilance would have greatly assisted in a more consistent means of tracking the adverse reactions of patients to the controversial drugs celecoxib (Celebrex) and rofecoxib (Vioxx).

Collaborative Prescribing

28. PSA supports a consumer-focused, multidisciplinary team approach to health care delivery which provides consumers with access to the expertise of health

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[13] World Health Organisation. Pharmacovigilance: ensuring the safe use of medicines. WHO Policy Perspectives on Medicines. October 2004: 1

[14] Royal Pharmaceutical Society of Great Britain. The contribution of pharmacy to making Britain a safer place to take medicines. London. RPSGB. 2009.: 11

[15] Sweiden M and Andersson S. Public health pharmacy: a greater role for pharmacists. Aust Pharmacist 2007: 26(12): 965.

[16] See for example: Senate Community Affairs References Committee. Reference: National Health Amendment (Pharmaceutical and Other Benefits–Cost Recovery) Bill 2008. Transcript of Evidence. 28 July 2008: CA7.

[17] World Health Organisation. *Op cit*: 1.

professionals in a targeted manner and in a team environment to promote synergies and holistic care. PSA believes such models are cost-effective for government, deliver optimal outcomes for consumers and are professionally valuable for practitioners.

29. PSA believes prescribing by non-medical health professionals will integrate well into a multidisciplinary care model, for example through 'collaborative prescribing'. With this approach, once a diagnosis has been established by a medical practitioner or a treatment plan prepared for an individual patient, part of the responsibility for management and some activities associated with ongoing prescribing are undertaken by a non-medical health professional based on patient responses and outcomes. It has been suggested[18] that this model could, in particular, be applied to disease states such as asthma, diabetes, hypertension, dyslipidaemia, hypothyroidism, heart failure and thromboembolic disorders requiring anticoagulation therapy.

30. By having practitioners with different health expertise working closely together, it is likely that patient outcomes can be more closely monitored and any adverse or unintended outcomes can be attended to and modified. This is of particular relevance to a patient's pharmacotherapy where early identification of medication-related issues and appropriate modification is more likely to contribute to better health outcomes for the patient and cost savings to government through reduced adverse drug-related hospital admissions and enhanced continuity of care.

31. The application of pharmacists' unique knowledge of the range of available medicines, the rationale and evidence-base behind their use, and the costs to the consumer and the health system will facilitate cost-effective use of subsidised (and non-subsidised) pharmaceuticals through more appropriate use and less wastage.

32. PSA also believes the involvement of other health professionals in this manner is likely to make a positive contribution to participation, innovation and productivity of the health workforce and provide synergies to patient care.[19]

IMPROVING ACCESS TO THE PBS

Patient Co-payments

33. Patient co-payments have been a feature of the PBS for many years and have been supported by successive Federal Governments.[20] Increases have generally occurred annually based upon increases in the Consumer Price Index but there have also been sizeable ad hoc increases in excess of inflation. PSA contends that patient co-payments have now reached such a high level[21] that there is a danger of patients foregoing some of their necessary medications due to cost.

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[18] Pharmaceutical Council of Western Australia, unpublished submission to the Western Australian Government, 2004.

[19] Pharmaceutical Society of Australia. Principles for a national framework for prescribing by non-medical health professionals. Canberra. PSA. June 2009.

[20] Harvey K. Securing the future of the Pharmaceutical Benefits Scheme? www.australianreview.net/digest/2002/06/harvey.html accessed 22/3/10.

[21] From 1 January 2010, the General Patient Co-payment is $33.30 and the Concessional Patient Co-payment is $5.40 per prescription. Safety-net arrangements also apply. Further information is available from: http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pbs-phbensna.htm-copy2

34. For example, a recent survey of attitudes towards the health system, which specifically examined the interaction of financial stress and the health system, found that 20% of the sample reported some form of financial stress (8% high levels of stress) and that "21% [of this group] failed to collect a prescription or missed doses of drug compared to 14% of those with no financial stress."[22] It is worth noting that this survey was completed in July-August 2008–i.e. before the worst of the financial crisis in Australia.

35. Similarly, a study of the impact of the 24% increase in PBS patient co-payments that took effect from January 2005 found that "the recent increase in Australian PBS co-payments have had a significant effect on dispensing of prescription medicines. The results suggest large increases in co-payments impact on patients' ability to afford essential medicines. Of major concern is that, despite special subsidies for social security beneficiaries in the Australian system, the recent co-payment increase has particularly impacted on utilisation for this group."[23]

SUMMARY

36. PSA welcomes the review by the Senate Community Affairs References Committee of issues relating to consumer access to pharmaceutical benefits and looks forward to working further with the Committee on the matters raised in this submission.

Prepared by:

Pharmaceutical Society of Australia
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31 March 2010

[22] Menzies Centre for Health Policy and the Nous Group. Survey of attitudes towards the Australian health system. Part 2. Financial stress and the Australian health system. 2009.

[23] Hynd A. Roughead E E. Preen D. Glover J. Bulsara M. Semmens J. The impact of co-payment increases on dispensing of government-subsidised medicines in Australia. Pharmacoepidemiology and Drug Safety. 17(11), September 2008: 1091-1099.