

**A report to the
Australian Health Ministers' Conference
on the results of the research into**

A COST-BENEFIT ANALYSIS

AND

RISK ASSESSMENT OF

**PHARMACIST ONLY (S3) &
PHARMACY MEDICINES (S2)**

AND

RISK-BASED EVALUATION OF THE STANDARDS

**by the
National Co-ordinating Committee
on Therapeutic Goods (NCCTG)**

August 2005

1. BACKGROUND

A review of drugs, poisons and controlled substances legislation (the Galbally Review) was commissioned by the Council of Australian Governments (COAG) as part of the National Competition Policy in 1999. One of the specific terms of reference of the Review was to consider the processes and arrangements for decisions on scheduling.

Medicines are grouped into 'Schedules' according to the appropriate level of control required over access and availability to protect public health and safety. This process, known as 'scheduling', is undertaken by the National Drugs and Poisons Schedule Committee. The schedules recommended by the Committee are published in the *Standard for the Uniform Scheduling of Drugs and Poisons* which is given legal effect through State and Territory legislation. Those that relate to non-prescription (also known as over-the-counter or OTC) medicines include:

- Pharmacy Medicine (Schedule 2) (medicines available from a pharmacy whose safe use may require advice from a pharmacist or a licensed person where there is no pharmacy service); and
- Pharmacist Only Medicine (Schedule 3) (medicines available from a pharmacist without a prescription. The pharmacist is required to be involved in the sale through the provision of professional advice to consumers to ensure that the product is used safely and effectively).

The Review process included extensive consultation with stakeholders, including submissions and face-to-face meetings. The Report of the Review was released in January 2001 and an Australian Health Ministers' Advisory Council (AHMAC) Working Party was established to prepare a response to the Report. The Report and the response were endorsed by the COAG in 2005.

Recommendation 5 of the Report (refer attachment 1) specifically addresses the current scheduling model in Australia and recommends that baseline data should be established and evaluated in order to measure the effectiveness, including any improvement in health outcomes, of the controls on access of over-the-counter medicines and the professional standards for the provision of counselling of consumers¹ on the appropriate selection and purchase of these products.

Leading to this recommendation, the Report noted that restrictions on access (or scheduling) is the most significant of the regulatory controls on medicines and that the extent to which the current controls on over-the-counter medicines that flow from scheduling provide a benefit to the community is dependent to a large degree on the effective level of professional intervention. The Report noted that the most important factor to consider in using OTC medicines is the interaction between the consumer and the product being used and the particular Schedule in which a product has been placed may not always be a good predictor of the potential harm it may cause if used inappropriately. The critical factors may well be the underlying health conditions of the consumer using it, whether that person is taking other medications, and how the consumer uses the medication. Thus the Report considered that the triggers which should elicit pharmacist intervention should focus more on the particular consumer than on the substance.

¹ The decision to establish national standards of practice for community pharmacy in the handling of pharmacist-only and pharmacy medicines followed the release in 1996 of the Industry Commission Report which examined the efficacy of existing medicine scheduling arrangements in Australia.

The Report considered that a system based on a single OTC schedule, supported by a framework which requires pharmacy intervention based on risk-based professional standards (which takes into account circumstances where face-to-face counselling is not feasible such as where purchase is via the internet or mail order) may deliver greater benefits than the current scheduling model. Under such a system, the professional standards would then identify the circumstances in which counselling should be given. In making this recommendation, the Report of the Galbally Review considered that new criteria would need to be developed which took into account any new requirements for professional standards and that it was not simply a matter of the current criteria for Schedule 2 (S2) or the current criteria for Schedule 3 (S3) applying to the single non-prescription schedule.

In taking this proposal forward, the Report recommended that the National Co-ordinating Committee on Therapeutic Goods (NCCTG) ², present the Australian Health Ministers' Conference with a report on the results of the research which would enable Health Ministers to determine whether the current scheduling system for OTC medicines is appropriate and cost effective and achieves its objectives.

2. THE RESEARCH

In response to Recommendation 5 of the Galbally Review, funding was provided by the Australian Commonwealth under the Third Community Pharmacy Agreement for the Pharmacy Guild to commission an independent study to consider whether there are benefits in retaining the dual S2/S3 non-prescription scheduling framework in Australia.

A research team consisting of academics and research staff from the University of Sydney, the University of South Australia and the University of Queensland were selected to conduct this project in 2001. The aim of the project was to provide policy makers with data to evaluate whether there is a net benefit to the community in retaining the Pharmacist Only (S3) and Pharmacy Medicines (S2) as two separate schedules, based on baseline data for a cost-benefit analysis of current professional interventions and a risk-based evaluation of the *Standards for the Provision of Pharmacist Only and Pharmacy Medicines*.

Following some delays due to the need for the research team to gather additional data, the final research report was submitted to the NCCTG for consideration in mid-April 2005. Information submitted by the Pharmaceutical Society of Australia on other professional tools and resources introduced to support the Pharmacy Standards since the release of the report of the Galbally Review also accompanied the report. The research team were subsequently invited to present their findings on their research at the NCCTG meeting of 26-28 April 2005.

3. SUMMARY OF RESEARCH CONDUCTED AND CONCLUSIONS

The study was divided into four key components:

- literature/ qualitative study (Section 2);
- epidemiological study (Section 3);
- evaluation of economic benefits (Section 4); and
- a risk assessment of the standards (Section 5).

² The NCCTG is a standing committee of the Australian Health Ministers Advisory Council (AHMAC) and is responsible for taking the action necessary to bring about co-ordination of legislative and administrative controls on therapeutic goods and poisons and to make recommendations to the AHMAC.

A. Literature / Qualitative Study

International models

Drawing on an international literature review, the study explores the impact of different scheduling models in terms of the scheduling classification of 117 drugs. The three scheduling models considered across 6 countries³ were:

- a) General sale / pharmacy / pharmacist / prescription;
- b) General sale / pharmacy / prescription; and
- c) General sale / prescription.

In comparing the scheduling classification of these drugs across these 6 countries, the report concludes that countries which do not have a pharmacy-only schedule have a greater tendency for products to be held as prescription medicines, thus restricting consumer access to medications and increasing healthcare costs⁴.

Risk assessment in current legislation

In considering the scheduling arrangements in place in other comparable countries, the researchers concluded that all of the systems studied essentially consider three aspects in determining an appropriate schedule for a substance:

- the characteristics of the drug;
- issues relating to professional practice; and
- consumer issues.

B. Epidemiological Study

There were two elements to the study of professional interventions – a census study and a sample study.

1. The census study

A census study was undertaken whereby pharmacies forwarded reports on interventions in the supply of non-prescription medicines which were significant (ie low incidence but averting emergency or routine medical attention or serious harm) over a 2 week period. Of 4981 pharmacies contacted nationally, 934 (18.8%) responded of which most were QCPP⁵ accredited (91.7%). 6463 intervention forms were received (average 6.9 forms per pharmacy) of which 4917 were accepted as an intervention (as independently assessed by a clinical panel).

75% of the interventions were in response to a request for a specific product. The most common problem identified in the census interventions was inappropriate/sub-optimal product choice due to contraindications/use with caution/warnings (1969 of the 4917 accepted (40%)).

2. The sample study

The sample study sought to provide information on the level of professional intervention that currently occurs with the supply of all non-prescription medicines (ie more frequent but less

³ New Zealand, Australia, Canada, France, United States of America and the United Kingdom

⁴ For the purposes of this comparison, in countries with only a single pharmacy schedule, all medicines were treated as if equivalent to S3 (ie held behind the counter with the pharmacist assessing level of intervention needed).

⁵ QCPP was introduced in 1997 to 1998 on the premise that Community Pharmacy needed to adopt the principles of quality assurance/ continuous quality improvement by way of a set of service/process standards. As a result of the implementation of the QCPP, which was funded through the first pharmacy agreement, it was expected that there would be benefits to consumers and Government, including improved societal health outcomes.

significant – averting minor harm) over a 2 week period. While the pharmacies were divided into QCPP accredited or not accredited, there was no significant difference found in the intervention rate. 101 pharmacies completed the study with 469 forms submitted by these pharmacies being accepted as interventions.

In considering whether there is a difference in the risk profile between S2 medicines and S3 medicines, the researchers concluded that the intervention rate for S2 medicines was more frequent but of less significance than the intervention rate for S3 medicines which was less frequent but of greater significance (thus supporting the view that S3 medicines have more capacity for harm than S2 medicines).

Based on the results of the census study and the sample study the researchers conclude that there is a need for better education of consumers in requesting specific OTC products, in particular where the consumer has a medical history of hypertension, asthma, heartburn/ulcer, arthritis, heart disease, diabetes or pregnancy.

C. Cost/Benefit analysis

The cost/benefit analysis on merging Schedule 2 and Schedule 3 is based on the interpolation of data from the census study and the sample study to estimate the economic impact of avoiding negative health outcomes⁶. In comparing the cost/benefit of a merger to a single schedule, it was assumed that such a merger would either be to S2 only or to S3 only. There was no analysis of the benefit of a single schedule which relied more heavily on professional standards to determine when intervention was necessary.

Bearing in mind that a significant number of broad assumptions needed to be made, the report concludes that there is a net benefit of \$2.47 billion (as a central estimate) in having 2 separate non-prescription schedules.

While some attempt was made to gauge the level of consumer satisfaction with pharmacy interventions the sample size was quite small (n= 57). 21 consumers reported partial resolution of their problems and 29 reported complete resolution (page 95). Professional satisfaction with pharmacy standards does not appear to have been explicitly addressed.

D. Review of risk assessment in professional standards

The process of risk management supported in the existing S2/S3 standards⁷ consists of:

- scheduling based on characteristics of the substance;
- mandated questioning and counselling of consumers based on the schedule of the product they wish to purchase (screening and referral); and
- barriers to alternative methods of distribution of scheduled substances (pharmacy design).

The report recognises that this is a one size fits all approach which doesn't take into account the individual circumstances of the consumer, as proposed by the Report of the Galbally Review.

It was noted that as a risk management program, the professional standards do not include assessment of risks and monitoring of outcomes. The researchers suggest that (subject to quantitative analysis) a formal risk management program is established to support the distribution methods of pharmacy medicines with this program including:

- identification of each relevant hazard;

⁶ The report emphasises that these “health outcomes” did not take into account the benefits of any general counselling/advice which may be provided with the supply of an S2/S3 medicine or where a consumer requests a medicine based on a description of their symptoms

⁷ As published in 1999 by the Pharmaceutical Society of Australia.

- assessment based on empirical evidence of the risks associated with each hazard;
- cost-benefit analysis of the various options available for managing each hazard; and
- routine monitoring of outcomes.

Other possible mechanisms for improving the management of the individual risk to consumers of S2/S3 medicines are described in:

- Recommendation 19 - that a national training program for all community pharmacists on S3 and S2 medicines should be developed emphasising clinical interventions in high risk patients with underlying conditions, age and specific products (as identified in the report); and
- Recommendation 20 - that patient education leaflets on problems associated with S3 and S2 medicines specific for at risk patients be circulated through patient support groups, general medical practitioners and community pharmacy.

4. ANALYSIS OF THE REPORT OF THE RESEARCH

While the overall results of the research demonstrated that there was likely to be a marginal benefit in retaining S2/S3 as a more flexible scheduling model (as supported by the comparison of the number of substances available OTC in Australia with the numbers of substances available OTC in countries with similar and different scheduling models), the evidence presented in the report was not compelling and NCCTG members were unable to conclude that the evidence clearly supported the benefit of retaining both schedules.

The cost/benefit elements of the research were based on comparing the current dual S2/S3 schedules with either a sole S2 schedule or a sole S3 schedule. NCCTG recognises the difficulties in comparing the current dual schedules to a new conceptual single schedule model as proposed by the Galbally Review, particularly given that the new model would rely heavily on the individual judgement of pharmacists as to when professional intervention is required in the supply of an OTC medicine rather than having any well defined legal framework (as is currently the case).

Due to the inherent difficulties in making valid comparisons and the limitations of the analysis, the conclusions drawn from this section of the report should be ‘interpreted with caution’ (as noted at the presentation given to NCCTG by the research team). The cost/benefit analysis is therefore of limited value in comparing the benefit of retaining both schedules compared to a new single schedule which would require new criteria to be developed.

The report of the research commissioned in response to Galbally Recommendation 5 outlines certain information, including several initiatives which aim to improve the performance of pharmacy in meeting the Quality of Care Standards. However, the NCCTG is of the view that these initiatives have not been in place long enough to be able to thoroughly assess the risks in moving to a single schedule for non-prescription medicines. It would therefore be premature at this stage to make any recommendations on the retention or otherwise of Schedules 2 and 3, particularly until these initiatives are allowed to mature and become entrenched work practices.

Supplementary information to the research report

NCCTG was particularly concerned that there was potential for the research methodology to skew the results of the epidemiology study as it relied on participants being self-selected rather than being selected at random. In order to address this issue, the presentation provided to the

NCCTG by the research team included provision of information on the Mystery Shopper Program⁸ by the Director of the Quality Care Pharmacy Support Centre⁹ (QCPSC).

While recognising that the objectives of the standards are focussed on education and professional development, the results of the Mystery Shopper Program demonstrated that there are a significant number of pharmacists who are not complying with the behavioural component of the S2/S3 pharmacy standard. Despite the requirements in place for the provision of counselling through the Quality of Care Standards, there appears to be considerable disparity in the level of counselling delivered and in some cases of supplying S3 medicines¹⁰ no counselling has been offered at all¹¹ (which not only constitutes non-compliance with the S2/S3 Pharmacy Standards but is also a breach of State/Territory drug legislation¹²).

While pharmacists play a key role in reducing the level of avoidable medicinal misadventures, this lack of compliance has not been shown to directly correlate with harm to the public, at least through the research undertaken to date. The Mystery Shopper Program data collected from 2002 – 2005 does appear to indicate that compliance of pharmacists with the S2/S3 standards is gradually improving.

Future activities

NCCTG members also noted that Version 2 of the Quality Care Pharmacy Program (QCPP) is to be launched in 2006 and in the lead up to this release consideration is to be given to building into the S2/S3 standards, guidelines for identifying and assessing risks and for monitoring and evaluating these risks and quality improvement. NCCTG also understands that other methodologies are being trialled to support sustainable pharmacist behaviour. However, it is unclear whether these risks will specifically include those relevant to long distance supply of scheduled medicines. NCCTG notes that the QCPP standards were reviewed in 2001 and new professional standard introduced for distance dispensing and internet pharmacy.

Other recommendations contained in the report

The report included a number of other recommendations which are not directly relevant to the implementation of Recommendation 5 of the Galbally Review. NCCTG suggests that these recommendations be referred to the Medical and Pharmaceutical Services Division of the Commonwealth Department of Health for any further action (as the sponsor of the research, originally funded under the Third Community Pharmacy Agreement).

⁸ This program (also known as Standards Maintenance Assessment (SMA) visits), which is designed to ensure that the S2/S3 standards are being applied effectively and consistently, only applies to pharmacies which are QCPP accredited. According to the Quality Care Pharmacy Support Centre, all accredited pharmacies can be expected to receive at least one SMA visit per year.

⁹ The QCPSC provides a focal point for maintaining the Quality Care Pharmacy Standards and manages the SMA program.

¹⁰ The S2/S3 pharmacy standards require that a pharmacist is directly involved with the supply of Pharmacist Only (S3) medicines – this means that the pharmacist must engage in a conversation directly with the patient.

¹¹ According to the data presented to the NCCTG by the Director of the QCPSC, 82 of the 1415 pharmacies (5.8%) who were “mystery shopped” between January 2004 and February 2005 failed to satisfy any criteria for the supply of an S3 medicine, as required by the Pharmacy Standards.

¹² State/Territory drug legislation generally provides that the pharmacist must take reasonable steps to establish the therapeutic need for an S3 medicine to be supplied to the consumer and provide directions for the safe and effective use of the medicine.

5. DIRECTIONS FOR FUTURE RESEARCH

NCCTG feels that the researchers have not completely considered all the factors involved in analysing this issue, in particular the capability of the pharmacy sector to voluntarily comply with pharmacy standards (irrespective of whether they are QCPP accredited) and the feasibility of introducing a standard which places more reliance on recognition of “at risk” consumers in determining an appropriate level of professional intervention. Without further analysis of the industry it is not prudent to assume that a single schedule for non-prescription medicines will deliver improved benefits to consumers or industry.

Further information should be gathered over the next 5 year period, including the formal integration of the mystery shopper data and reviewed at the end of that time in the trans-Tasman scheduling environment. It is expected that pharmacy will address the non-compliance of some pharmacies with both the Quality of Care Standards and legal requirements within this 5 year period, but if the review at the end of this time shows no improvement, regulatory options for improving compliance should be considered.

6. RECOMMENDATIONS

- a) The scheduling model for medicines retain the Pharmacy (Schedule 2) and Pharmacist-Only (Schedule 3) schedules for non-prescription medicines for an interim period of 5 years;
- b) The Quality Care Pharmacy Program (QCPP) be requested to submit the summarised results of the Mystery Shopper Program to the NCCTG on a yearly basis for the next 5 years in order for the NCCTG to monitor any improvement in compliance with the voluntary S2/S3 standards;
- c) At the end of the 5 year period, the restrictions on access to over-the-counter medicines be reassessed in Australia and New Zealand to determine if the objectives of these restrictions are being met, taking into account relevant data, including the data gathered from the Mystery Shopper Program and an analysis of pharmacies which are not QCPP accredited;
- d) The QCPP review of the S2/S3 pharmacy standards consider integrating into the standards:
 - the identification of risks to consumers making a product based request; and
 - appropriate professional intervention by pharmacists to address those risks.

Recommendation 5: Medicine schedules and associated professional support

That all Commonwealth, State and Territory governments agree:

- a) *That funds be allocated from the Pharmacy Development Program under the Third Pharmacy Agreement to commission:*
 - *independent research that provides baseline data and evaluation. Such research should demonstrate any improvements in health and other outcomes that can be attributed to the higher level and quality of pharmacy counselling flowing from the new Quality of Care Standards, the implementation of which is being supported and funded under the Third Community Pharmacy Agreement. The outcomes of this research should be reported to the National Coordinating Committee on Therapeutic Goods (NCCTG) by the end of June 2004.*
 - *the development of comprehensive standards that facilitate a risk-based approach to professional intervention in the supply (including the distance supply) of scheduled products to individual consumers. The Pharmaceutical Society of Australia should be responsible for developing these standards in consultation with Pharmacy Boards, the Pharmacy Guild of Australia, Pharmacists Branch of the Association of Professional Engineers, Scientists and Managers of Australia (APESMA), other relevant professional groups and consumer organisations, and presenting those standards to the National Coordinating Committee on Therapeutic Goods by the end of June 2004.*
- b) *That the National Coordinating Committee on Therapeutic Goods present the Australian Health Ministers Council (AHMC) with a report by the end of July 2004 on the results of the research and on the Standards proposed to be developed. This Report will enable Health Ministers to:*
 - *Monitor the extent to which the restrictions on access to scheduled medicines, supported by improved counselling, deliver improved health and other outcomes;*
 - *Determine whether there is an appropriate and cost effective control system for meeting the objectives of restricting access to over-the-counter medicines; and*
 - *Review the implications of the expanded standard for the integrated operation of schedules and pharmacy practice.*
- c) *That until the Australian Health Ministers have considered the report at the end of July 2004, Schedules 2, 3, 4 and 8, and associated Appendices, be retained. If at that time there is no evidence to support the benefits of retaining Schedules 2 and 3 they should be combined and new criteria developed.*