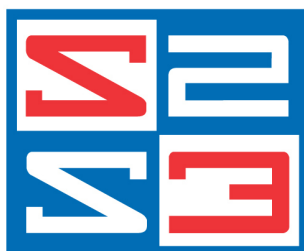


# **A Cost-Benefit Analysis of Pharmacist Only (S3) and Pharmacy Medicines (S2) and Risk-Based Evaluation of the Standards**

**FINAL REPORT  
JUNE 2005**



Cost Benefit Analysis of Non-Prescription Medicines

## **CHIEF INVESTIGATOR**

Prof SI (Charlie) Benrimoj

Faculty of Pharmacy  
The University of Sydney NSW 2006  
Tel: (02) 9351 2077  
Fax: (02) 9351 4391  
Email: [charlieb@pharm.usyd.edu.au](mailto:charlieb@pharm.usyd.edu.au)

# TABLE OF CONTENTS

<b>PERSONNEL</b>	<b>4</b>
<b>EXECUTIVE SUMMARY</b>	<b>6</b>
<b>1. INTRODUCTION</b>	<b>18</b>
1.1 PROJECT OVERVIEW	19
1.1.1 FORMATION OF RESEARCH GROUPS	20
1.2 PROJECT OBJECTIVES	22
1.2.1 TENDER REQUIREMENTS	22
1.2.2 OPERATIONAL HYPOTHESES	27
1.3 ASSUMPTIONS OF A MERGED SCHEDULE	29
<b>2. REVIEW OF LITERATURE/QUALITATIVE STUDY REPORT</b>	<b>30</b>
2.1 BACKGROUND	31
2.1.1 RESEARCH OBJECTIVES	31
2.2 METHOD	32
2.3 RESULTS	33
2.3.1 REVIEW OF CURRENT SCHEDULING	33
2.3.2 NDPSC	34
2.3.3 INTERNATIONAL PERSPECTIVES	42
2.4 DISCUSSION	48
<b>3. STUDY OF PROFESSIONAL INTERVENTIONS EPIDEMIOLOGY STAGE REPORT</b>	<b>54</b>
3A METHODOLOGY	55
3A.1 OVERVIEW	55
3A.2 CENSUS METHODOLOGY	60
3A.3 SAMPLE METHDOLOGY	63
3A.4 PMS METHDOLOGY	67
3A.5 COMMON METHDOLOGIES	68
3A.6 CLINICAL PANEL EVALUATION	70
3A.7 DATA INTEGRATION, REPRESENTATIVENESS OF SAMPLES AND WEIGHTING	73
3A.8 CALCULATION OF INTERVENTION RATES	79
3B RESULTS	82
3B.1 CENSUS	82
3B.2 SAMPLE STUDY	86
3B.3 INTEGRATED RESULTS	92
3B.4 INTERVENTION RATES	94
3B.5 EVALUATION OF SOCIAL AND HEALTH IMPACTS	99

3B.6	PMS RESULTS	100
3B.7	CASE STUDIES	101
3C	DISCUSSION	105
<b>4.</b>	<b>STUDY OF PROFESSIONAL INTERVENTIONS COST BENEFIT STAGE REPORT</b>	<b>114</b>
4.1	BACKGROUND	116
4.2	METHOD	118
4.2.1	BENEFITS	118
4.2.2	DISEASE COSTING	119
4.2.3	COST OF DEATH	121
4.2.4	PRODUCER COSTS	121
4.2.5	EFFECTS OF SCHEDULE MERGING	123
4.2.6	OTHER COSTS	125
4.3	RESULTS	128
4.3.1	KEEP THE SCHEDULES SEPARATE	128
4.3.2	MERGE INTO PHARMACY MEDICINES (S2)	129
4.3.3	MERGE INTO PHARMACIST ONLY (S3) MEDICINE	130
4.3.4	LIMITATIONS AND SENSITIVITY ANALYSIS	132
4.4	CONCLUSIONS	135
<b>5.</b>	<b>RISK MANAGEMENT ASSESSMENT REPORT</b>	<b>137</b>
5.1	BACKGROUND	138
5.1.1	THE STANDARDS	138
5.1.2	COMPETITION POLICY	138
5.2	RISK MANAGEMENT	142
5.2.1	BACKGROUND	142
5.2.2	METHODOLOGY	145
5.3	STANDARDS FOR THE PROVISION OF PHARMACIST ONLY AND PHARMACY MEDICINES IN COMMUNITY PHARMACY	146
5.3.1	COMPONENTS OF THE STANDARDS	146
5.4	QUALITY CARE PHARMACY PROGRAM	148
5.5	ASSESSMENT OF THE STANDARDS	149
5.6	CONCLUSION	152
<b>6.</b>	<b>PROJECT CONCLUSIONS AND RECOMMENDATIONS</b>	<b>153</b>
6.1	CONCLUSIONS	154
6.2	RECOMMENDATIONS	158
	<b>REFERENCES</b>	<b>162</b>
	<b>APPENDICES</b>	<b>167</b>

## PERSONNEL

<p><b>CHIEF INVESTIGATOR*</b></p> <p><b>Prof SI (Charlie) Benrimoj</b> Dean, Professor of Pharmacy Practice Faculty of Pharmacy The University of Sydney</p> <p><b>*The Chief Investigator was a member of all research groups.</b></p>	<p><b>HEALTH ECONOMICS GROUP</b></p> <p><b>Mr Peter Davey</b> Director</p> <p><b>Ms Anna Cordony</b> Economist</p> <p><b>Mr Adam Gordois</b> Senior Economist M-TAG Pty Ltd Medical Technology Assessment Group</p> <p><b>Mr David Gadiel</b> Health Care Intelligence Pty Ltd</p> <p><b>Mr Robin Boudeville</b> Medical Coder Westmead Hospital</p>
<p><b>EPIDEMIOLOGY GROUP</b></p> <p><b>Dr Lynne Emmerton</b> Senior Lecturer School of Pharmacy The University of Queensland</p> <p><b>Prof Richard Taylor</b> School of Public Health The University of Sydney</p> <p><b>Dr Kylie Williams</b> Lecturer Faculty of Pharmacy The University of Sydney</p>	<p><b>RISK MANAGEMENT GROUP</b></p> <p><b>John Kelly</b> John G Kelly &amp; Associates Pty Ltd</p> <p><b>Mr Peter Carroll</b> Health Care Intelligence Pty Ltd</p>
<p><b>QUALITATIVE ASSESSMENT GROUP</b></p> <p><b>Assoc. Prof. Andrew Gilbert</b> Co-investigator</p> <p><b>Mr Neil Quintrell</b> Co-Project Officer</p> <p><b>Dr Susan Semple</b> Project Officer</p> <p><b>Ms Jennifer Cullen</b> Project Administrator School of Pharmaceutical, Molecular and Biomedical Sciences University of South Australia</p>	<p><b>CLINICAL PANEL MEMBERS</b></p> <p><b>Mr Bob Austic</b> Community Pharmacist</p> <p><b>Mr John Bell</b> Community Pharmacist</p> <p><b>Dr Nicholas Bennett</b> General Medical Practitioner</p> <p><b>Ms Stephanie Bennett</b> Community Pharmacist</p> <p><b>Mr Stephen Carter</b> Community Pharmacist</p> <p><b>Dr Royle Crooks</b> General Medical Practitioner</p> <p><b>Ms Margaret Jordan</b> Hospital Pharmacist</p> <p><b>Ms Ruth Khouri</b> Community Pharmacist</p>
<p><b>RESEARCH TEAM</b></p> <p><b>Ms Catherine Raffaele</b> Project Manager</p> <p><b>Mr Joel Werner</b> Research Officer</p> <p><b>Mr Celal Bayari</b> Research Assistant Faculty of Pharmacy The University of Sydney</p>	

	<p><b>Dr Karen McCartney</b> General Medical Practitioner</p> <p><b>Dr Winston Liauw</b> Clinical Pharmacologist Clinical Trials Centre St Vincents Hospital</p> <p><b>Dr Brindin Murnion</b> Clinical Pharmacologist St Vincents Hospital</p> <p><b>Prof J Paul Seale</b> Professor of Clinical Pharmacology Department of Pharmacology Faculty of Medicine The University of Sydney</p>
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## ETHICS APPROVAL

This research was conducted with ethical approval from the University of Sydney Human Research Ethics Committee (Reference Numbers: 6981, 7320).

## TERMINOLOGY

The terms OTC (over-the-counter) and non-prescription medicines are used interchangeably in this report.

“S3” and “Schedule 3” refers to Pharmacist Only Medicines.

“S2” and “Schedule 2” refers to Pharmacy Medicines.

“S4” and “Schedule 4” refers to prescription medicines.

‘Standards for the Provision of *Pharmacist Only* and *Pharmacy Medicines* in Community Pharmacy’ is also referred to as *Standards*.

## EXECUTIVE SUMMARY

The Cost-Benefit Analysis and Risk Assessment of Pharmacist Only (S3) and Pharmacy Medicines (S2) and Risk-Based Evaluation of the Standards Project used a number of studies and various methodologies to address the issue of non-prescription scheduling and the 'Standards for the Provision of *Pharmacist Only* and *Pharmacy Medicines* in Community Pharmacy' (*Standards* is also used in this report for convenience). Personnel consisted of academics and research staff from The University of Sydney, The University of South Australia, The University of Queensland and consultants from Healthcare Intelligence Pty Ltd, M-TAG Pty Ltd and John G Kelly & Associates Pty Ltd. Research groups were developed to focus on specific stages of the project: the Qualitative Assessment Group was responsible for delivery of the Review of Literature and the Qualitative Study; the Epidemiology Group was responsible for the delivery of the Epidemiology Stage of the Study of Professional Interventions which included a Census, a Sample Study (linked to a Post-Marketing Surveillance Study) and a Clinical Panel Assessment Stage; the Health Economics Group had the primary responsibility of undertaking the economic analysis of the data gathered from Epidemiology Stage of the Study of Professional Interventions.

No other studies of a similar nature were found in the published or grey literature. It appears that decisions relating to the promulgation of various scheduling arrangements for non-prescription medications internationally are made on grounds other than on research data. The lack of a previous conceptual and/or theoretical approach presented a major challenge to the research team. The overview of the research as outlined in Figure 2 (Section 1.1 Project Overview) therefore represents an innovative and possibly a seminal approach to future international studies. An issue which created a major obstacle was that of pharmacy recruitment. Both in the Census and Sample Study, extensive efforts and resources had to be made available to recruit community pharmacists. The reasons for this reluctance to participate in the study must inevitably be multi-factorial.

### **Review of international scheduling processes**

An international analysis, including Canada, France, the United States of America, New Zealand and the United Kingdom, was carried out. The analysis of the processes of Australia's National Drugs and Poisons Schedule Committee found that, overall, processes conform to international best-practice. Notwithstanding this, a number of issues were identified which could enhance the risk assessment process. These include support for the recommendation to divide the drugs and poisons functions of the committee, recommendations relating to processes to enhance the quality of submissions to the Committee, and recommendations for changes designed to streamline the decision-making process. It was the opinion of Committee members that the current scheduling arrangements provide a workable and useable framework to support the Quality Use of Medicine in Australia. Committee members were firmly of the opinion that the current scheduling arrangements provide a preferred model where consumer access, public health and professional management issues are

appropriately balanced. In the opinion of the members of the NDPSC, more restrictive scheduling arrangements may lead to drugs being held in prescription only schedules or delays in their release to a less restrictive schedule. A review of the 'Standards for the Provision of *Pharmacist Only* and *Pharmacy* Medicines in Community Pharmacy' was undertaken to determine whether these could be improved to provide better individual risk assessment at the community pharmacy level. The *Standards* had been developed through an extensive consultative process and were judged to be fundamentally sound, although a range of modifications is recommended. There were perceived weaknesses in the current application of the *Standards* enunciated by members of the NDPSC. Recommendations include mandatory training for pharmacy assistants and the continued monitoring of the implementation of the *Standards* by the profession. The *Standards* were also assessed from a risk-management point of view by the Risk Management Group (Section 5).

### **Census and Sample Study methods**

The Epidemiology Stage of the Study of Professional Interventions involved two separate field studies: a census to determine the baseline incidence rates for 'highly significant' yet low incidence interventions relating to non-prescription medicines (Stage 1) and a sample study (Stage 2/3) to collect data on the less significant non-prescription interventions and examine pharmacy performance according to QCPP accreditation. A Post-Marketing Surveillance Study was linked to the Sample Study to monitor consumer outcomes and satisfaction.

For the purposes of this study, an intervention was defined as: "The promotion of the Quality Use of Medicines by the identification and attempted resolution of an actual or potential drug- or symptom-related problem arising from an over-the-counter request." It is important to note that this study measures "interventions" that pharmacy staff perform on non-prescription medicines. It does not include a measurement of the value of general counselling that is provided with or without the sale of medicines. The study did consider an intervention had taken place where patients came into a pharmacy requesting treatment for a particular symptom and the pharmacy staff member either discovered that patients had misdiagnosed symptoms or that treatment would have been harmful. However, the study did not consider interventions had occurred in cases where patients had asked the pharmacy staff member for advice on presenting symptoms and requested a treatment, nor discussion reinforcing correct consumer self-medication practices. Nonetheless, it should be recognised that these staff-patient consultations still provide considerable economic and clinical benefit to the community. Consumers are known to use pharmacies as a first step in ascertaining whether they needed to seek further medical advice. In many cases, the advice provided may have saved the consumer the cost of a doctor's visit. Aside from the primary health care savings, this general counselling also provides education of the quality use of medicines which can aid to prevent the need for future interventions. While the study recorded interventions of pharmacy staff alerting customers to the possibilities of unintentional abuse or sedative dependence, incidents involving preventing intentional illicit use were not part of the data analysis.

For both the Census and the Sample Study, community pharmacists and pharmacy staff aged 16 years and over were asked to record on pre-printed forms all specified interventions that occurred in their pharmacy during an allocated two-week study period to determine baseline incidence rates of interventions. For the Census,

pharmacies were asked to collect all *significant* (“averted routine medical treatment”), *highly significant* (“averted emergency medical treatment”) or *potentially life-saving* interventions for non-prescription medicines in order to capture conservatively the highly significant and potentially life-saving interventions. In the Sample Study, pharmacies were asked to record *all* of their interventions for non-prescription medicines: this included minor (“averted minor harm”), significant, very significant and potentially life-saving interventions. Pharmacies were not asked to collect instances where only general counselling was provided nor were they asked to record instances of suspected illicit use. Sample Study pharmacies were also asked to recruit patients for whom an intervention was performed into a Post-Marketing Surveillance Study. All community pharmacies in Australia were invited to participate in the Census with 4891 pharmacies being sent recruitment materials and 934 (18.8%) pharmacies completing the study. Three groups of pharmacies were recruited for the Sample Study: Group 1 were QCPP-accredited pharmacies that were highly compliant with the relevant standards; Group 2 were QCPP-accredited pharmacies that were moderately-to-poorly compliant with the relevant standards or had not been tested (this group was used so the results could be extrapolated back to the Australian population); and Group 3 were non-QCPP-accredited pharmacies, registered for accreditation but with no accreditation date booked. Recruitment material was faxed to all Group 1 and 3 pharmacies and a random selection of Group 2 pharmacies. Of 1238 pharmacies contacted, 101 pharmacies completed the study.

Once intervention forms were received at the research centre, they were coded according to a coding frame to determine clinical significance, intervention characteristics and action taken was created (Fig 4: Clinical Coding Frame for Interventions), with reference to previous limited literature. Initial significance coding was assigned by the research team so as to enable a sample to be taken of the intervention forms for assessment by the clinical panel. Final year pharmacy students who were currently working in community pharmacy were employed to assign the initial significance coding. This coding was checked by two pharmacists in the research team by sampling the original significance coding and the two researchers independently coding similar interventions. The initial significance coding was then amended to the agreed final coding.

A selection of intervention forms was then assessed by clinical panels each consisting of one general medical practitioner, one pharmacist and one clinical pharmacologist. Three panels convened for the Census to assess a total of 310 intervention forms with a preliminary clinical significance coding of highly significant (“averted emergency medical treatment”) or potentially life-saving. The intervention forms were divided equally amongst the three panels to examine independently, with 20 intervention forms being common across the three Census panels and a Kappa statistic calculated to determine correlation between panellists (Appendix 33). Two panels convened for the Sample Study to assess a randomly selected range of 189 intervention forms stratified across all significance levels and observation pharmacy groups. The intervention forms were divided equally amongst the two panels to examine separately with 18 intervention forms being common across the two Sample Study panels and a Kappa statistic calculated (Appendix 33). Intervention forms were examined to assess the adverse consequence avoided (or created) as a result of the interaction recorded. Once results had been finalised from the clinical panel, the panel assessment data were joined in a database with their corresponding intervention form data and matching pharmacy demographic data. Separate databases were created for



the Census and Sample Study of these integrated clinical panel data. These data were subsequently weighted for extrapolation to the Australian population for the purposes of clinical and economic analyses.

### **Interventions performed**

6463 intervention forms were received as part of the Census data collection, with 4917 assessed as interventions meeting the criteria of the study. Of the 888 intervention forms received for the Sample Study, 469 were assessed as interventions. In both the Census and Sample Study, approximately three-quarters of the interventions arose from customers directly requesting a product. Pharmacists were involved in about half the interventions recorded (alone in 49% of cases in both studies, or including a pharmacy assistant, 79% and 77% of the time in the Census and Sample Study respectively) spending an average estimate of 6.12 (s.d.=4.1) minutes on each intervention in the Census and 4.73 (s.d.=3.7) minutes in the Sample Study. Pharmacy assistants were recorded as spending an average estimated 4.48 (s.d.=3.5) minutes on each intervention in the Census and 3.65 (s.d.=4.0) minutes in the Sample Study. In the interventions recorded, pharmacy assistants were more likely to refer customers to the pharmacist in the Census where higher significance interventions were asked to be recorded than the Sample Study (67% of Census interventions where a pharmacy assistant was involved compared to 60% in the Sample Study, and 29.5% compared to 27.3% of the total interventions in the Census and Sample Study respectively). Pharmacists were involved in more interventions with a higher clinical significance (three-quarters of the potentially life-saving interventions in the two-week period of the Sample Study and Census) than pharmacy assistants. However, pharmacy assistants' interventions were seen across a spectrum of clinical significance.

Ideally, the calculation of rates of interventions would be based on actual sales from pharmacy. However, no such data were available to the research team. IMS Health provided national and individual pharmacy purchase (after individual consent) data as a surrogate for sales data. These data are considered to be of a very high integrity and are used by the industry as a whole to analyse the industry. The other limitation in determining the intervention rate is the ability of pharmacy to under-report or over-report interventions. The evidence available suggests that, on balance, there has been under-reporting. The counter-balance to the under-reporting could be that participating pharmacies may be biased to high performers than non-participants. With these limitations, the study estimated that the annual Australian intervention rate was 5.66 interventions per 1000 units purchased for all non-prescription medicine products, with the Pharmacy Medicines (S2) rate 5.76 per 1000 units and Pharmacist Only (S3) Medicines with 5.34 per 1000. Although there was no statistically significant difference observed between rates, an examination of the rates of intervention for Pharmacist Only (S3) and Pharmacy Medicines (S2) show that there are differences in magnitude between the rates, and as such differentiation in how the two schedules are supplied. While there was a higher rate of intervention overall on Pharmacy Medicines (S2), this is due to the fact that there were more interventions made of a minor significance nature made on Pharmacy Medicines (S2) than Pharmacist Only (S3) Medicines. When the high significance interventions were separated out, there was a higher rate for Pharmacist Only (S3) Medicines than Pharmacy Medicines (S2) (1.41 highly significant interventions per 1000 units for Pharmacist Only (S3) Medicines, compared to 1.12 interventions for Pharmacy Medicines (S2)). The result provides epidemiological evidence on the different nature

of the medicines in the two schedules and suggests that Pharmacist Only (S3) Medicines have more capacity for harm with a higher risk than Pharmacy Medicine (S2), thereby benefiting from being provided by a professional with extensive health training rather than an assistant. The consequences of modelling for an amalgamated non-prescription schedule indicate that, in essence, the number of interventions would increase if the amalgamated model mimicked the current Pharmacy Medicines (S2) schedule as Pharmacist Only (S3) Medicines would be subjected to a total higher rate. By contrast, if the amalgamated model mimicked the current Pharmacist Only (S3) Medicines schedule, the total intervention rate would decrease, since Pharmacy Medicines (S2) would be subjected to the lower overall intervention rate for Pharmacist Only (S3) Medicines. However, if one takes into account the level of significance associated with the intervention, an amalgamation to the Pharmacist Only (S3) Medicines amalgamated model would be preferred, since the rate for high significance interventions is lower in Pharmacy Medicines (S2) than Pharmacist Only (S3) Medicines. It appears from the empirical evidence that the current system provides a balance between convenience and ensuring safety for the consumer. Lower risk medicines are available with some screening and higher risk medicines are kept separately with the provision of higher level professional screening.

There appears to be no significant difference in intervention rates between the three groups of QCPP accreditation-grouped pharmacies tested in the Sample Study with total intervention rates on non-prescription medicines of 8.2 (Group 1- “Excellent” QCPP Accreditation), 7.6 (Group 2 - “Low” - “Medium” QCPP accreditation and QCPP-accredited but untested ) and 7.9 (Group 3 - Not QCPP-accredited) interventions per 1000 units purchased. However in actual numbers, Group 1 (“Excellent” QCPP Accreditation) outperformed the other two groups. By contrast, Group 3 (Not QCPP-accredited) showed a higher Pharmacist Only (S3) Medicines rate (18 interventions per 1000 units purchased) than any other group. Based on these results it was therefore difficult to make any recommendations regarding the differential impact of standards on practice. However it is likely that the concept of standards has meant that the market as a whole is performing at higher level than previously.

Patients were most likely to be aged 13-64 years (73.3% in the Census and 73% in the Sample Study) and female (58.3% in the Census and 59.3% in the Sample Study). Hypertension was the most commonly reported pre-existing medical condition accounting for one in five of the patients in the Census and Sample Study. Asthma, the second most reported known pre-existing condition, accounted for approximately one in ten of the patients in both Census and the Sample Study. Surprisingly, in practice, pregnant women were also shown to be an at-risk group. The most common problem identified in interventions overall was 'Inappropriate/suboptimal drug/product choice' (82.5% in the Census, 72.3% in the Sample Study), with the most likely cause 'Drug-condition contraindications/use with caution/warnings' (40% in the Census, 35.4% in the Sample Study), 'Therapeutic duplication' (14.8% in the Census, 9.2% in the Sample Study) and 'Untreated/under-treated indications' (13.4% in the Census, 14.9% in the Sample Study). The most common products involved in both the Census and the Sample Study were cold and flu medications, non-steroidal anti-inflammatory agents, combination simple analgesics, narcotic analgesics and antihistamines.

### **Evaluation of Clinical Benefits**

From the epidemiological data, it is estimated that Australian pharmacies perform 485,912 interventions per annum in the process of dealing with non-prescription medicines, with 101,324 per annum being high significance interventions (averting emergency medical attention, serious harm or potentially life-saving). The most common estimated annual cases avoided were exacerbations of asthma, peptic ulcers, hypertension and unspecified adverse effects of drugs which suggest that the high-risk groups were patients with those underlying diseases. The rank for Sample Study interventions varied from the ranked Census interventions. However, the same groups of patients appear to be at risk. When the probability of the pharmacy intervention preventing the adverse event (assigned by the clinical panel) was taken into account to derive a count of annual cases avoided by pharmacy interventions, it is estimated that each year pharmacy staff prevent 30,808 visits to Accident and Emergency at hospital, 76 cases of being in an intensive care unit and 84,650 urgent visits to a general medical practitioner. This is based on the current rate of intervention. If there were an improvement in the intervention rate of 10%, this would result in an additional 48,591 interventions being made each year.

### **Evaluation of Economic Benefits**

The analysis examines the economic implications of interventions for each schedule and merging the Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules in Australia. Using epidemiological data collected in the course of this project, the economic benefit of pharmacy interventions associated with the sale or pharmacy customer requests for Pharmacist Only (S3) or Pharmacy Medicines (S2) was estimated. Data employed for this purpose were collected from an assessment of the impact of interventions in avoiding diseases. Estimation of the extent of diseases avoided for a 12-month period was extrapolated from a survey comprising the Census and Sample Study (Epidemiology Stage). For each disease category, information was collected on the following: annual expenditure at 2000/01 prices (the most recent year for which such data are available) – including medical, hospital, pharmaceutical, allied health expenses, and long-term care (from the Australian Institute of Health and Welfare); its disability weight (from Mathers *et al* [1]); the mean duration of disability with which it was associated (from survey); the incidence of disability avoided (from survey); deaths avoided and survival times (from survey); the value of life (from literature). From the above information set, the various elements of the cost per case for each of the diseases avoided calculated consisted of the annual cost of treatment per case per disease category, the cost of disability, and the cost of death. Producer costs which are the costs of staff time required to produce the benefits (avoided diseases and deaths) were also estimated. These include the time costs of both the pharmacist and pharmacist assistant involvement in dispensing products on the Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules.

Under the current situation where the Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules are separate and distinct, the epidemiological model suggests a central estimate of some \$2.75B in benefit annually, with a lower-bound estimate of \$152M and an upper-bound estimate of \$13.69B. This is the benefit derived from preventing cases of temporary disability and death. This outweighs the costs required to deliver these benefits in terms of the pharmacy staff time involved in providing positive interventions. Our central estimate of current net benefit per year is \$2.61B.

The situations in which the Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules are merged into a single schedule were examined. In the situation where the Pharmacist Only (S3) Medicines schedule is eliminated, Pharmacist Only (S3) Medicines would shift into Pharmacy Medicines (S2), and net benefits are predicted to decrease by \$100.9M to \$2.51B. In the situation where the Pharmacy Medicines (S2) schedule is eliminated, Pharmacy Medicines (S2) would shift into Pharmacist Only (S3) Medicines, and net benefit is predicted to increase by \$113.5M to \$2.73B. Therefore, it would appear that, given the evidence available, merging the two schedules by eliminating Pharmacy Medicines (S2) would confer the greatest net benefit. However, it is estimated that in achieving this, net benefit producer costs would increase by \$90M. It is estimated that this increase in within pharmacy activity would require an additional 2,735 pharmacists in Australia. Any decision on changing the Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules would therefore require consideration of potential labour constraints.

However, there are a number of qualifications to the analyses. First, in relation to the epidemiological evidence, one needs to bear in mind that it is self-reported and that pharmacies that participated in the survey may have contributed to a pro-selective bias for which it would have been impossible to control in weighting the results of the survey. Second, there is also a lack of evidence for the impact of Pharmacist Only (S3) and Pharmacy Medicines (S2) products shifting into the unscheduled or prescription market following a merger. We assumed that if Pharmacy Medicines (S2) were eliminated, all Pharmacy Medicines (S2) products would shift into the Pharmacist Only (S3) Medicines schedule. However, it is possible that some may shift to unscheduled 'open seller' availability. Likewise, if the Pharmacist Only (S3) Medicines schedule were eliminated, some high-risk products may shift to the Prescription Medicine schedule (S4). Therefore, the net economic benefit estimates are subject to a not inconsiderable degree of uncertainty.

Limited data were available to calculate producer time costs. Therefore, simplifying assumptions were made as to the extent of staff involvement in sales not accompanied by a positive intervention. Gross and net benefit estimates are dependent on the value of a statistical life, and the assumptions required to generate from this the value of a statistical life year. There are a variety of estimates in the literature, the selection of which would lead to different estimates of benefit. These parameters were tested in sensitivity analyses. For these reasons, any use of this analysis to make new policy decisions that would impact on the provision of health services in Australia should be made with extreme caution.

### **Risk Assessment of the *Standards***

The 'Standards for the Provision of *Pharmacist Only* and *Pharmacy Medicines* in Community Pharmacy', originally developed by The University of Sydney and the University of South Australia and adopted by the Pharmaceutical Society of Australia in 1999, were qualitatively analysed using the Australian/New Zealand Standard on Risk Management AS/NZS 4306:2004. Generally, the *Standards* followed a risk-based process in assessing the approach of a community pharmacy to its activities, decisions and operations. However, a number of issues would need to be addressed to bring the *Standards* in line with best-practice risk-management processes proposed by the Australian/New Zealand Standard on Risk Management AS/NZS 4360:2004. It is recommended that consideration is given to developing further guidelines within the *Standards* to assist community pharmacies in better identifying, assessing and documenting risks. A component that could usefully gain from a greater focus from

the assessment of environments is the development of a more clearly defined set of criteria upon which risk is to be evaluated. The risk criteria must correspond to the type of risks and the way in which risk levels are expressed. This could occur more effectively in respect of Standards 2.1 and 4. Standards 2 and 3 focus particularly on identifying risks in the context of community pharmacy. The protocols also provide guidance on what methods can be used to collect information. However, the protocols would benefit from a review to ensure that community pharmacies (via the *Standards*) can be provided with greater certainty in relation to Standard 2.1 and the protocols.

It would be prudent that a simple documentary record for Pharmacist Only (S3) Medicines interventions becomes a part of the risk-management approach to the *Standards*. Representatives from community pharmacy, government and consumers would need to decide the acceptable level of risk using qualitative data available from the Census and Sample Study and other sources. It may be that not all non-prescription medicines may need documentation. This might be achieved via further protocols or additions to the standard operating procedures. Furthermore, consideration needs to be given to increasing the external audit component of the monitoring of the *Standards* to provide greater certainty of their effectiveness.

## **SUMMARY OF RECOMMENDATIONS**

### **Overall Project Recommendation:**

That, from an analysis of Australian and international scheduling arrangements, clinical benefit perspective, cost-benefit and risk-management perspective, the current non-prescription scheduling system be maintained with regards to separate Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules.

### **Recommendation 1:**

That the current system used by the NDPSC be reviewed so that the following issues are taken into account by the Committee in its deliberations: an examination as to the characteristics of the drug, an examination of issues relating to professional practice, and consideration of consumer issues.

### **Recommendation 2:**

That the recommendation 7(a) of the National Competition Review of Drugs, Poisons and Controlled Substances Legislation that the National Drugs and Poisons Schedule Committee be disbanded and replaced with two separate committees – a Medicines Scheduling Committee and a Poisons Scheduling Committee - be supported and moved forward.

### **Recommendation 3:**

That the guidelines for the provision of information by sponsors and expert advisers to the Medicines Scheduling Committee be amended to require all submissions to conform to those described in the Cochrane Library Reviewers' handbook [23].

### **Recommendation 4:**

That provision be made within the processes of the Medicines Scheduling Committee to allow the Committee to have direct dialogue with experts and clinicians who provide opinion to the Committee.

### **Recommendation 5:**

That all Commonwealth, State and Territory governments agree that decisions of the NDPSC (or its equivalent replacement by a Medicines Scheduling Committee) on the scheduling status of medicines shall be made by consensus or, failing consensus, by a two-thirds majority of all members.

**Recommendation 6:**

That the NDPSC (or a Medicines Scheduling Committee) consider whether it should be required for sponsors to produce evidence of efficacy of products for which a schedule switch is sought.

**Recommendation 7:**

That, from qualitative analysis of Australian and international scheduling arrangements, the current non-prescription scheduling system be maintained with regards to separate Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules to encourage the switch of products from prescription to non-prescription.

**Recommendation 8:**

That a national system for tracking clinical interventions on Pharmacist Only (S3) and Pharmacy Medicines (S2) be instituted as part of a quality assurance and improvement system. The system should include the ability to report on individual products and patient characteristics.

**Recommendation 9:**

That a post-switching (from prescription to Pharmacist Only (S3) Medicines and Pharmacist Only (S3) Medicines to Pharmacy Medicines (S2)) a pharmaco-vigilance system be developed and implemented on a national basis to assist in the analysis and management of risk.

**Recommendation 10:**

That the competency statement for pharmacists be reviewed to explicitly include a core competency for performing clinical interventions for Pharmacist Only (S3) and Pharmacy Medicines (S2).

**Recommendation 11:**

That a national program be instituted to increase the clinical intervention rate for Pharmacist Only (S3) and Pharmacy Medicines (S2).

**Recommendation 12:**

That national policy and protocols should be developed, concentrating on when and how pharmacy assistants should refer at-risk patients to pharmacists. These policies should be incorporated in the 'Standards for the Provision of *Pharmacist Only* and *Pharmacy Medicines* in Community Pharmacy'.

**Recommendation 13:**

That all universities and pre-registration programs should incorporate clinical intervention education on Pharmacist Only (S3) and Pharmacy Medicines (S2) as part of their curricula.

**Recommendation 14:**

That there be a formal requirement for those pharmacy staff members who are not pharmacists to have a formal qualification for handling Pharmacist Only (S3) and Pharmacy Medicines (S2).

**Recommendation 15:**

That, due to the clinical benefits provided by the current non-prescription medicine scheduling system, separate Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules be retained.

**Recommendation 16:**

That a national training program for community pharmacy on Pharmacist Only (S3) and Pharmacy Medicines (S2) be developed, emphasising clinical interventions in high-risk patients with underlying conditions, age and specific products identified in this report.

**Recommendation 17:**

That existing patient education leaflets be revised to address problems associated with Pharmacist Only (S3) and Pharmacy Medicines (S2) specific for patients with underlying conditions identified at-risk in this report. These leaflets are to be circulated through patient support groups, general medical practitioners and community pharmacy.

**Recommendation 18:**

That a review of labelling requirements for Pharmacist Only (S3) and Pharmacy Medicines (S2) be undertaken, as this study has shown that currently a significant number of at-risk consumers are not complying with labelling instructions.

**Recommendation 19:**

That further analysis of data collected as part of the Study of Professional Interventions includes interventions performed on unscheduled medicines, and further analysis take place on the data collected in the Study of Professional Interventions at the product level to determine the relative risk of products.

**Recommendation 20:**

That a study investigate the incidence and outcomes of inappropriate use of unscheduled medications sold in non-pharmacy outlets (e.g. supermarkets).

**Recommendation 21:**

That research be conducted into the nature of clinical interventions reported in this study to identify practice behaviour patterns of pharmacists and pharmacy staff.



**Recommendation 22:**

That an investigative study of pharmacies with higher intervention rates be conducted to identify factors contributing to the higher rate, and these incorporated into national training programs.

**Recommendation 23:**

That, from a cost-benefit perspective, there be no change to the current scheduling arrangements.

**Recommendation 24:**

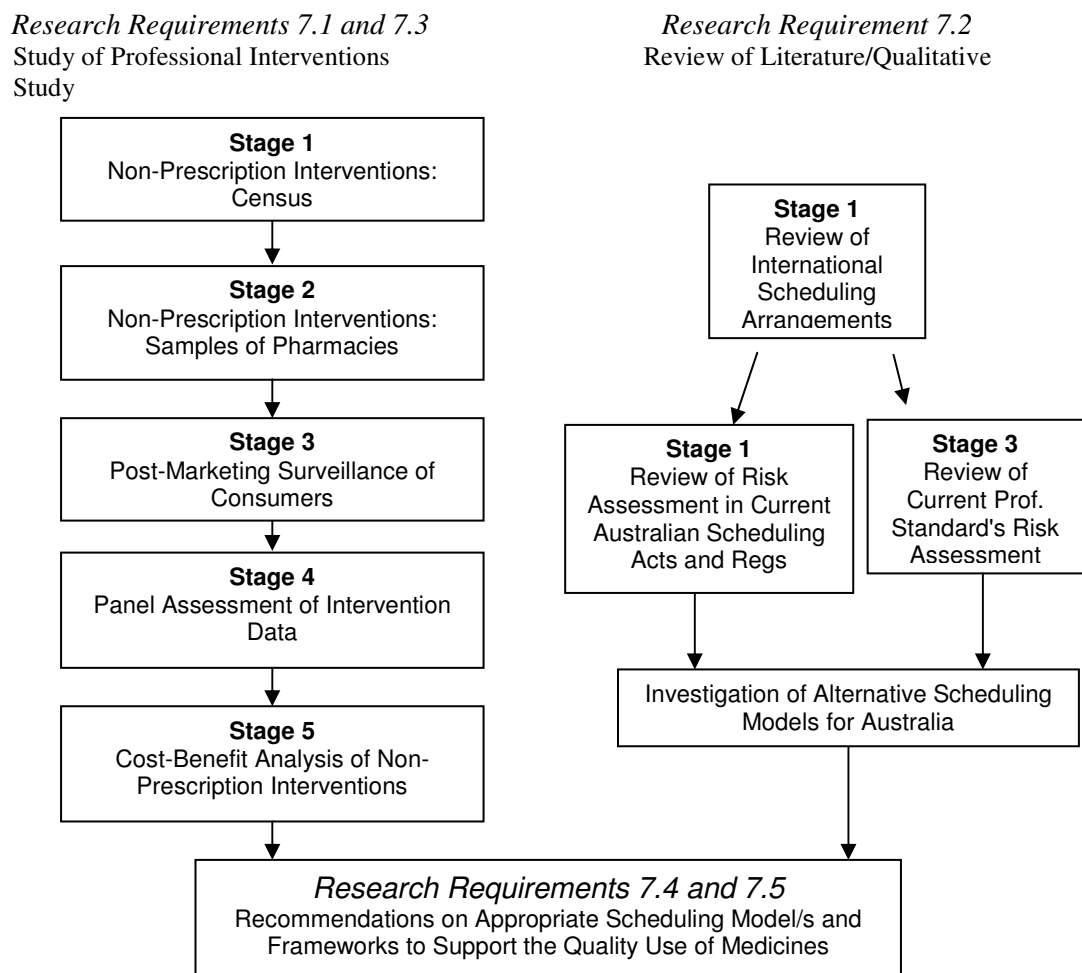
That consideration be given to developing further guidelines within the *Standards* to assist community pharmacies in better identifying, assessing and documenting risks so that the *Standards* appropriately meet best-practice risk-management processes. Further, that consideration be given to increasing the external audit component of the monitoring of the *Standards* to provide greater certainty of their effectiveness.

**SECTION 1**  
**INTRODUCTION**

## 1.1 PROJECT OVERVIEW

The Cost-Benefit Analysis of Pharmacist Only and Pharmacy Medicines and Risk-Based Evaluation of the Standards project consisted of academics and research staff from The University of Sydney, The University of South Australia, The University of Queensland and consultants from Healthcare Intelligence Pty Ltd and M-TAG Pty Ltd. The project used a number of studies and various methodologies to address the issue of non-prescription scheduling and the ‘Standards for the Provision of *Pharmacist Only* and *Pharmacy Medicines* in Community Pharmacy’. These involved a review of the literature, qualitative and quantitative methodologies. (Fig 1).

**Figure 1:** Overview of Research



### **1.1.1 FORMATION OF EXPERT RESEARCH GROUPS**

Research groups were developed to focus on specific stages of the project. Respective lines of responsibility were clearly defined. The research groups were required to report regularly to the Chief Investigator, Prof SI (Charlie) Benrimoj at The University of Sydney.

#### **REVIEW OF LITERATURE/QUALITATIVE STUDY**

This involved three stages:

- STAGE 1: Review of the literature on international scheduling models, including the schedules themselves, scheduling criteria and legislation, as well as literature relating to professional practice standards. In particular, models with a risk-based approach were sought.
- STAGE 2: Evaluation of the Australian scheduling criteria, using data on the nature of the risk assessment decisions that are used by scheduling committees and from available documentation. Recommendations were made for improving the risk-based elements of the legislation.
- STAGE 3: Review of the current *Standards*, with focus on their risk-assessment and risk-management elements, followed by recommendations for inclusion of appropriate risk-based elements. [This stage was subsequently transferred to The University of Sydney and a separate Risk Management Group to do additional assessment as the Qualitative Assessment Group (SA) chose to evaluate the *Standards* from the evidence collected in the other parts of the Review of Literature/Qualitative Study (Appendix 4), rather from a risk-management focus. The Risk Management Group's findings are reported in Section 5.]

This research was undertaken with qualitative methodologies.

#### **Qualitative Assessment Group (SA)**

The Qualitative Assessment Group was responsible for delivery of the Review of Literature and the Qualitative Study. The Qualitative Assessment Group consisted of research staff from the University of South Australia headed by Assoc Prof Andrew Gilbert (Co-Investigator).

#### **STUDY OF PROFESSIONAL INTERVENTIONS**

This involved collection and analysis of data on non-prescription interventions occurring in community pharmacies. This took place in five stages, the first four stages were epidemiological in nature and were the responsibility of the Epidemiology Group; the final and fifth stage was the Cost Benefit Analysis, and this was undertaken by the Health Economics Group. The two groups liaised on a regular basis to ensure consensus on methodology and data collection instruments.

### **Epidemiology Group**

The Epidemiology Group was responsible for the delivery of the Epidemiology Stage of The Study of Professional Interventions (Stages 1 – 5). The EPIDEMIOLOGY STAGE consisted of four stages:

- STAGE 1 – Census: A nationwide census in which pharmacy staff recorded their most ‘highly significant’ yet low incidence non-prescription interventions over a two-week period. This was a cost-effective approach as opposed to using large samples of pharmacies in an experimental design.
- STAGE 2 – Sample Study: This sample study was used to determine baseline levels of practice with regards to supply Pharmacist Only and Pharmacy Medicines. Within this stage, there was a comparison of interventions collected for Pharmacist Only and Pharmacy Medicines by samples of pharmacies representative of three different levels of practice (Quality Care in Pharmacy Practice (QCPP) accreditation and non-QCPP accreditation). The third group was representative of the other levels of QCPP accreditation.

The results of the Census and Sample Study were integrated and extrapolated to the Australian population.

- STAGE 3: A post-marketing surveillance study of consumers was undertaken in conjunction with Stage 2 (Sample Study) to determine the impact of pharmacy interventions and subsequent consumer behaviour.
- STAGE 4: Professional clinical panels assessed intervention data collected by the Census and Sample Study (Stages 1 and 2).

### **Health Economics Group**

The Health Economics Group had the primary responsibility of undertaking the economic analysis of the data gathered from Epidemiology Stage of the Study of Professional Interventions. Input was periodically given in discussions of the first four stages of the project with the Epidemiology Group so that the Health Economics Group’s requirements for the final analysis were incorporated. Health Care Intelligence Pty Ltd contributed to the economic content of the work, however, sole professional responsibility for the final economic model resides with M-TAG Pty Ltd. All questions regarding the cost-benefit analysis should be addressed to M-TAG Pty Ltd.

The COST-BENEFIT STAGE consisted of the last and final stage:

- STAGE 5: A cost benefit analysis on the non-prescription schedules was undertaken using data collected in Stages 1, 2 and 4.

### **Risk Management Group**

The Risk Management Group worked closely with the Qualitative Assessment Group and the Health Economics Group on the risk assessment aspects of the project. Qualitative and quantitative assessment of the *Standards* took place using empirical risk-management theories and the results of the Census and Sample Study.

## 1.2 PROJECT OBJECTIVES

### 1.2.1 TENDER REQUIREMENTS

The aim of the project was to fulfil the following tender requirements. The figure below outlines how the project has fulfilled the tender requirements.

Requirements 7.1 and 7.3	Project Fulfilment
1. Development of methodology and collection of baseline data.	<p>A range of data collection instruments were developed and two studies, a census and sample study, were undertaken as part of the Study of Professional Interventions – Epidemiology Stage.</p> <p>⇒ <b>Section 3A: Study of Professional Interventions – Methodology.</b></p> <p>⇒ <b>Section 3B: Study of Professional Interventions – Results.</b></p>
2. Evaluation of social, economic and health impacts.	<p>For the evaluation of social and health impacts see Results and Discussion of the Study of Professional Interventions – Epidemiology Stage.</p> <p>⇒ <b>Section 3A: Study of Professional Interventions – Methodology.</b></p> <p>⇒ <b>Section 3B: Study of Professional Interventions – Results.</b></p> <p>The evaluation of the economic impact was part of the Study of Professional Interventions – Cost Benefit Stage.</p> <p>⇒ <b>Section 4: Study of Professional Interventions – Cost Benefit Stage.</b></p>
3. A focus on the current legislative requirements, current <i>Standards</i> , and current practice.	<p>A Literature Review/Qualitative Study was undertaken focussing on the current national and international legislative requirements.</p> <p>⇒ <b>Section 2: Literature Review/Qualitative Study</b></p> <p>The current <i>Standards</i> were evaluated by a risk-management expert.</p> <p>⇒ <b>Section 5: Risk Assessment Report</b></p> <p>The results of the Sample Study were reviewed in light of the current <i>Standards</i> and current practice</p> <p>⇒ <b>Section 3C: Study of Professional Interventions – Discussion.</b></p>

<p>4. Determination of compliance with the legislative requirements and <i>Standards</i>.</p>	<p>The interventions collected as part of the Census and Sample Study gave an insight into compliance with legislative requirements and the <i>Standards</i>.  ⇒ <b>Section 3B: Study of Professional Interventions – Results.</b>  ⇒ <b>Section 3C: Study of Professional Interventions – Discussion.</b></p>
<p>5. Determination of the level of professional intervention that currently occurs (for ‘at-risk’ consumers and practices), with stratified representative sampling of pharmacies according to QCPP accreditation and/or training in the <i>Standards</i>.</p>	<p>The Sample Study addressed the level of professional intervention that currently occurs and identified ‘at-risk consumers. The Sample Study was stratified to test the issue of QCPP accreditation. The Census identified consumers at high risk.  ⇒ <b>Section 3B: Study of Professional Interventions – Results.</b></p>
<p>6. Determination of the number of interventions in relation to each schedule, including the null hypothesis that <i>there is no difference in the way Schedule 2 and Schedule 3 medicines are supplied within the community practice setting</i>.</p>	<p>The integrated data from the Census and Sample Study tested this hypothesis.  ⇒ <b>Section 3B: Study of Professional Interventions – Results.</b></p>
<p>7. Determination of the staffing input into interventions, and level of referral from assistant to pharmacist.</p>	<p>Both the Census and Sample Study identified the staffing input into interventions at pharmacist, pharmacy assistant and pre-registration graduate level, and determined the level of referral from assistant to pharmacist.  ⇒ <b>Section 3B: Study of Professional Interventions – Results.</b></p>
<p>8. Determination of the types of conditions and the specific products involved.</p>	<p>Both the Census and Sample Study identified the types of conditions and specific products involved in non-prescription interventions.  ⇒ <b>Section 3B: Study of Professional Interventions – Results.</b></p>
<p>9. Determination of the potential of the intervention to encourage appropriate use of non-prescription medicines and prevent harm.</p>	<p>The nature of interventions for non-prescription medicines was identified by both the Sample and Census data and extrapolated nationally.  ⇒ <b>Section 3B: Study of Professional Interventions – Results</b>  ⇒ <b>Section 3C: Study of Professional Interventions – Discussion.</b></p>

10. Monitoring of consumers' health, other outcomes and satisfaction post-intervention.	The Sample, Census and PMS studies gave an indication of outcomes and satisfaction post-intervention. ⇒ <b>Section 3B: Study of Professional Interventions – Results.</b>
11. Analysis and reporting on the costs and benefits of the two schedules to the pharmaceutical industry, including sponsors, wholesalers, government, co-regulators, community pharmacy and consumers, based on the intervention data.	Evaluation of the costs and benefits was undertaken as part of the Study of Professional Interventions – Cost Benefit Stage. ⇒ <b>Section 4: Study of Professional Interventions – Cost Benefit Stage.</b>

Requirements 7.2	Project Fulfilment
12. Review of the current legislation for scheduling of non-prescription medicines, including the scheduling criteria.	A Literature Review/Qualitative Study was undertaken focussing on the current national and international legislative requirements. ⇒ <b>Section 2: Literature Review/Qualitative Study.</b>
13. Review of the current <i>Standards</i> with respect to Best Practice in consumer risk-management and quality use of medicines.	The current <i>Standards</i> were evaluated by a risk-management expert. ⇒ <b>Section 5: Risk Assessment Report.</b>
14. Recommendations for improving consumer risk-management in the current scheduling legislation and <i>Standards</i> , including the null hypothesis that <i>there is no difference in risk profile of S2 or S3 substances.</i>	A Literature Review/Qualitative Study was undertaken focussing on the current national and international legislative requirements. ⇒ <b>Section 2: Literature Review/Qualitative Study.</b>  The current <i>Standards</i> were evaluated by a risk-management expert. ⇒ <b>Section 5: Risk Assessment Report.</b>  The interventions collected as part of the Census and Sample Study highlighted the risks of non-prescription medicines which were discussed as part of the Study of Professional Interventions – Epidemiology Stage. ⇒ <b>Section 3C: Study of Professional Interventions – Discussion.</b>



Requirements 7.4 and 7.5	Project Fulfilment
<p>15. Determination of alternative models for scheduling of non-prescription medicines, including amalgamation of schedules.</p>	<p>A Literature Review/Qualitative Study was undertaken focussing on the current national and international legislative requirements.  <b>⇒ Section 2: Literature Review/Qualitative Study.</b></p> <p>The issue of alternative models for scheduling of non-prescription medicines, including amalgamation of schedules was addressed in the Study of Professional Interventions, Epidemiology Stage (Census and Sample Study) and Cost Benefit Stage.  <b>⇒ Section 3: Study of Professional Interventions – Epidemiology Stage.</b>  <b>⇒ Section 4: Study of Professional Interventions – Cost Benefit Stage.</b></p>
<p>16. Evaluation of the alternative scheduling models with respect to risk-management, standards required, and other relevant issues.</p>	<p>A Literature Review/Qualitative Study was undertaken focussing on the current national and international legislative requirements.  <b>⇒ Section 2: Literature Review/Qualitative Study.</b></p> <p>The relevant risk-management issues were assessed in the Section 5 Risk Assessment Report.  <b>⇒ Section 5: Risk Assessment Report.</b></p> <p>The Census and Sample Study provided the impact of the intervention rates (the intervention rates relate to the risk-management).  <b>⇒ Section 3B: Study of Professional Interventions – Results.</b>  <b>⇒ Section 3C: Study of Professional Interventions – Discussion.</b></p>

<p>17. Proposal of the structure of alternative scheduling models for Australia, to allow Cost Benefit analysis at a later stage.</p>	<p>A Literature Review/Qualitative Study was undertaken focussing on the current national and international legislative requirements.</p> <p>⇒ <b>Section 2: Literature Review/Qualitative Study.</b></p> <p>Proposed structures of alternative scheduling models and their analysis can be found in the Study of Professional Interventions – Cost Benefit Stage and the discussion of the Census and Sample Study in the Study of Professional Interventions – Epidemiology Stage.</p> <p>⇒ <b>Section 4: Study of Professional Interventions – Cost Benefit Stage.</b></p> <p>⇒ <b>Section 3C: Study of Professional Interventions – Discussion.</b></p>
<p>18. Recommendations on the retention or amalgamation of the current schedules, or introduction of alternative models.</p>	<p>Recommendations for the retention or amalgamation of the current schedules or alternative models can be found in the Project Conclusions and Recommendations.</p> <p>⇒ <b>Section 6: Project Conclusions and Recommendations.</b></p>

## **1.2.2 OPERATIONAL HYPOTHESES**

Key tender requirements were translated into operational hypotheses and research questions, as indicated in the following sections.

### **1.2.3.1 LITERATURE REVIEW/QUALITATIVE STUDY AND RISK MANAGEMENT REPORT OBJECTIVES**

The qualitative project sought answers to the following questions:

1. Can substantial improvement be offered to the Australian scheduling criteria by international models?
2. Can the current legislation relating to non-prescription schedules be substantially improved with respect to additional risk-based elements?
3. Can the current *Standards* for the provision of non-prescription medicines be substantially improved with risk-based elements?

One specific hypothesis was tested qualitatively:

H<sub>0</sub>: That there is no difference in risk profile of Pharmacist Only and Pharmacy Medicines.

### **1.2.3.2 CENSUS HYPOTHESES**

The Non-Prescription Medicines Interventions Census was undertaken to collect 'highly significant' yet low incidence non-prescription intervention data.

The specific objectives of this research stage were to address the following research questions:

Primary research questions:

- (i) What is the *rate* of high significance interventions occurring for non-prescription medications (Pharmacist Only (S3) and Pharmacy Medicines (S2)) in all pharmacies in Australia?
- (ii) What are the *types* of high significance pharmacy interventions for non-prescription medications, and in relation to which medications, in this nationwide survey?
- (iii) What is the *nature* of the pharmacy intervention?

It was hypothesised:

H<sub>0</sub>: That there is no significant difference in the *incidence rate of high significance interventions* between patients requesting Pharmacist Only (S3) Medicines and Pharmacy Medicines (S2).

### **1.2.3.3 SAMPLE AND PMS STUDY OBJECTIVES**

The Non-Prescription Medicines Interventions Sample Study was undertaken to:

1. Collect data on the full range of non-prescription interventions that pharmacy staff make on non-prescription medicines and related conditions.
2. Compare the rate and significance of interventions made by those pharmacies that are highly compliant with the *Standards* and those pharmacies that have yet to undergo formal *Standards* accreditation using QCPP pharmacies.
3. Determination of the level of consumer acceptance of pharmacist and pharmacy staff advice.
4. Follow-up a selection of consumers to collect evidence on the actual outcomes and whether or not pharmacy advice was followed.

For the purposes of this study, it was hypothesised that:

H<sub>01</sub>: There is no difference in the incidence rates of interventions between Pharmacist Only (S3) and Pharmacy Medicines (S2) in community pharmacies.

H<sub>02</sub>: There is no difference in incidence rates of interventions between pharmacies at different levels of accreditation of the Quality Care Pharmacy Program (QCPP) of The Pharmacy Guild of Australia.

### **1.2.3.4 COST BENEFIT ANALYSIS OBJECTIVES**

It was hypothesised:

H<sub>0</sub>: That there is no increase in the economic benefit for consumers when there is a single merged schedule for non-prescription medicines compared to when there are two separate non-prescription medicine schedules (Pharmacy Medicines and Pharmacist Only Medicines).

### 1.3 ASSUMPTIONS OF AN AMALGAMATED SCHEDULE

If there were to be one amalgamated schedule, there are two broad possibilities:

**Scenario 1:** Similar to the current Pharmacy Medicines (S2) schedule, where medicines must be sold in a pharmacy but may be sold by either a pharmacy assistant or a pharmacist.

**Scenario 2:** Similar to the current Pharmacist Only (S3) Medicines schedule, where medicines must be sold by a pharmacist.

If a Pharmacy Medicines (S2) type schedule were adopted, theoretically only the Pharmacy Medicines (S2) rates would apply across the current Pharmacist Only (S3) Medicines. This would mean the number of cases currently detected for Pharmacy Medicines (S2) would stay the same and that these detection rates for Pharmacy Medicines (S2) would only apply to current Pharmacist Only (S3) Medicines. Similarly, if a Pharmacist Only (S3) Medicines type schedule were adopted, theoretically only the Pharmacist Only (S3) Medicines rates would apply. This would mean the number of cases currently detected for Pharmacist Only (S3) Medicines would stay the same and these rates for Pharmacist Only (S3) Medicines would also apply to current Pharmacy Medicines (S2) schedule medications. Since for these two schedules, different types of staffing apply (Pharmacist Only (S3) Medicines by legislation need be supplied by a pharmacist and Pharmacy Medicines (S2) can be supplied by pharmacy assistants), there would be an inevitable change in the current labour force with economic and professional implications to community pharmacy and consumers.

Although this is a simplistic model that does not take into account the possibility of active ingredients being switched to a different schedule, it does serve the purpose of answering the question regarding the amalgamation of schedules. It may be presumed that if there were only a Pharmacy Medicines (S2) type schedule, a number of products that are currently Pharmacist Only (S3) Medicines would move to Prescription only, as they would require higher professional advice than that provided by non-pharmacist staff. A Pharmacist Only (S3) Medicines type schedule would mean that many lower risk products that are commonly dealt with by pharmacy assistants would need to be supplied by pharmacists. In addition, it may be assumed that some products may become unscheduled and be available in outlets other than pharmacies.

**SECTION 2**

**REVIEW OF LITERATURE/QUALITATIVE STUDY  
REPORT**

## 2.1 BACKGROUND

The Review of Drugs, Poisons and Controlled Substances Legislation [1] concluded *inter alia* that

there are sound reasons for Australia to have a comprehensive system of legislative controls that regulates drugs ... notwithstanding the fact that many of these controls restrict competition. (Part A; p xii)

The Review noted that, in many cases, the risk to an individual purchasing a Pharmacy Medicines (S2) product may be as high or higher than the risk to a person purchasing a Pharmacist Only (S3) Medicines product, and

sees the risk in relation to OTC medicines as relating more to the individual circumstances of the consumer and the way the consumer uses the medicine than to the toxicity of the substance. (Part B; p 44)

Recommendation 5(c) of the Report states that

If [by July 2004] there is no evidence to support the benefits of retaining Schedules 2 and 3 they should be combined and new criteria developed. (Part A; p. xvi)

### 2.1.1 RESEARCH OBJECTIVES, QUESTIONS AND HYPOTHESES

The research was designed to address the above issues in order to make recommendations on appropriate scheduling models and frameworks to support the Quality Use of Medicines in Australia [2]. This part of the research sought answers to the following questions:

1. Can substantial improvement be offered to the Australian scheduling criteria by international models?
2. Can the current legislation relating to non-prescription schedules be substantially improved with respect to additional risk-based elements?
3. Can the current *Standards* for the provision of non-prescription medicines be substantially improved with risk-based elements?

One specific hypothesis was qualitatively examined:

H<sub>0</sub>: That there is no difference in risk profile of Pharmacist Only and Pharmacy Medicines.

## 2.2 METHOD

A step-wise investigation and analysis of the scheduling processes for drugs in Australia, with special emphasis on the scheduling of OTC drugs, was undertaken. This included:

- identification of the bodies responsible for scheduling drugs and a description of the scheduling process
- analysis of the guidelines used in making scheduling decisions
- an analysis of the reasons given for scheduling decisions made over the last three years
- the development of a questionnaire based on the reasons given (Following assessment and documentation of the decisions taken by the NDPSC the questionnaire was formulated to access the domains that emerged from that process. The draft version was reviewed by members of the project team and the revised document pilot tested by telephoning and administering the questionnaire to two existing members and one immediate past member of the NDPSC. Their responses and comments were used to prepare the final version of the questionnaire.), and
- structured telephone interviews with individual members of the NDPSC using the questionnaire.

Concurrent with the above, an analysis of overseas scheduling processes was undertaken. This included identification of guidelines for scheduling in countries judged to have sufficient similarity to Australia with respect to

- the presence of substantial pharmaco-vigilance processes
- the use of a similar range of drugs, and
- access to detailed descriptions of decision-making processes and guidelines

The following countries satisfied these criteria and were chosen for study: Canada, France, the United States of America (USA), New Zealand and the United Kingdom (UK) (with reference to the developing processes of the European Union). For each of these countries, scheduling and legislative requirements for drugs available over-the-counter (without prescription) in each of the countries under study were identified. One hundred and seventeen drugs were identified as available over-the-counter in at least one of the six comparison countries. A comparative analysis of the way these drugs are handled across these six countries was undertaken with a view to developing an understanding of the ways different scheduling requirements might affect the availability of drugs to the public. Contact was made with relevant organisations in these the countries to obtain information on legislative requirements for storage and access and training levels for staff who handle over-the-counter medicines.

Findings were brought together and discussed in detail by the research team in order to address the key research questions and the relevant research hypothesis. The outcomes from these discussions were used to review the 'Standards for the Provision of *Pharmacist Only* and *Pharmacy Medicines* in Community Pharmacy' (Appendix 4). Further assessment of the *Standards* from a risk-management focus can be found in Section 5.



## 2.3 RESULTS

### 2.3.1 REVIEW OF CURRENT SCHEDULING REQUIREMENTS IN AUSTRALIA

All medicines manufactured for supply in Australia must be listed or registered in the Australian Register of Therapeutic Goods (ARTG) unless specifically exempted. 'Listed' medicines include such things as herbal, mineral and vitamin products. These are assessed for quality and safety but not efficacy. 'Registered' medicines include all prescription medicines, most injectables, and medicines assessed as having a higher level of risk. 'Risk' is not an absolute concept. It is

the potential for a product to do harm to those it is intended to help or to others who may come in contact with it – regardless of whether the harm results from following or disregarding the directions for use. (p.1) [3].

The administration of drug scheduling in Australia is the responsibility of the Therapeutic Goods Administration (TGA). The Therapeutic Goods Act (1989) provides

a national framework for the regulation of therapeutic goods in Australia to ensure their quality, safety and efficacy ... [which is] ... based on a risk-management approach designed to ensure public health and safety while, at the same time, freeing industry from any unnecessary regulatory burden. (p.1) [3].

The committee structure of the TGA as it relates to OTC medicines includes:

1. The Medicines Evaluation Committee (MEC) that 'advises the minister and Secretary on matters relating to the registration of OTC medicines' (p.1) [4].
2. The National Co-ordinating Committee on Therapeutic Goods (NCCTG) that 'provides recommendations on administrative and regulatory controls for therapeutic goods'. (p.1) [4].
3. The National Drugs and Poisons Schedule Committee (NDPSC) that 'considers submissions for the additions or alterations to the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and undertakes policy development, harmonisation between Australia and New Zealand and has other tasks associated with the public health aspects of the scheduling of drugs and poisons'. (p.2) [4].

### 2.3.2 THE NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE

The NDPSC makes decisions relating to the scheduling of medicines and switches of drugs from Prescription Medicines to Pharmacist Only or Pharmacy Medicines, or to general sale. The terms of reference of the Committee are:

- to classify or to amend the scheduling classification of, and to develop policies relating to the legislative restrictions, including availability, labelling, packaging and advertising of drugs ... for which scheduling is appropriate;
- to revise and maintain the *Standard for the Uniform Scheduling of Drugs and Poisons* to facilitate uniform scheduling under State and territory legislation;
- to develop requirements for the harmonisation of packaging and labelling of scheduled drugs ... and, where possible, scheduling between Australia and New Zealand;
- to undertake public consultation on scheduling matters of public interest and/or significance;
- to liaise with the National Health Advisory Committee of the National Health and Medical Research Council (NHMRC) on public health matters which extend beyond scheduling. (p.3) [5].

New drug substances are evaluated by the TGA. The outcomes of such evaluation are provided to the NDPSC for consideration of appropriate scheduling. Usually, a new drug will be scheduled for prescription use only. To consider applications for rescheduling a drug, two years of local post-marketing experience has been required. However, earlier applications may be considered with provision of suitable evidence. This could include:

- evidence from comparable overseas countries where the drug is available as a non-prescription product (such as Canada, Sweden, Netherlands, New Zealand, USA, UK, or Europe);
- relevant public 'exposure' information in countries with a greater population base than Australia;
- any available information from post-marketing surveillance;
- any relevant previous Australian consideration of the drug (e.g. different route of administration);
- any relevant Australian experience with the drug including a different route of administration. (p.19) [5].

The Guidelines of the NDPSC state that:

the purpose of Schedule 2 is to allow effective drugs or preparations for which pharmacist advice on use may be required by the consumer, to be available to the public without a prescription ...(p. 36) [5].

*Pharmacy Medicines (S2) poisons* are substances or preparations for therapeutic use:

- which are substantially safe in use but where advice or counselling is available if necessary, and are for
- minor ailments and symptoms which
  - can be easily recognised by the consumer
  - do not require medical diagnosis or management (p. 36) [5].

Drugs suitable for inclusion as *Pharmacy Medicines (S2)* should have the following characteristics:

- Suitability for self-treatment of a minor ailment or symptom capable of being monitored by the consumer
- Extremely low abuse potential
- Low potential for harm from appropriate use
- Low or well-characterised incidence of adverse effects or side effects, and contraindications for which advice or counselling is available
- A wide Therapeutic Index
- Low risk of masking a serious disease
- Low risk of compromising medical management of disease (p. 36) [5].

The purpose of *Pharmacist Only (S3) Medicines* is:

to allow effective drugs or preparations that require professional advice on use to be made available to the public from a pharmacist without prescription. (p.38) [5].

*Pharmacist Only (S3) Medicines* are substances or preparations for therapeutic use

- which are substantially safe in use but require professional advice or counselling by a pharmacist,
- the use of which requires pharmacist advice, management or monitoring, and
- are for minor ailments and symptoms which
  - can be identified by the consumer and verified by a pharmacist, and
  - do not require medical diagnosis or only require initial medical diagnosis, and do not require close medical management (p.38) [5].

Drugs suitable for inclusion in *Schedule 3* should have the following characteristics:

- Low abuse potential
- Low potential for harm from inappropriate use
- Low incidence of severe adverse effects or side effects which are likely to require medical intervention
- Only interactions with commonly used drugs or food which can be managed by a pharmacist
- Medium to wide Therapeutic Index
- The risk of masking a serious disease or compromising medical management of a disease can be dealt with by a pharmacist
- Only contraindications that can be dealt with by a pharmacist
- Safety in use with counselling by a pharmacist (p.38) [5].

The Committee's procedures allow for public consultation in relation to decisions that have a regulatory impact. There is provision for public consultation. This is limited to notification in the Government Gazette 30 days prior to and following a meeting of the Committee. There is a 'two-tier' decision-making process in the NDPSC. The whole committee considers submissions made to it, mainly sponsored by the pharmaceutical industry, and scientific and clinical evidence relevant to the submissions. The Committee's Guidelines state that decisions shall be made

by consensus or require agreement of the majority of Commonwealth, States, Territories and New Zealand. (p.15) [5].

In practice, this means that a vote of the whole Committee can be overturned by a vote by jurisdictional members, and such a vote is taken by jurisdictional members (not proxies) present and voting at any meeting. Table 1 provides a summary of assessment factors for Schedules 2 and 3 (with Schedule 4: Prescription Medicines added for comparison), and Table 2 provides an analysis of reasons given for decisions relating to the scheduling of drugs by the NDPSC for the six meetings of the committee from November 2000 to October 2002.

**Table 1:** Summary of assessment factors for drugs in Schedules 2, 3 and 4 (derived from the NHMRC Guidelines [5]).

Characteristics of the drug			
Determinant	Schedule 2	Schedule 3	Schedule 4
Suitability for self-treatment	Ailment or symptom capable of being monitored by consumer	Safety in use with advice or counselling by pharmacist	Requires medical diagnosis, monitoring or management
Abuse potential	Extremely low	Low	Low to moderate
Potential for harm from inappropriate use	Low	Low	New substances or substances for which safety or efficacy may require further evaluation
Incidence of side /adverse effects	Low or well-characterised	Low	May produce serious side effects
Contraindications	Low incidence	Only those that can be dealt with by pharmacist	Requires medical supervision
Therapeutic Index	Wide	Medium to wide	Narrow
Risk of masking serious disease	Low	Can be managed by a pharmacist	Requires medical supervision
Risk of compromising medical management of disease	Low	Can be managed by a pharmacist	Requires medical supervision
Indications for use, other considerations			
Requirement for medical diagnosis or close management	Not required	Easily recognised and treatment by a pharmacist	Requires medical diagnosis and/or monitoring
Recognition of ailment/symptoms	Easily recognised by consumer	Easily recognised with assistance from pharmacist	Requires medical diagnosis
Amenability to short-term treatment and management	Amenable to treatment and management by consumer with advice/counselling if needed	Amenable or capable of being monitored with assistance from pharmacist	Requires medical monitoring
OS experience may be considered	Yes	Yes	Yes
Public health issues considered <sup>1</sup>	Yes	Yes	Yes

**Table 2:** Frequency of reasons given for scheduling decisions, NDPSC, meetings from November 2000 to October 2002. [6].

Dimension	S2 to open sale	S2 retained	S2 to S3	S3 to S2	S3 retained	S4 to S3	S4	Appendix H	Total reasons
Safety	4	2	-	3	1	3	2	1	16
Abuse, or diversion	-	-	1	-	-	-	1	-	2
Level of diagnosis required	2	2	-	-	-	-	9	-	13
Level of management required	2	3	-	1	3	3	12	-	24
Side effects, adverse effects	-	3	-	2	1	2	2	1	11
Capacity to mask disease or compromise management	-	-	-	-	-	-	-	-	-
Patient choice, accessibility	1	-	1	-	2	1	-	1	6
Public health issues e.g. resistance	1	-	-	-	1	-	3	1	6
Harmonisation, scheduling consistency	-	1	-	-	2	1	1	-	5
Therapeutic index	-	-	-	1	-	-	-	-	-
Number of instances	4	5	1	3	3	3	15	2	36
									83

Notes:

1. The number of products or product classes included in analysis = 36. As most decisions contain more than one reason, the number of reasons exceeds the number of products or product classes.
2. Decisions involving establishing consistency across classes of drugs (e.g. solanaceous plants and alkaloids) have not been included in the above analysis.
3. Decisions include decisions to reschedule (normally to a lower level of scheduling, but occasionally to a higher schedule); decisions regarding differential scheduling of drugs based on different strengths and sizes of packages, scheduling of new drugs, decisions relating to harmonisation and consistency, and requests for advertising of Schedule 3 products.
4. When classes of drugs have been considered together, e.g. Nitrates for the treatment of angina, they have been counted as one entry.
5. Injectable forms of drugs are almost invariably scheduled in Schedule 4 due to their mode of administration and have not been included in the analysis.

Three categories account for the majority of decisions – ‘safety’ (including the presence of side effects and potential adverse effects), ‘level of diagnosis required’ and ‘level of management required’. Decisions depend on the committee’s assessment of whether the condition to be treated can be diagnosed and monitored primarily by consumers (Pharmacy (S2) Medicines, Pharmacist Only (S3) Medicines or medical practitioners (S4)). Questions to do with abuse or diversion rarely emerged in the reasons for decisions. The category ‘capacity to mask disease or compromise treatment’ did not emerge in reasons during the period studied, although it is possible that, in the thinking of committee members, this may have been subsumed under the level of management required. Examples of comments from decisions of the NDPSC are provided in Appendix 1.

Decisions made by the New Zealand Medicines Classification Committee (December 2001) [7] show a similar pattern of reasons and include

- Harmonisation with Australia (e.g. pack size of paracetamol)
- Toxicity (e.g. new strength of paracetamol)
- Labelling (e.g. omeprazole, new strength of paracetamol)
- Safety (e.g. omeprazole, paracetamol, fluocortolone)
- Need for medical supervision (e.g. fluocortolone, paracetamol)
- Need for medical diagnosis (e.g. omeprazole)
- Potential for misuse (e.g. fluocortolone).

Table 3 collapses the data of Table 2 into four categories, based on the final decision as to which Schedule the product would be assigned.

**Table 3:** Frequency of reasons for scheduling decisions, NDPSC, meetings from November 2000 to October 2002, by Schedule allocated to products considered.

Dimension	Schedule 2	Schedule 3	Schedule 4	Unscheduled	Total
Safety	5	5	2	4	16
Abuse, or diversion	-	1	1	-	2
Level of diagnosis required	2	-	9	2	13
Level of management required	4	6	12	2	24
Side effects, adverse effects	5	4	2	-	11
Capacity to mask disease or compromise management					-
Patient choice, accessibility		5	-	1	6
Public health issues e.g. resistance	-	2	3	1	6
Harmonisation, scheduling consistency	1	3	1	-	5
Therapeutic index					-
Number of instances	17	26	30	10	83

### **2.3.2.1 INTERVIEWS WITH MEMBERS OF THE NATIONAL DRUGS AND POISONS SCHEDULE COMMITTEE**

A questionnaire was developed from the above analysis [Appendix 2] and telephone interviews were conducted with those members of the NDPSC who were available and willing to be interviewed over a three-week period in June and July 2003. Interviews were conducted with 12 of the 14 committee members, and one of the four expert members. Absences and competing commitments of members meant that, despite repeated attempts to contact them, not all members could be interviewed. Interviewees were provided with a copy of the questionnaire in advance and advised that the report would be in the form of a summary of findings and would not identify individual members. The interviews provided the following information on the committee's perspectives on the decision-making processes.

#### **Summary of interviews**

All of the Committee members were provided with the analysis derived from the *Records of Reasons* and in a subsequent telephone call, were asked directly by the interviewer (Neil Quintrell) as to whether they thought the analysis represented a fair summary of the decision making process and were asked to make any comments or changes to the summary. All of the Committee members individually agreed that it was a fair summary and had no comments or changes to make to the analysis.

Members made the following points:

1. Issues of public health and safety are fundamental in the decision-making process.
2. The Committee strives at all times to base its decisions on the best available scientific evidence.
3. In assessing risk, the committee considers
  - Issues of individual consumer safety, including the potential for harm from inappropriate use, the incidence and seriousness of side effects, toxicity, level of therapeutic index, and any contraindications for use
  - Issues of general public health including the possibility of development of resistance, potential for abuse and dependence, and bioaccumulation where these are relevant factors
  - Issues of diagnosis including the need for medical, other professional or self-diagnosis, and the risk of product use masking serious disease states
  - Issues of management, including the extent to which medical or other professional management is needed, or the ability of consumers to self-manage the condition; and the risk of compromising the management of other current medical conditions
  - Other issues, including consistency within Australian scheduling, harmonisation with New Zealand, and ease of consumer access, although considered, are secondary to the Committee's primary considerations regarding public safety.
4. Although not all points of the guidelines are mentioned in the *Records of Reasons*, all points are considered. Distortions in the rate of reporting of reasons may be due to matters such as the need to respond to specific arguments presented by sponsors of a schedule switch, or an issue not having relevance to a particular product.
5. The question of costs is not a factor in making scheduling decisions.

It is clear both from an analysis of the *Records of Reasons* and from the interviews with individual members that, once issues of public safety have been satisfied, scheduling decisions turn on judgements about the level of diagnosis and management required. For a Prescription Only to Pharmacist Only switch, the Committee must be satisfied that the condition to be managed can be safely diagnosed in interaction between consumer and pharmacist and that any problems arising from treatment can be similarly managed. For a Pharmacist Only to Pharmacy Medicine switch, the Committee must be satisfied that the condition can be self-diagnosed and self-managed, but that professional advice is available to assist such diagnosis and management. For a Pharmacy Medicine to general sale switch, the Committee must be satisfied that there is evidence of safe use (or lack of evidence of any significant level of harm in self-treatment) and that consumers can self-diagnose and treat without the need for access to professional advice. Some concerns about the committee processes were voiced. These include:

- The combining of decisions on both drugs and poisons means that members are sometimes asked to make decisions outside their particular range of expertise. The recommendation of the Galbally report [1] that the two separate committees be formed would be supported. If a separate committee charged with the scheduling of drugs only is to be formed, its composition needs to include an appropriate number of clinicians and practitioners with an understanding of public health issues.
- The material presented to the Committee by sponsors of a switch, experts and the Secretariat often lacks sufficient detail to enable members to critique the data presented, e.g. details of what databases were accessed are not provided, so members do not know if the literature search is comprehensive.
- The material presented to the Committee does not always indicate that key stakeholders (e.g. Diabetes Australia, Asthma Foundation etc) have been informed, or that relevant policy (e.g. Quality Use of Medicines) has been addressed.
- A view that the decision-making process is not always as rigorous as desirable (i.e., a formally structured process of working through the guidelines). The New Zealand guidelines [8] was one model suggested as a possible framework for consideration.
- The inability to engage in dialogue with experts and clinicians. It was suggested that it would help the Committee's deliberations if such dialogue were possible.
- The Gazetting process as a strategy for community consultation may act to limit input from key stakeholders.

It was the opinion of Committee members that the current scheduling arrangements provide a workable and useable framework to support the Quality Use of Medicine in Australia. They see it as providing a flexible system that balances the need to offer good consumer access with appropriate consumer and public health protection. Although recognising that the presence of two pharmacy schedules may place some additional costs on manufacturers and consumers, they believe that the benefits to consumers and society outweigh these cost considerations.

Some members held the view that the fact that certain products are only held in pharmacies sends a clear message to consumers that these are not 'ordinary items of commerce' and that they need to be used judiciously. The ready access to professional



advice provided by the structure of community pharmacy provides at least an opportunity, if not a guarantee, for the provision of objective advice. It was observed that consumers do use pharmacists regularly for advice and these interactions provide the opportunity for education of consumers on the wise use of medicines. Scheduling provides one means of directing consumers on which medicines need advice for optimum effect.

A number of members expressed concern about the application of the schedules in practice. They noted that pharmacies often have time and resource limitations, but are concerned that many pharmacists are not exercising the responsibility that comes with Pharmacist Only (S3) Medicines scheduling. They also suggest that many sales assistants need better training in the rationale for and application of the scheduling arrangements. However, it was also noted that assistants cannot be expected to have the basic science training necessary to provide informed advice, and that their training needs to be directed towards understanding their limitations relative to advice on the use of medicines.

Committee members saw no advantages and several disadvantages with a prescription only/open sale form of scheduling (e.g. in the USA). Although some members said that a prescription only/pharmacy only/general sale structure would be workable, most strongly favoured the current Australian structure. They thought that a prescription only/pharmacy only structure would place pressure on decision-makers to be more reluctant to move products from ‘prescription only’ to ‘pharmacy only’ unless they were convinced that adequate oversight could be ensured. There would therefore be a tendency to either delay or refuse applications for switching products from prescription to a merged Pharmacist Only (S3) and Pharmacy Medicines (S2) schedule.

Committee members were firmly of the opinion that the current scheduling arrangements provide a preferred model where consumer access, public health and professional management issues are appropriately balanced. Table 4 provides a summary of perceived advantages and disadvantages of scheduling models in the countries of comparison.

### 2.3.3 INTERNATIONAL PERSPECTIVES

The World Medical Association (WMA) suggests that for drugs to be available for self-medication, their ‘safety, quality and efficacy’ must be demonstrated, and consumers must be able to:

- recognise the symptoms to be treated
- determine that the condition is suitable for self-medication
- choose an appropriate product
- understand and follow directions, and
- evaluate the balance between risks and benefit [9].

**Table 4:** Advantages and disadvantages of scheduling arrangements in the models used in Australia/New Zealand/Canada, the USA and the UK/France.

Model	Advantages	Disadvantages
Australia/New Zealand/Canada <ul style="list-style-type: none"> <li>• S4: prescription only</li> <li>• S3: pharmacist involvement required, consumer access prohibited</li> <li>• S2: pharmacy only: pharmacist involvement discretionary, consumer self-selection possible</li> <li>• General sale</li> </ul>	<ul style="list-style-type: none"> <li>• Flexible approach is likely to provide a wider range of products off prescription</li> <li>• Professional advice available at point of purchase</li> <li>• Indicates to consumers the levels of advice needed</li> </ul>	<ul style="list-style-type: none"> <li>• Not all pharmacists may fulfil professional responsibility</li> <li>• Costs of individual items may be higher (but are likely to be balanced by lower GP costs and lower costs to consumers in time and convenience)</li> </ul>
UK/France <ul style="list-style-type: none"> <li>• POM: prescription only</li> <li>• P: pharmacy only; pharmacist involvement discretionary, consumer access prohibited</li> <li>• General sale</li> </ul>	<ul style="list-style-type: none"> <li>• Places responsibility on pharmacists to assess level of intervention needed</li> <li>• Simplicity of schedules</li> </ul>	<ul style="list-style-type: none"> <li>• Not all pharmacists may fulfil professional responsibility</li> <li>• More limited range of medicines available (‘emergency supply’ only of some medicines available from pharmacies in Australia)</li> <li>• Restricts all scheduled items to areas that prevent consumer self-selection</li> </ul>
USA <ul style="list-style-type: none"> <li>• Prescription only</li> <li>• General sale</li> </ul>	<ul style="list-style-type: none"> <li>• Better consumer access - medicines available at a wider range of outlets</li> <li>• Consumer assesses own level of need</li> <li>• Lower medicine costs due to competition and availability of medicines in stores with lower-overhead structures</li> </ul>	<ul style="list-style-type: none"> <li>• Disjunction between points of supply and advice</li> <li>• Medicines perceived as ‘safe’</li> <li>• Greater demand for detailed labelling and clear printed information</li> </ul>

### 2.3.3.1 UNITED STATES OF AMERICA

The USA has only two relevant categories for drugs: prescription or non-prescription. The key question that determines whether drugs are available to consumers without prescription is whether patients alone can achieve the desired medical results without endangering their safety.

The Durham-Humphrey amendment to the food, drug and cosmetic act (1938) provided specific criteria for differentiating prescription from OTC drugs. A drug was to be classified as 'prescription only' if it was 'habit-forming', if it was a new drug approved for use under professional supervision, and/or it can only be used safely under the supervision of a licensed health practitioner. The latter category subsumed such concepts as the potential for toxic or harmful effects, the method of use, and any requirements for collateral measures such as clinical or laboratory [10].

The Kefauver-Harris Amendment (1962) required the Food and Drugs Administration to assess the efficacy of drugs when used without supervision as well as their safety. The amendment asks the following questions regarding over-the-counter medicines:

- Can patients recognise and diagnose the condition to be treated?
- Can the patient extract key information for effective use from the package labelling?
- Is the drug effective when used as directed?
- Is the drug safe? [10].

Key concepts of US legislation include:

- Safety – including toxicity, potential for misuse, minimal side effects
- Effectiveness – effective for short-term treatment
- Diagnosis – can consumer self-diagnose?
- Management – are routine tests needed?
- Information – can patients understand correct use?

Since 1976, there have been 65 switches to non-prescription, with no evidence of any escalation in frequency over the years [10]. Recent movements from prescription to non-prescription include:

- Nicotine patches/gum
- Ibuprofen for children
- Ketoprofen and naproxen for analgesia
- Butoconazole nitrate for vaginal yeast infections
- Minoxidil for hair growth
- Famotidine, nizatidine, cimetidine, ranitidine for heartburn.

When a drug is introduced into the market for prescription use, Canada and the USA evaluate active ingredients (rather than products) for safety and effectiveness. All prescription to non-prescription switch approvals require that the product is demonstrated to be safe and effective for self-care. This requires clinical trials to assess the general effectiveness of the product in OTC or 'OTC-like' settings. In the USA this requirement pertains whether the switch is 'complete' (the product has the same indication, strength, dose, duration of use, dose form, route of administration

and target population as the original prescription-only product), or if approval is sought at different dose etc., levels.

### **2.3.3.2 NEW ZEALAND**

New Zealand has four categories matching those of Australia: Prescription Medicines, Pharmacist Only Medicines, Pharmacy Medicines, and general sale medicines.

New Zealand regulations state that

[m]edical products which may be available without prescription shall show a substantial safety in use in the treatment of minor ailments or symptoms usually capable of rapid and spontaneous relief which are easily identifiable by users and do not justify a medical consultation [11].

In order to achieve classification change, the NZ Medicines Classification Committee considers whether there are:

- consumer and public benefits
- ease of self-diagnosis, or pharmacist diagnosis
- relevant comparative data for like compounds
- local data or special considerations
- significant interactions with other medicines
- significant contraindications
- likelihood for the development of resistance
- potential serious adverse effects
- potential for misuse or abuse.

In Australia, the TGA assesses drugs for quality and safety prior to marketing. Those that are judged to be ‘of higher level of risk’ are assessed for efficacy, and those of lower risk are assessed for quality and safety only. Switches to a lower classification do not require assessment for efficacy. New Zealand regulations make no reference to efficacy.

### **2.3.3.3 CANADA**

The Canadian system, like Australia, has Prescription Only, Pharmacist Only, Pharmacy Only and general sale categories. Key concepts in determining classification are ‘safety and efficacy’. Decisions on whether an approved drug is to be scheduled as ‘prescription’ or ‘non-prescription’ is taken by Health Canada. If a drug is deemed to be prescription only by the federal government, no provincial body can over-rule this decision and move it to a lower schedule. Each province has the authority to make further restrictions on the sale of drugs designated as non-prescription and, prior to 1995, each province made its own decisions on scheduling. In 1995, the National Drug Scheduling Advisory Committee (NDSAC) was formed and National Harmonised Schedules were established. All provinces, with the exception of Quebec, have accepted the national harmonised schedules and have implemented them [personal correspondence: National Association of Pharmacy

Regulating Authorities; Canada]. Membership requirements for the NDSAC are included in Appendix 6.

Preparations are listed as ‘prescription’ if:

- Direct practitioner supervision is required, adjunctive treatment with scheduled drugs or routine laboratory monitoring is required
- There is a narrow therapeutic index esp. relating to specific populations such as pregnant or nursing mothers, geriatric, paediatric
- There are potential or known undesirable or severe side effects at normal therapeutic doses
- The preparation has high toxicity
- Treatment of the condition to be treated is easily mis-diagnosed by the public
- Use of the preparation may mask other ailments
- Use of the preparation may or is likely to contribute to development of resistant strains
- There is dependence or abuse potential
- There is a high level of risk relative to expected benefits.

Key questions for shift from prescription to non-prescription are:

- Does removal of physician control endanger the public, and/or increase the risk of significant adverse effects?
- Is the drug safe? Have potential adverse effects been overlooked in randomised controlled trials?
- Is there evidence of good compliance in adhering to labelled instructions and warnings?
- What are the patterns of consumer use and misuse?

It is worthy of note that, in Canada, dispensary technicians and pharmacy assistants have no legal status with respect to the sale of scheduled items and cannot make decisions to sell a ‘pharmacist only’ drug, or to provide advice on ‘pharmacy medicines’ [Personal communication: National Association of Pharmacy Regulating Authorities: Canada].

In Canada, trials are required if dosage regimes differ from those approved for prescription use.

#### **2.3.3.4 UNITED KINGDOM, FRANCE**

France and the UK have three categories of drugs: Prescription Medicines, Pharmacy Only Medicines and general sale medicines. Regulations use European Community definitions, which state that the essential aim ... [of scheduling decisions] ... is to safeguard public health [12]. Items for general sale are those that can “with reasonable safety, be sold or supplied otherwise than by, or under the supervision of, a pharmacist”. Drugs which are to be supplied on prescription are those which:

- are likely to present a direct or indirect danger to human health even when used correctly, if used without the supervision of a doctor; or
- are frequently, and to a very wide extent, used incorrectly, and as a result is likely to present a direct or indirect danger to human health; or

- contain substances ... of which the activity requires, or the side effects require, further investigation; or
- are normally prescribed ... for parenteral administration [13].

‘Indirect danger’ refers to the masking of disease, resistance, and the need for management of underlying disease states. In both France and the UK, all ‘pharmacy medicines’ must be stored ‘behind the counter’ and, at least in theory, all sales must be supervised by a pharmacist. For prescription to non-prescription switches in the UK and France, efficacy data are only required when indications, dosages or age ranges differ from the authorised product and the EC regulations note that

A product’s efficacy is not normally considered in the application for changing the classification for supply [12]

Macdonald *et al* [14] reported on a meeting of experts from the European community that considered criteria required to show safety equivalence of OTC medicines with particular consideration of non-steroidal anti-inflammatory drugs (NSAIDs). They reported nine consensus statements relating to safety issues and study design. These refer to assessment of benefits and risks (statement 1), an exhaustive review of the safety and utilisation data (statement 2), and that both serious and non-serious adverse events ... play an important role (statement 5). Attention is given to appropriate study design to determine safety and identify serious adverse effects. No mention is made of the concept of ‘efficacy’.

### **2.3.3.5 INTERNATIONAL SCHEDULING COMPARISONS**

The World Medical Association’s guidelines on non-prescription medicines states that ‘Safety, efficacy and quality of non-prescription medicines must be proved according to the same principles as prescription medicines’ [9].

A comparison of the scheduling requirements for drugs in the countries of comparison was undertaken. The world self-medication industry website [15] lists 216 drugs available in 27 countries. Of these, 100 drugs are available in each of the six countries selected for study. As different scheduling arrangements pertain to different forms (external, internal) or doses and pack sizes, the total number of drugs and drug forms for comparison was 117. A complete list of the drugs and their scheduling requirements in the countries of comparison, with explanatory notes, appears as appendix 7, and Table 5 (below) provides a comparison of the scheduling requirements of the 117 drugs (including different forms of a drug) available in all of the countries.

**Table 5:** A comparison of the scheduling status of 117 drugs (including different forms of a drug) available for non-prescription sale in any of Australia, New Zealand, the UK, USA, Canada, and France.

Country	1 Drugs available for general sale	2 Drugs available from pharmacies without prescription	3 Total drugs available without prescription	4 Drugs for which a prescription is required
New Zealand	11	67	78	39
Australia	14	59	73	44
UK	6	61	67	50
Canada	14	46	60	57
France	1	58	59	58
USA	50	0	50	67

The results indicate that there is a greater tendency for preparations to be made available off-prescription in countries that have ‘pharmacy only’ schedules (France, NZ, UK, Canada and Australia) and a matching tendency for preparations to be held in ‘prescription only’ schedules in USA where a pharmacy only schedule does not exist. Australia and New Zealand have the most liberal drug scheduling arrangements, in that more drugs are available off prescription. These findings support the opinion of the members of the NDPSC that more restrictive scheduling arrangements may lead to drugs being held in prescription only schedules or delays in their release to a less restrictive schedule.

Economic models of outcomes of prescription to OTC switches generally indicate that there are savings to individuals and health systems arising from such switches, including reductions in both direct and indirect costs and reductions in GP visits. This has been shown in relation to H<sub>2</sub>-receptor antagonists [17]; [18], nicotine replacement therapy [19], and vaginal antifungals [20]; [19], and for 16 drugs switched to OTC sale in Sweden [21]. However, one Australian study highlighted the fact that savings may not be universally enjoyed. When vaginal antifungals were shifted from prescription only, they were subsequently delisted from the Pharmaceutical Benefits Scheme with the result of increased costs for pensioners and health card holders [22]. The limited literature available suggests that schedule switches have resulted in an increase in social benefits with little discernable social costs, supporting a view that decisions about schedule shifts are being made appropriately.

The results suggest that the presence of a pharmacy only schedule provides a structure whereby greater consumer access to medication is available. Some support is provided for the view that a structure offering two pharmacy schedules offers greater consumer access than one offering a single schedule, but the situation in Canada is not consistent with this view. In Canada, pharmacy technicians and pharmacy assistants are not legally allowed to handle sales for pharmacist only drugs, and may not offer advice on pharmacy medicines. This may lead to a slightly more restrictive environment in which the application of the schedules in practice is more like their application in a single-schedule environment such as the UK.

## 2.4 DISCUSSION

A literature search was undertaken and the search strategies are listed in Appendix 5. There are no studies that compare scheduling arrangements between countries and the analysis summarised in Table 5 is the first of its kind. Studies of health and economic outcomes relating to scheduling arrangements are rare. Only one study satisfies the criteria of randomised, control group double-blind experimental design. This study addressed the evaluation of the impact of pharmacist advice giving on the outcomes of self-medication in patients suffering from dyspepsia [16] and showed improvements in quality of life measures for both experimental and control groups with the latter group showing significantly higher scores.

This qualitative research sought answers to the following questions:

**Q1: Can substantial improvement be offered to the Australian scheduling criteria by international models?**

**Q2: Can the current legislation relating to non-prescription schedules be substantially improved with respect to additional risk-based elements?**

The development of the research process shows that these questions are linked and the following discussion and recommendations address them together.

An examination of international models indicates that there is considerable consistency between countries in the essential issues taken into account when considering shifts from ‘prescription only’ to more liberal consumer access. All systems studied use a similar, seemingly logical decision-making process that may be described in three key steps.

### **1. An examination of characteristics of the drug.**

Primary consideration is given to matters of public safety, including questions relating to:

- Toxicity – the potential for the drug to produce adverse effects that are serious, severe and/or frequent
- Therapeutic Index – the margin between therapeutic and unwanted effects
- Interactions – the presence of interactions between other drugs, foods or health conditions that may produce serious or severe adverse effects
- Potential for abuse or dependence
- Misuse – the likelihood that taking the drug incorrectly may produce significant unwanted effects
- Possibility for the development of resistance
- Efficacy
- Risk/benefit ratio.



Drugs that are judged to raise questions regarding their safety are assigned to prescription only status. If a drug is judged to be safe and effective, issues relating to professional practice – diagnosis and management - are taken into account.

## **2. An examination of issues relating to professional practice**

Issues of professional practice relate to the level of professional expertise needed to diagnose, treat and monitor the medical condition for which the drug is designed. Prescription only status is assigned if:

- The symptoms to be treated by self-medication are difficult to diagnose
- Misdiagnosis may lead to inappropriate treatment, failure to treat, or delays in treating and underlying pathology
- Drugs are to be administered by the parenteral route
- Laboratory tests are required to monitor treatment significant adverse effects may arise that require monitoring by a medical professional
- Directions for use are complex and require instruction from a medical professional.

In countries where pharmacy only schedules are available, the ability of the consumer to diagnose, treat and manage with the assistance of a pharmacist is considered.

## **3. Consideration of consumer issues**

If a drug is judged to be a safe, effective and convenient means of self-treatment, and the symptoms to be treated by self-medication are capable of self-management (or, where pharmacy only schedules exist, capable of diagnosis and management with the assistance of the pharmacist) it may be assigned a non-prescription schedule.

Considerations are then given to questions of effective information transfer:

- Can consumers extract key information for effective use from the package label?
- Is information on potential hazards provided?
- Are all contraindications, warnings and precautions described in lay terms?
- Are there clear directions on actions to be taken if the medicine does not have the desired effect or has adverse effects?

The Australian system conforms to the decision-making strategies that operate in similar countries in which the risks and benefits of access to self-medication are dealt with and it is judged that the current decision-making is substantially sound. Notwithstanding this finding, interviews with members of the NDPSC have pointed to some ways in which the Australian process may be improved and the following recommendations address these issues.

### **Recommendation 1:**

That the current system used by the NDPSC be reviewed so that the following issues are taken into account by the Committee in its deliberations: an examination as to the characteristics of the drug, an examination of issues relating to professional practice, and consideration of consumer issues.

The combining of decisions on both drugs and poisons means that members are sometimes asked to make decisions outside their particular range of expertise. The

recommendation of the Galbally report [1] that the two separate committees be formed would be supported. If a separate committee charged with the scheduling of drugs only is to be formed, its composition needs to include an appropriate number of clinicians and practitioners with an understanding of public health issues.

**Recommendation 2:**

That the recommendation 7(a) of the National Competition Review of Drugs, Poisons and Controlled Substances Legislation [1] that the National Drugs and Poisons Schedule Committee be disbanded and replaced with two separate committees – a Medicines Scheduling Committee and a Poisons Scheduling Committee - be supported and moved forward.

As indicated, the Committee's first concerns when considering submissions for a schedule shift relate to issues of safety. If these are satisfied, decisions on the scheduling of drugs emphasise issues of management including the level of expertise needed for diagnosis and oversight and the level of detail required for consumer information. It is therefore important that the Committee is provided with credible and objective scientific and clinical information.

The material presented to the Committee by sponsors of a switch, experts and the Secretariat often lacks sufficient detail to enable members to critique the data presented, e.g. details of what databases were accessed are not provided, so members do not know if the literature search is comprehensive.

**Recommendation 3:**

That the guidelines for the provision of information by sponsors and expert advisers to the Medicines Scheduling Committee be amended to require all submissions to conform to those described in the Cochrane Library Reviewers' handbook [23].

The material presented to the Committee does not always indicate that key stakeholders (e.g. Diabetes Australia, Asthma Foundation etc) have been informed, or that relevant policy (e.g. Quality Use of Medicines) has been addressed. There was a view that the decision-making process is not always as rigorous as desirable (i.e., a formally structured process of working through the guidelines). The New Zealand guidelines [8] was one model suggested as a possible framework for consideration. The ability to engage in dialogue with experts and clinicians would assist the committee members to make decisions in areas where current or new clinical use of a medicine may be controversial.

**Recommendation 4:**

That provision be made within the processes of the Medicines Scheduling Committee to allow the Committee to have direct dialogue with experts and clinicians who provide opinion to the Committee.

It is argued that the NDPSC's current decision-making process, in which jurisdictional members 'present and voting' can effectively veto a decision made by the whole Committee, is seen as adding nothing to the Committee's process of risk

assessment. In addition, it provides an impediment to national consistency of consumer access and product packaging and labelling without conferring significant benefit to industry, consumers or the pharmacy profession. While it is understood that, from time to time, local conditions may require a variation in scheduling, State and Territory legislations allow for local variation where cogent reasons exist for such action. It is therefore recommended that the decisions of the Committee regarding medicines be taken by the whole committee and that the process of allowing an additional vote by jurisdictional members be discontinued.

**Recommendation 5:**

That all Commonwealth, State and Territory governments agree that decisions of the NDPSC (or its equivalent replacement by a Medicines Scheduling Committee) on the scheduling status of medicines shall be made by consensus or, failing consensus, by a two-thirds majority of all members.

The concept of ‘efficacy’ is discussed in the Introduction and it was noted that Australia only requires information on efficacy for drugs that are scheduled for prescription only. When shifts to non-prescription schedules are considered, efficacy does not have to be demonstrated. As submissions for schedule shifts may involve drugs to be administered at different doses or concentrations, or in different combinations than those approved for prescription use, an argument can be mounted that sponsors should be able to demonstrate that the product to be re-scheduled is efficacious in the dose/strength/combination presented. Notwithstanding the additional costs, international best-practice would require the provision of such information.

**Recommendation 6:**

That the NDPSC (or a Medicines Scheduling Committee) consider whether it should be required for sponsors to produce evidence of efficacy of products for which a schedule switch is sought.

**Q3: Can the current *Standards for the Provision of Pharmacist Only and Pharmacy Medicines in Community Pharmacy* be substantially improved with risk-based elements?**

The current *Standards* [24] were developed in 1998 by The University of Sydney and the University of South Australia in an extensive consultation process that included all key stakeholders. They have been subsequently accepted, promulgated and tested in practice across Australia [25]. The outcomes of research that tracked the implementation of the *Standards* indicated that pharmacies were successful in meeting standards that related to Resource Management, Customer Care and Advice, Documentation, Display and Storage and Customer Rights and Needs and successful, at a somewhat lower rate of compliance with standards relating to Indirect Supply of medicines. At the level of individual patient care, pharmacies were able to demonstrate good levels of compliance with protocols relating to symptom-based requests for assistance, but lower rates of compliance with respect to product requests, especially where pharmacists were not directly involved in sales [25]. Further assessment of the *Standards* was undertaken in Section 5.

The research also tested qualitatively the hypothesis that:

**There is no difference in risk profile of Pharmacist Only and Pharmacy Medicines.**

The analysis of assessment factors for Schedules 2, 3 and 4 summarised in Table 1 indicates that there are different risk profiles of drugs in different schedules, however, product characteristics encompassed may be similar. Schedules 2 and 3 with regard to product characteristics in some cases are comparable but in others, are quite different. There are significant distinctions between the schedules with respect to the levels of expertise required to diagnose, manage conditions to be treated with the drug and product characteristics.

In addition, analysis of the placement of drugs within schedules in countries of comparison indicates the following:

- in countries with no ‘pharmacy only’ schedules, drugs are more likely to be held in ‘prescription only’ schedules than in countries with ‘pharmacy only’ schedules
- in countries with a single ‘pharmacy only’ schedule, where the distinction between ‘pharmacist only’ and ‘pharmacy medicines’ is removed, all drugs are treated as if they were in the higher category and consumer access to drugs is significantly more restricted than in countries with two pharmacy schedules.

**Recommendation 7:**

That, from qualitative analysis of Australian and international scheduling arrangements, the current non-prescription scheduling system be maintained with regards to separate Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules to encourage the switch of products from prescription to non-prescription.

The evidence available suggests that there are discernible differences in risk at the level of consumer access. These relate to issues of diagnosis, underlying disease, management and of complexity of information.

Recommendation 5(c) of the *Galbally* Report [1] relates to the examination of Schedules 2 and 3. Without clear indication of the legislation that might pertain to such a merger with respect to storage and access, the following notes on possible outcomes of such an action are necessarily speculative. The following comments are based on information relating to the ‘Pharmacy Only Medicine’(P) schedule of the UK and France, and on the comments from interviews with members of the NDPSC.

If a single ‘pharmacy only’ schedule were available in Australia, it is likely that:

1. There would be a tendency to hold drugs in Schedule 4 or delay schedule shifts to a ‘pharmacy only’ schedule.
2. Many drugs currently available for self-selection under Pharmacy Medicines (S2) would require the involvement of a pharmacist in their sale.
3. The increased demand for involvement of pharmacists in the sale of all pharmacy only medicines may lead to a decrease in the time given to

intervention in the sales of drugs requiring higher levels of intervention for diagnosis and management.

4. Some drugs currently held in Pharmacy Medicines (S2) may be scheduled for general sale, with resultant lower consumer cost.

The conclusions from the above qualitative analysis is that the current Australian system of having pharmacist only and pharmacy medicines schedules :

1. provides Australian consumers with a wider range of medicines for self-medication than in any comparable country.
2. provides for more efficient allocation of scarce resources (pharmacist time) by indicating to consumers and pharmacy assistants which medicines require additional intervention
3. allows for targeted training of pharmacy assistants to enable them to provide advice at an appropriate level and a bridge for consumers who require pharmacist's attention.

## **SECTION 3**

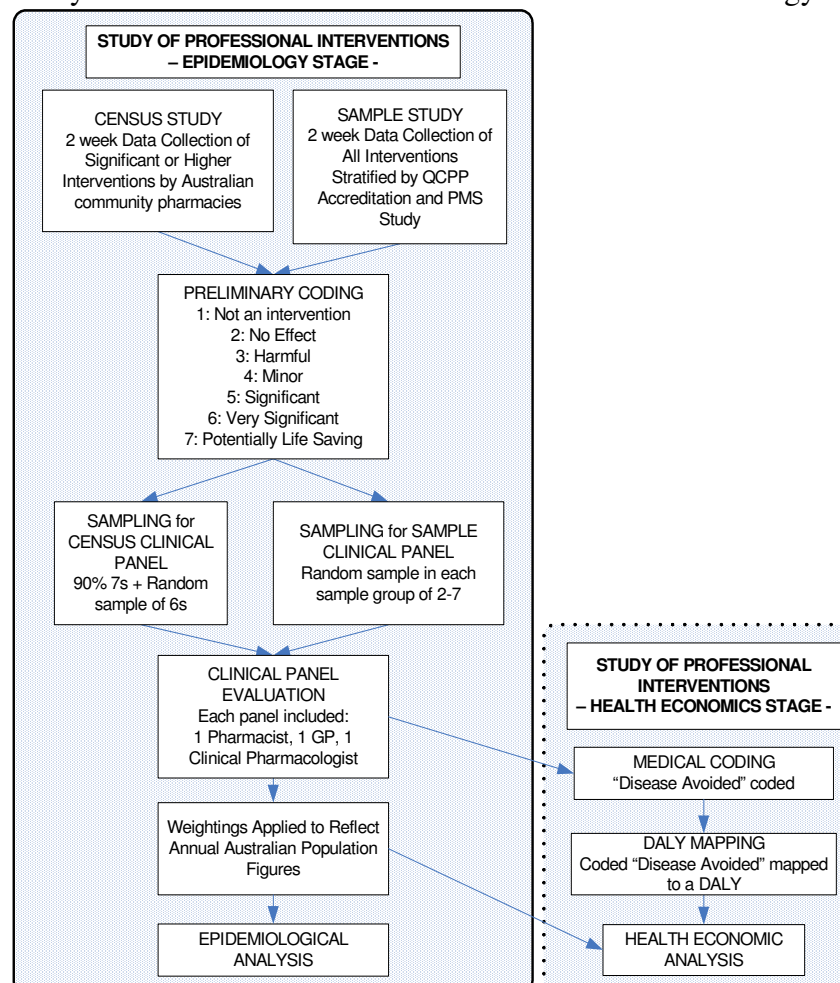
### **STUDY OF PROFESSIONAL INTERVENTIONS – EPIDEMIOLOGY STAGE –**

## 3A EPIDEMIOLOGY STAGE

### 3A.1 OVERVIEW

The Study of Professional Interventions investigated interventions performed in Australian community pharmacies by practising community pharmacists and pharmacy staff aged 16 years and over. The Epidemiology Stage of the Study of Professional Interventions involved two separate field collection studies: a census to determine the incidence rates for ‘highly significant’ yet low incidence interventions relating to non-prescription medicines (Stage 1) and a sample study (Stage 2/3) to collect data on the less significant non-prescription interventions and examine pharmacy performance according to QCPP accreditation. Interventions are defined in 3A.1.1. A sample of data collected from both these studies was presented to a clinical panel for assessment. These results were then weighted to reflect the annual Australian population experience and used for clinical analysis. Sample Study pharmacies were also asked to recruit patients for whom an intervention was performed into a Post-Marketing Surveillance Study. Data from the Epidemiology Stage were also used in the Health Economics Stage of the study (Fig 2).

**Figure 2: Study of Professional Interventions Flowchart of Methodology**



An epidemiological study of this size and nature had not previously been performed, hence considerable time was necessary to conceptualise and test the study methodology. A literature review failed to provide authoritative guidelines for clinical intervention operational definitions or coding frames for Pharmacist Only (S3) and Pharmacy Medicines (S2) interventions, so these needed to be developed empirically by the research team. A pilot study was undertaken which informed the creation of study materials and the research protocol. The final methodology for the epidemiological stage of the project was determined in consultation with the project's expert groups. All study materials and the protocol for the Pilot Study, Census, Sample/PMS studies were approved by the Human Research Ethics Committee of The University of Sydney (Reference Numbers: 6981, 7320).

### **3A.1.1 OPERATIONAL DEFINITIONS OF CLINICAL INTERVENTIONS**

For the purposes of this study, an intervention was defined as:

The promotion of the Quality Use of Medicines by the identification and attempted resolution of an actual or potential drug- or symptom-related problem arising from an over-the-counter request.

Interventions were classified by researchers as 'potentially life-saving', 'very significant', 'significant', 'minor', 'no impact' or 'harmful'. In order to make these definitions more easily understood by pharmacy staff, the definitions were operationally defined in non-scientific language and given a descriptive label on all Census and Sample Study data collection instruments and instructions. Hence, interventions that were 'very significant' were defined as 'interventions [that] potentially averted medical attention or serious harm', those that were 'significant' were defined as 'interventions [that] averted routine medical attention' and those that were 'minor' were defined as 'interventions [that] averted minor harm' (Figure 3: Classification of Interventions).

The definition of an intervention includes:

- interactions where a patient came into a pharmacy requesting a product directly and the pharmacy staff member either discovered that the patient had misdiagnosed symptoms or that the proposed treatment would have been harmful;
- interactions where patients came into a pharmacy requesting treatment for a particular symptom and the pharmacy staff member either discovered that patients had misdiagnosed symptoms or that the proposed treatment would have been harmful;
- interactions where pharmacy staff alerted customers to the possibilities of unintentional abuse or sedative dependence.

It does not include:

- measurement of the value of general counselling that is provided with or without the sale of medicines;



- cases where patients had asked the pharmacy staff member for advice on presenting symptoms and requested a treatment (ie they did not have preconceived ideas about appropriate causes or treatment);
- discussion reinforcing correct consumer self-medication practices;
- incidents involving the prevention of diversion to illicit use.

It is important to note that this study measured ‘interventions’ that pharmacy staff perform on non-prescription medicines.

Thus, instances where the consumer came into the store specifically to obtain pharmacy advice on symptoms without any preconceived notions of their problems or desired treatments were not regarded as interventions. Nonetheless, these staff-patient consultations arguably provide considerable economic and clinical benefit to the community.

Consumers are known to use pharmacies as a first step in ascertaining whether they needed to seek further medical advice. In many cases, the advice provided may have saved the consumer the cost of a doctor’s visit. Aside from the primary health care savings, this general counselling also provides education of the quality use of medicines which can aid to prevent the need for future interventions.

Indeed, several instances were documented in which consumers had purchased medicine elsewhere (for example paracetamol at a supermarket) and visited the pharmacy specifically to ask for advice on use of the medicine without any purchase from that pharmacy. Although advice was provided, this scenario was not considered an intervention for the purposes of this study. Likewise, this study does not measure the value of consumer discussion with pharmacy staff to confirm appropriate self medication (this may or may not include further pharmacy advice) – these type of interactions may also play a part in optimising future consumer medicine use

### **Illicit Use**

While the study recorded interventions of pharmacy staff alerting customers to the possibilities of unintentional abuse or sedative dependence, incidents involving preventing intentional illicit use were not part of the data collection. A comprehensive quantitative study on the incidence of illicit use prevention by pharmacy would involve other factors which should be addressed in-depth by a separate study. For example, data on interventions associated with illicit transactions would need to be collected and differentiated between the following categories:

1. true negatives (proper transactions, correctly interpreted);
2. false negatives (illicit transactions incorrectly interpreted as proper);
3. true positives (illicit transactions, correctly interpreted);
4. false positives (proper transactions, incorrectly interpreted as illicit).

This information was not able to be collected using the current project methodology, hence any reliable value of illicit use prevention due to schedule configuration was unable to be measured by this project.

**Figure 3:** Classification of Interventions According to Potential Outcome

**POTENTIALLY LIFE-SAVING INTERVENTIONS**

- The patient was at substantial risk of death at the time of the event; or
- It is suspected that use, or continued use, of the medication(s) would have resulted in death.

### **VERY SIGNIFICANT INTERVENTIONS** **or Interventions that Potentially Averted *Emergency* Medical Attention or Serious Harm**

- The intervention averted *emergency* medical attention, with or without hospitalisation.
- This included:
  - Prevention of disability, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life
  - Prevention of a birth defect
  - Prevention of serious drug toxicity or major adverse event.

### **SIGNIFICANT INTERVENTIONS** **or Interventions that Averted *Routine* Medical Attention**

- The intervention resulted in an improvement in patient care and/or optimisation of therapy.
- This included:
  - Prevention of a GP visit
  - Decrease in length of hospital stay
  - Decrease in risk of moderate adverse events or symptoms
  - Prevention of exacerbation of the condition.

### **MINOR INTERVENTIONS** **or Interventions that Averted *Minor Symptoms***

- The intervention resulted in a minor improvement in patient care and/or minor optimisation of therapy.
- This included:
  - Improvement in quality of life, mobility or comfort
  - Improvement in symptoms usually left untreated or treated with non-prescription medicines.

### **INTERVENTIONS THAT HAD *NO IMPACT* ON THE PATIENT**

- Interventions that had no real impact on the patient or the patient's wellbeing.

### **INTERVENTIONS THAT WERE *HARMFUL* TO THE PATIENT**

- Interventions that have had, or may have had, a harmful or negative impact on the patient or the patient's wellbeing.

#### **3A.1.2 PILOT STUDY**

A pilot study of the Census/Sample Study was staged in August-September 2003 to test the research instruments and protocol. The data collection instrument was tested in two versions, Form A (Appendix 8) or Form B (Appendix 9), using two convenience samples of 20 community pharmacies in NSW (n=34) and Brisbane (n=6), with 28 pharmacies returning the data collection forms. The reasons for non-participation included sickness, staffing issues, lack of time, renovations or equipment failure, and the pharmacist-in-charge being on leave.

Form A contained numerous categories of tick-boxes for the staff to classify the intervention, in addition to a 'longhand' description, while Form B relied on a longhand description, with minimal categorisation by staff. Pharmacies asked to use Form A were also provided with brief on-site training to explain the data collection procedure and the terms on the form. Pharmacies were asked to send their intervention collection forms back at the end of both recording weeks in reply-paid envelopes.

A total of 303 intervention forms were received for the pilot study (range 0-25 per pharmacy). Ninety Form As were received (29.7% of the 303) and 213 (70.3%) Form Bs were received. Documentation in Week 2 of the recording period was overall lower than Week 1: 125 forms (41.3%) compared with 178 forms (58.7%) in Week 1. However, as one-third of the pilot pharmacies either recorded the same number or more in the second week, it was decided that the Census would still be conducted with a two-week data collection period to maximise the number of forms received and give each pharmacy a chance to participate around any compromising circumstances (e.g. staff on leave, renovations).

Recording fluctuated according to the day of the week (Table 6). Sunday recording was the lowest, presumably due to reduced opening hours, lower sales volume, and/or casual staff in the pharmacy. Monday recording was the lowest of the weekdays. Saturdays and Tuesdays were associated with the highest recording of interventions.

**Table 6: Interventions by Weekday**

Day of the Week	Intervention Forms (n)	Percent of Total
Monday	13	5.3
Tuesday	48	19.5
Wednesday	37	15.0
Thursday	36	14.6
Friday	47	19.1
Saturday	53	21.5
Sunday	12	4.9
Total*	246	100.0

\* Date not recorded: n=57

Qualitative feedback was sought from the participating pharmacies at the conclusion of the survey. Generally, the forms were well received and found to be easy to understand, with Form B being preferred over Form A. The major problem reported by pharmacies was that they were very busy and had insufficient time to record interventions, with only an estimated 50-80% of interventions recorded. However, a number of pharmacies also reported that their staff had increased morale due to the recognition of the benefits of their non-prescription medicine interventions.

Analysis of the pilot study data was a valuable exercise to determine the documentation behaviour of participating pharmacy staff, the disparities in their interpretation of the recording form and their correct usage of the intervention recording form. As a consequence, the recording form and accompanying instructions were refined.

## **3A.2 CENSUS METHODOLOGY**

### **3A.2.1 TIME PERIOD**

A two-week period was chosen for the data collection to aid in the calculation of incidence rates for extrapolation to a national level. This two-week period was staggered over November-December 2003 and March-July 2004 to allow for seasonality analysis and sufficient recruitment.

### **3A.2.2 RECRUITMENT**

A target sample size could not be developed as the incidence rates or non-prescription medicines were unknown (the only similar study on community pharmacy intervention rates [1] was limited to prescription medicines). Instead, to determine incidence rates for 'highly significant' yet low incidence interventions relating to non-prescription medicines, a census was undertaken with all identified community pharmacies with PBS dispensing approval in Australia invited to take part.

#### **Census Pharmacy Contact List**

A complete list of pharmacy contact details was requested from the Health Insurance Commission, however they were unable to provide this information due to current Australian privacy legislation. The contact list used was thus compiled from state pharmacy registration boards, with the exception of the Australian Capital Territory (ACT) and Queensland. The ACT list was sourced from the ACT Health mailing list as recommended by the ACT Pharmacy Board. The Queensland list was compiled from the Telstra Yellow Pages and White Pages from searches of business names

including “chemist” or “pharmacy”, which were then cross-referenced and duplicates deleted. The various state lists were amalgamated into one national contact database. This provided a list of 4981 pharmacies as of October 2003.

### Census Recruitment Contact

National pharmacy print media (*Pharmacy News*) featured an editorial outlining the study and its aims. Notice of the study and an invitation to participate was posted to the AusPharmList email discussion forum. An endorsement letter signed by the respective Presidents from The Pharmacy Guild of Australia and the Pharmaceutical Society of Australia was included with all recruitment correspondence. Recruitment contact was staggered along with the study over October-November 2003 and February-May 2004 to coincide with the study periods. Pharmacies were initially sent a recruitment pack, addressed to the pharmacist-in-charge, consisting of:

- A letter explaining the study (Appendix 10),
- An information sheet (Appendix 11),
- An endorsement letter from the Pharmaceutical Society of Australia and The Pharmacy Guild of Australia (Appendix 12)
- A consent form (Appendix 13).

The pharmacist-in-charge was asked to sign and return the consent form by fax or by mail in order to participate in the study. The response rate to this initial mailing out was low (approximately 5%), so this was followed up by a telephone call. All pharmacies that had not responded to the initial mail-out and telephone call were re-mailed the recruitment pack, with one more follow-up call being made. The time allocated for recruitment was extended in order to increase the possible number of respondents.

### 3A.2.3 PHARMACY PARTICIPATION

Of the (n=4981) pharmacies contacted, the Census recruited n=1574 respondents (31.6%), n=934 (18.8%) of whom completed the study and returned demographic data (participants). Most participating pharmacies came from New South Wales (34.2%) and Queensland (22.2%), with the majority located in metropolitan areas (58.9%). Almost all participating pharmacies were either QCPP-accredited (91.7%), or undergoing accreditation (1.9%). Almost 30% of participating pharmacies reported earning more than \$2m annually. Pharmacies reported having an average of 1.4 (s.d.=0.7) registered pharmacists and 3.4 (s.d.=3) pharmacy assistants. (Tables 7-11)

**Table 7: Pharmacies/State (Census)**

State	No. of Participating Pharmacies	% of Participating Pharmacies
ACT	14	1.5
NSW	319	34.2
NT	6	0.6
QLD	207	22.2
SA	87	9.3
TAS	37	4.0
VIC	181	19.4
WA	83	8.9
Total	934	100.0

**Table 8: Self-reported Pharmacy Location (Census)**

Location	No. of Participating Pharmacies	% of Participating Pharmacies
Metropolitan	551	58.9
Non-metropolitan	336	35.9
Not Reported	47	5.0
Total	934	100.0

**Table 9: Self-reported QCPP Accreditation (Census)**

QCPP Accreditation	No. of Participating Pharmacies	% of Participating Pharmacies
Accredited	856	91.7
Undergoing accreditation	18	1.9
Never applied	8	0.9
Not recorded	52	5.6
Total	934	100.0

**Table 10: Self-reported Annual Turnover (Census)**

Annual Turnover	No. of Participating Pharmacies	% of Participating Pharmacies
Up to \$500,000	36	3.9
\$500,000 - \$700,000	38	4.1
\$700,000 - \$900,000	70	7.5
\$900,000 - \$1.2m	150	16.1
\$1.2m - \$1.5m	117	12.5
\$1.5m - \$2m	101	10.8
Over \$2m	275	29.4
Not recorded	147	15.7
Total	934	100.0

**Table 11: Self-reported Staff numbers (Census)**

Pharmacy Staff Member	Total No. of Staff Reported in Participating Pharmacies	Average Staff Numbers /pharmacy	Std. Deviation of Mean Staff Numbers
Registered Pharmacists	885	1.44	0.77
Pre-registered Graduates	168	1.06	0.49
Pharmacy Assistants	883	3.43	3.02
Other	151	2.14	2.14

The demographic characteristics of the participating pharmacies were compared to the national population when weighting the received data for representativeness (See Section 3A.7 Representativeness of Samples and Weightings).

### 3A.2.4 DATA COLLECTION INSTRUMENTS

Once the consent form was received by the researchers, the respondent pharmacy was mailed a study pack with data collection materials and instructions. Study packs were addressed to the pharmacist-in-charge indicated on the consent form with instructions

to circulate the instruction material to all eligible pharmacy staff (practising community pharmacists and pharmacy staff aged 16 years and over) and to ensure that the data collection forms and reference materials were kept prominent and accessible. To ensure that pharmacy staff were clear on the required data collection procedure, a summary of the instructions (Brief Instructions Appendix 16) were included on the wraparound placeholder cover of the pad of intervention forms. Census pharmacies were sent a study pack consisting of:

- An introductory letter (Appendix 14),
- Two copies of Reference instructions (Appendices 15),
- A Data Collection Pad (printed on white paper, glue-bound with Brief Instructions (Appendix 16) on wrap-around placeholder cover) consisting of 25 data collection forms (Appendix 17),
- A pharmacy demographic form (Appendix 18),
- 1 x reply-paid envelope.

Community pharmacists and pharmacy staff aged 16 years and over were asked to record on pre-printed forms all specified interventions that occurred in their pharmacy during the study period. For the Census, pharmacies were asked to record all significant (“averted routine medical treatment”), highly significant (“averted emergency medical treatment”) or potentially life-saving interventions for non-prescription medicines (refer to Section 3A.5.2 Operational Definitions of Clinical Interventions). While the study was only specifically interested in collecting the highly significant or potentially life-saving interventions, the instructions were expanded to include ‘significant’ interventions so as to ensure that none of the former interventions were missed. Pharmacies were asked not to collect standard patient counselling, extra services (e.g. a blood monitoring service), drug information that was not patient-specific (e.g. a general medical practitioner asking pharmacy staff about non-prescription products) or deliveries of medications to customers.

Pharmacy follow-up was extremely extensive with the research team devoting considerable time and effort to achieve a higher response from the pharmacies concerned. Census pharmacies were requested to mail back the intervention recording forms at the end of the study period in a reply-paid envelope provided. Pharmacies were contacted to ensure they had received the study pack, commenced the data collection and returned their completed intervention forms. Pharmacies that had agreed to participate but did not send back their data collection instruments were contacted and reminded to do so if they had completed the study.

### **3A.3 SAMPLE METHODOLOGY**

#### **3A.3.1 TIME PERIOD**

A two-week period was chosen for the data collection to aid in the calculation of incidence rates for extrapolation to a national level. Each pharmacy was allocated a two-week period with data collection taking place over August-September 2004.

#### **3A.3.2 RECRUITMENT**

The original tender documentation specified testing two groups:

1. Pharmacies that are QCPP-accredited pharmacies and highly compliant with the relevant QCPP standards, and

## 2. Non-QCPP registered pharmacies.

However, the number of non-QCPP registered pharmacies dropped to impractically small numbers by the time that study participants were being recruited. Consequently, with EAG approval, this sample was re-defined as pharmacies that were QCPP *registered* but without a date booked for accreditation. A middle group was also added to comprise the rest of the Australian population of pharmacies so that the Sample Study data could later be extrapolated to all Australian pharmacies. Thus, the three groups of community pharmacies to be tested were:

- Group 1: QCPP-accredited pharmacies that were highly compliant (scored “Excellent” in QCPP testing) with the relevant standards (target n=60),
- Group 2: QCPP-accredited pharmacies that were moderately-to-poorly compliant (scored “Satisfactory” or “Unsatisfactory” in QCPP testing) with the relevant standards or had not been tested (target n=40),
- Group 3: Non-QCPP-accredited pharmacies, registered but with no accreditation date booked (target n=60).

### **Sample Study Pharmacy Contact**

Pharmacies were to be sent recruitment material directly by the researchers. However, because of privacy concerns, the researchers at The University of Sydney were not able to have direct access to the lists of QCPP-registered pharmacies and their accreditation results. The Pharmacy Guild of Australia's Quality Care Pharmacy Support Centre extracted the following number of pharmacies from their QCP Database:

- Group 1: n = 300,
- Group 2: n = 400,
- Group 3: n = 538.

Group 1 and Group 3 were total populations. A sample from Group 2 was randomly selected from the QCP Database. The total population size for Group 2 (n=4019) was too large to all be contacted. 400 pharmacies was judged to be a sufficient number to recruit the target sample size (n=40). Participation in the previous Census was neither a requirement nor reason for exclusion. Sampled pharmacies were sent an initial fax-out consisting of:

- A cover letter from the QCP Division (Appendix 19)
- An introductory letter to the pharmacist-in-charge (Appendix 20)
- An information sheet (Appendix 21)
- A consent form (Appendix 22).

Additional notice of the Sample Study part of the study and an invitation to participate was posted to the AusPharm email discussion forum. An endorsement letter from The Pharmacy Guild of Australia and the Pharmaceutical Society of Australia was included with all recruitment correspondence. Staff at the national office of The Pharmacy Guild of Australia in Canberra undertook the fax-outs and telephone follow-ups. Once the consent release forms were faxed to The University of Sydney, researchers there were able to follow up participants directly. The response rate to the initial fax was poor (approximately 1%), so this was followed by a repeat fax-out of the previous recruitment materials and a telephone follow-up. Pharmacies from Groups 1 and 3 that had signalled interest in the study on the telephone follow-up but had yet to send in consent forms received a further fax-out (Appendix 23) and telephone follow-up. While it was felt by the researchers that target samples which



allowed for drop-outs had not yet been reached, further follow-up was not possible due to time constraints.

### Determination of QCPP accreditation

One issue compounding the difficulties in recruitment was the non-static nature of QCPP accreditation. Lists of consenting pharmacies were regularly forwarded to the QCP Division of The Pharmacy Guild of Australia to be matched according to the sample criteria. In this process, the study found that a number of non-accredited pharmacies (Group 1) became accredited in the time period from recruitment to commencement of the study. Furthermore, because QCPP testing is continuous and frequent, there was shifting between groups classified “Excellent” (identified in this study as High *Standards* compliers) (Group 1) and those classified “Satisfactory/Unsatisfactory” (identified in this study as medium to poor *Standards* compliers) (Group 2), with a number of those who were originally untested (Group 2) being tested and found to be “Excellent” (Group 1). To counter this, sample group classification was reassessed at the commencement of the study (12th August 2004) and this used in the final definition of the sample groups.

### 3A.3.3 PHARMACY PARTICIPATION

Of the (n=1238) pharmacies contacted, 182 pharmacies responded and agreed to participate in the study. Of these 182 respondents, 101 pharmacies actually completed the study and were considered participants (Table 12). Most participating pharmacies came from New South Wales (26.7%) and South Australia (20.8%), with the majority located in metropolitan areas (61.4%). Over 30% of participating pharmacies reported earning more than \$2m annually. Pharmacies reported an average 2.6 (s.d.=9.9) registered pharmacists and 4.8 (s.d.=10.1) pharmacy assistants (Tables 12-16).

**Table 12:** Participating Pharmacies by Sample Group

Sample Group*	No. of Pharmacies in Study	% of Pharmacies in Study	% of Each Sample Group's National Population	% of Total Number of Pharmacies Nationally
Group 1	37	36.63	12.33	0.75
Group 2	42	41.58	1.05	0.86
Group 3	22	21.78	3.72	0.45
Total	101	100.00		2.06

\* \* Group 1 = “Excellent” QCPP Accreditation; Group 2 = “Satisfactory”- “Unsatisfactory” QCPP accreditation and QCPP-accredited but untested; Group 3 = Not QCPP-accredited.

**Table 13:** Pharmacies/State (Sample Study)

State	No. of Participating Pharmacies	% of Participating Pharmacies
NSW	27	26.7
QLD	19	18.8
SA	21	20.8
TAS	7	6.9
VIC	19	18.8
WA	8	7.9
Total	101	100.0

**Table 14: Self-reported Pharmacy Location (Sample Study)**

Location	No. of Participating Pharmacies	% of Participating Pharmacies
Metropolitan	62	61.4
Non-metropolitan	34	33.7
Not recorded	5	5.0
Total	101	100.0

**Table 15: Self-reported Annual Turnover (Sample Study)**

Annual Turnover	No. of Participating Pharmacies	% of Participating Pharmacies
\$500,000 - \$700,000	2	2.0
\$700,000 - \$900,000	6	5.9
\$900,000 - \$1.2m	20	19.8
\$1.2m - \$1.5m	15	14.9
\$1.5m - \$2m	11	10.9
Over \$2m	31	30.7
Not recorded	16	15.8
Total	101	100.0

**Table 16: Self-reported Staff numbers (Sample Study)**

Staff Member	Total No. of Staff Reported in Participating Pharmacies	Average Staff No. /pharmacy	Std. Dev. of Average Staff No.
Registered Pharmacists	98	2.57	9.88
Pre-registered Graduates	10	10.9	30.96
Pharmacy Assistants	96	4.81	10.11
Other	1	99	.

The demographic characteristics of the participating pharmacies were compared to the national population when weighting the received data for representativeness (see Section 3A.5 Representativeness of Samples and Weightings).

### 3A.3.4 DATA COLLECTION INSTRUMENTS

Once the consent form was received by the researchers, the respondent pharmacy was mailed a study pack with data collection materials and instructions. Study packs were addressed to the pharmacist/manager indicated on the consent form with instructions to circulate the instruction material to all eligible pharmacy staff (community pharmacists and pharmacy staff aged 16 years and over) and to ensure that the data collection forms and reference materials were kept prominent and accessible. To ensure that pharmacy staff were clear on the required data collection procedure, a summary of the instructions (Brief Instructions Appendix 26) were included on the wraparound placeholder cover of the pad of intervention forms.

#### Sample Study Pack

All study materials were contained in a brightly coloured project folder so that pharmacy staff members could easily find and store the data collection instruments and instructions. The Sample Study Packs consisted of:

- Introductory Letter (Appendix 24)
- Reference Instructions (Appendix 25)

- 2 x Data Collection Pads (printed on cream paper, glue-bound with Brief Instructions (Appendix 26) on wraparound placeholder cover) consisting of 50 data collection forms (Appendix 27)
- 1 x Pharmacy Demographics Form (Appendix 18)
- 2 x reply-paid envelopes.

In the Sample Study, pharmacies were asked to record *all* of their interventions for non-prescription medicines: this included minor, significant, very significant and potentially life-saving interventions (refer to Section 3A.5.2 for definition). Community pharmacists and pharmacy staff aged 16 years and over were asked to record on pre-printed forms all specified interventions that occurred in their pharmacy during the study period. Pharmacies were asked not to collect standard patient counselling, extra services (e.g. a blood monitoring service), drug information that was not patient-specific (e.g. a GP asking pharmacy staff about a new non-prescription product on the market) or deliveries of medications to customers.

### **Pharmacy Follow-up**

Sample pharmacies were asked to mail back the completed intervention forms at the end of each study week, and were given two reply-paid envelopes. Pharmacies were contacted to ensure they had received the study pack, commenced the data collection and returned each week's forms. Pharmacies that had agreed to participate but did not send back their data collection instruments were contacted and reminded to do so if they had completed the study.

## **3A.4 POST-MARKETING SURVEILLANCE STUDY**

Pharmacies participating in the Sample Study were asked to recruit customers for whom interventions took place (up to a maximum of 25 customers) into a post-marketing surveillance (PMS) study to assess outcomes and satisfaction of the customers post-intervention. In all pharmacy and consumer correspondence this study was referred to as the "Consumer Follow-up Study". Pharmacies were reimbursed \$10 per customer recruited (up to 25 customers) as remuneration for their staff's time.

### **PMS Study Pack**

All study materials were contained in a brightly coloured project folder so that pharmacy staff members could easily find and store the data collection instruments and instructions. Material for the Post-Marketing Surveillance (PMS) Study was included as part of the Sample Study pack mail-out. Each pharmacy received 25 PMS Study packs. The PMS Study Packs consisted of:

- PMS study information sheet (Appendix 28)
- PMS study consent form (Appendix 29)
- PMS cover letter (Appendix 30)
- PMS questionnaire (Appendix 31)
- 1 reply-paid envelope

### **PMS Study Instructions**

When pharmacy staff members performed interventions on a non-prescription medicine as part of the Sample Study, they were asked to recruit the patient into the PMS study. If the patient was interested in participating, the pharmacy staff member

was required to supply an information sheet (Appendix 28) and a consent form (Appendix 29). The consent form was to be completed by the patient in the pharmacy and returned by fax/mail by the pharmacy staff member to the research centre. Consumers who consented to participate in the PMS study were given a PMS Study Pack by the pharmacy. This consisted of a cover letter, a questionnaire and a Non-steroidal envelope. The questionnaire was to be filled out a week after the intervention took place and returned to the research centre using the Non-steroidal envelope. PMS study consent forms and questionnaires were assigned the same identifying number. This number was to be recorded on the corresponding intervention form by the pharmacy staff member so that the research centre could trace the questionnaire back to the originating intervention.

### **PMS Study Consumer Participation**

A total of 4550 questionnaires were distributed amongst the 182 respondent Sample Study pharmacies (25 questionnaires per pharmacy). Of these, 118 questionnaires were distributed by pharmacy staff and a total of 57 were returned to the research centre. Forty-three of these questionnaires could be linked with the corresponding returned intervention forms.

## **3A.5 COMMON METHODOLOGY – CENSUS & SAMPLE STUDY**

### **3A.5.1 DATA ENTRY AND DATABASES**

Once data collection of the interventions was complete, the subsequent processes for the Census and the Sample Study were merged. Upon receipt of the intervention recording forms at the centre, the data were screened for completeness and double-entered for validity checking into a spreadsheet for statistical analysis. A separate database was created for demographic form data, which was then linked via pharmacy number to the intervention forms. Pharmacy reports of the products requested and sold were coded according to brand, product detail, active ingredient, strength, formulation, pack size, schedule and therapeutic group using medicine data from the *MIMs* database. For the purposes of determining the schedule of the intervention, the schedule of the product requested was used.

Eight databases were used for the study, three each for the Census and Sample Study. A demographics database housed self-report data for all respondent pharmacies across 31 variables. A merged database housed data for each intervention form returned included research coding data, and was linked to demographic data across 121 variables. The third database housed clinical panel data, and was linked to the merged database across 119 variables. Two additional databases of pharmacy purchase data were provided by IMS Health.

### **3A.5.2 PRELIMINARY SIGNIFICANCE AND CLINICAL CODING**

A coding frame for determination of clinical significance, intervention characteristics and action taken was created (Fig 4: Clinical Coding Frame for Interventions), with reference to previous limited literature. Initial significance coding was assigned by the research team so as to enable a sample to be taken of the intervention forms for assessment by the clinical panel. Final year pharmacy students who were working in

community pharmacy were employed to assign the initial significance coding. This coding was checked by two pharmacists in the research team by sampling the original significance coding and the two researchers independently coding similar interventions. The initial significance coding was then amended to the agreed final coding. The coding frame that was developed also coded the ‘freehand’ sections of the intervention form (“Describe the problem you have identified” and “Describe the intervention you undertook for this problem”) according to its characteristics and action taken. The coding frame classified the intervention as far as problem identified by the pharmacy staff member, the cause of the problem as recorded by the staff member and whether there were any other considerations that the pharmacy staff member took into account in performing the intervention. The action taken by the staff member was coded taking into account both the ‘freehand’ sections and the “Action Taken” and “Patient Referred” tick boxes on the intervention form (Appendices 17 and 27).

**Figure 4: Clinical Coding Frame for Interventions**

<b>OUTCOME of INTERVENTION (choose ONE)</b>	
NOT an intervention (no problem found and acted upon)	1
Intervention had no impact on the patient	2
Intervention was harmful to the patient’s wellbeing	3
Intervention averted minor symptoms	4
Intervention averted routine medical attention	5
Intervention averted emergency medical attention	6
Intervention was potentially life-saving	7

<b>PROBLEM IDENTIFIED</b>
Incorrect strength
Incorrect duration of therapy
Incorrect dose
Incorrect dosing schedule
Incorrect dosage form or route
Dosing problems, e.g. spacing, food
Inappropriate/suboptimal drug/product choice
Therapeutic duplication
Untreated/undertreated indications
Drug used without indication
Treatment of drug-induced symptoms
Possible abuse or misuse
Adverse drug reaction
Drug-drug interaction
Drug allergy
Drug-condition contraindications/use with caution/warnings
Other
Missing

<b>CAUSE OF THIS PROBLEM</b>
Incorrect strength
Incorrect duration of therapy
Incorrect dose
Incorrect dosing schedule

Incorrect dosage form or route
Dosing problems, e.g. spacing, food
Inappropriate/suboptimal drug/product choice
Therapeutic duplication
Untreated/undertreated indications
Drug used without indication
Treatment of drug-induced symptoms
Possible abuse or misuse
Adverse drug reaction
Drug-drug interaction
Drug allergy
Drug-condition contraindications/use with caution/warnings
Other
No cause/not applicable

<b>OTHER CONSIDERATIONS</b>
Dosing problems, e.g. spacing, food
Inappropriate/suboptimal drug/product choice
Therapeutic duplication
Untreated/undertreated indications
Drug used without indication
Treatment of drug-induced symptoms
Possible abuse or misuse
Adverse drug reaction
Drug-drug interaction
Drug allergy
Drug-condition contraindications/use with caution/warnings
Other
No other considerations/not applicable

<b>ACTION(S) TAKEN</b>
<b>Advice</b>
Review of patient medication history
Contact with patient's GP
Contact with patient (if absent) or caregiver
Original product suggested
Alternative product suggested
Non-drug therapy suggested
<b>Patient Referred</b>
To GP – next scheduled visit
To GP – conditional on response
To GP – immediately
To Accident and Emergency
To other health professional
Other action taken
Missing

## **3A.6 CLINICAL PANEL EVALUATION**

### **3A.6.1 TIME PERIOD**

The clinical panel methodology was developed in consultation with the epidemiology and health economic groups. Relevant literature available was limited and not authoritative, hence considerable time was allocated to method conceptualisation. Once the research groups had finalised a draft clinical panel assessment form, pilot testing of the evaluation procedure occurred during January–April 2004 using intervention forms received from the first round of the Census (Nov/Dec 2003). A total of five clinical panels were conducted, with three Census panels operating from August until September 2004 and two Sample Study panels operating during September–October 2004.

### **3A.6.2 DATA COLLECTION INSTRUMENT**

A clinical panel assessment form (Appendix 32) was developed with reference to past studies [1] and the needs of clinical and health economic analysis. This form assessed the adverse health consequence avoided or created, the probability of the adverse health consequence, the healthcare most needed to treat the adverse health consequence, the likely duration of the adverse health consequence and the significance of the adverse health consequence (for details of assessment procedure, please see **3A.6., “Independent Assessment, Consensus Matching and Group Consensus Assessment”**). The draft assessment form was pilot tested by a panel constituting one hospital pharmacist, one GP and one clinical pharmacologist. Thirty-six intervention forms were assessed in the pilot phase. Subsequent changes to the form included rewording instructions to address feedback from the panel about clarity and ensure consistency in interpretation.

### **3A.6.3 CLINICAL PANEL MEMBERS**

The constitution of the trial clinical panel was considered appropriate, as the group members were able to reach consensus. Consequently, each clinical panel established to assess the intervention data consisted of one community/hospital pharmacist, one general medical practitioner and one clinical pharmacologist recruited for their professional expertise. The constitution of the panel was an attempt to reduce pharmacy bias. This was achieved by only having one pharmacist in each panel of three members, which reduced the ability of that pharmacist to dominate over a consensus position. While a panellist could sit on both a Census clinical panel and a Sample Study clinical panel, panellists did not sit on two Census clinical panels or two Sample Study clinical panels (Table 17). Panellists were aware of the identity of the other panel members.

In order to ensure that panel members complied with the clinical panel procedures in a standardised way, the researchers sought to recruit possible panel members who both had experience with previous research projects and were active practitioners. Relevant professionals with suitable experience were then contacted, the study and its aims explained. The recruitment of panel members was found to be resource and time consuming, as there exists a limited number of suitable panel members with the necessary professional expertise, and many of these were often not able to fulfil the

duties required. The time commitment of 20 hours per panel member per panel assessment was seen as a significant deterrent. As an incentive and as recognition of their professional expertise, panel members were remunerated to the value of \$100/hour. The resultant panels included three panel members who had been involved in a previous similar study on prescription medicines [1], two pharmacists who were involved in university teaching in the area of clinical interventions, two clinical pharmacologists recommended by Prof Paul Seale, Professor of Clinical Pharmacology (Department of Pharmacology, The University of Sydney), and additional panel members who had been involved in previous research projects and were current practitioners.

**Table 17: Clinical Panel Member Participation on Census and Sample Panels**

Panellist	Census			Sample	
	Panel 1	Panel 2	Panel 3	Panel 1	Panel 2
Pharmacist 1				x	
Pharmacist 2	x				
Pharmacist 3					x
Pharmacist 4		x			
Pharmacist 5			x		
General Medical Practitioner 1			x		
General Medical Practitioner 2	x			x	
General Medical Practitioner 3		x			x
Clinical Pharmacologist 1		x			x
Clinical Pharmacologist 2	x			x	
Clinical Pharmacologist 3			x		

### 3A.6.4 CLINICAL PANEL INTERVENTION SELECTION

The initial significance coding (Section 3A.5.2) assigned by the research team was used to sample the intervention forms for the panellists.

#### Census Clinical Panel Selection

Although 100% of interventions that had an initial significance coding of potentially life saving were originally going to be assessed, due to the staggering of the Census over a long period, only 90% were used to adhere to the timeline of the study. For practical reasons, each panel could only assess a maximum number of intervention forms; the balance constituted a random sample of highly significant interventions (11.5%) selected for evaluation. The intervention forms were divided equally between the panels with 20 intervention forms common across a number of panels with a Kappa statistic calculated (Appendix 33). This led to a maximum number of intervention forms that the panel could assess. Thus a total of 310 distinct intervention forms were selected for the Census clinical panel assessment.

#### Sample Panel Selection

A random sample of interventions stratified across all preliminary significance coding, including ‘potentially lifesaving’ to ‘no effect’, and the three arms of the study (Groups 1-3) was selected for evaluation. The intervention forms were divided equally between the panels with 18 intervention forms common across a number of panels with a Kappa statistic calculated (Appendix 33). This led to a maximum number of intervention forms that the panel could assess. Thus a total of 189 distinct intervention forms were selected for the Sample Study clinical panel assessment.



### **3A.6.5 CLINICAL PANEL EVALUATION PROCEDURE**

#### **Training**

Panellists were required to attend a training meeting prior to inclusion in a clinical panel. This involved detailed explanation of the study terminology, operational definitions and procedures for assessing significance of the interventions. Panel members were asked to independently complete a number of practice clinical panel evaluation forms using interventions forms, with the opportunity to ask questions.

#### **Independent Assessment, Consensus Matching and Group Consensus Assessment**

Intervention forms were selected and photocopied, with the relevant sample for each panel being mailed to the individual panellists. The panellists were instructed to assess each intervention form independently. Once assessment had occurred, the completed assessment forms were returned to the researchers for consensus matching. Clinical Panel evaluation data were entered into a spreadsheet and matched for consensus for outcome avoided/created. Consensus was identified if at least two out of the three panellists agreed on the potential outcome avoided. Further consensus was also sought for the healthcare most needed to treat the adverse health consequence. In the case of the probability of the outcome being avoided, the likely duration of the health consequence, and the significance of the adverse health consequence, if disease outcomes matched, the mean was used. Intervention forms with no consensus were put through a separate process of group consensus assessment. When a consensus position could not be achieved through independent assessment, the members of the same clinical panel were invited to a meeting. Intervention forms were discussed amongst the panel members to determine if consensus could be reached. As with the independent assessment, in items where consensus was required (outcome avoided/created, healthcare most needed to treat adverse health consequence), consensus was declared where agreement was reached between at least two of the three panel members. In the other items (probability of the outcome being avoided, the likely duration of the health consequence, and the significance of the adverse health consequence), the mean was used, however, as this was derived in a group situation, this was often a matter of consensus.

### **3A.7 DATA INTEGRATION, REPRESENTATIVENESS OF SAMPLES AND WEIGHTING**

Once results had been finalised from the clinical panel, the panel assessment data was joined in a database with its corresponding intervention form data and matching pharmacy demographic data. Separate databases were created for the Census and Sample Study of this integrated clinical panel data. These data were subsequently weighted for extrapolation to the Australian population for the purposes of clinical and economic analyses. Weighting was applied to the data collected from pharmacies that participated in the Census and Sample Study concerning interventions to avert possible adverse events from Pharmacist Only (S3) or Pharmacy Medicines (S2) sold over a two-week period. The purpose of the weighting was to: (a) correct for some differences in the characteristics of the pharmacies sampled in both studies compared to the known national distribution of these characteristics; and (b) to weight the sample so that the numbers of interventions would reflect that expected in all

Australian pharmacies over a period of one year. The strategy of the studies was to obtain information on the interventions for more severe adverse events (potentially lifesaving or averting emergency medical attention) from the Census, since these are relatively rare, and to obtain information interventions on less serious events (requiring medical attention or mild/moderate not requiring medical attention) from the Sample Study which involved fewer pharmacies since these are relatively common. The Sample Study would also be used for an analysis of the consequences of accreditation, and over-sampled accredited high compliance pharmacies and the un-accredited pharmacies, but included the group in-between.

### 3A.7.1 STATE DISTRIBUTION

The distribution of pharmacies in the Census resembled the national distribution reasonably closely and the differences were not statistically significant ( $p>0.05$ ). However, given the importance of nationally representative data, and the fact that the  $p$  value was close to significant, it was decided to weight data for these minor differences.

**Table 18:** Census: distribution of pharmacies by state compared to national distribution

State	National*		Study participants		Weight (a/b)
	No.	%(a)	No.	%(b)	
ACT	62	1.2	14	1.5	0.830
NSW	1700	34.1	319	34.2	0.999
NT	26	0.5	6	0.6	0.813
QLD	1019	20.5	207	22.2	0.923
SA	388	7.8	87	9.3	0.836
TAS	138	2.8	37	4.0	0.699
VIC	1160	23.3	181	19.4	1.202
WA	488	9.8	83	8.9	1.102
Total	4981	100	934	100	

$$\chi^2_{(7)}=13.7 \text{ } p=0.0561$$

\* Data from CG Berbatis, VB Sunderland, CR Mills and M Bulsara, National Pharmacy Database Project[2].

The distribution of pharmacies in the Sample Study showed some differences from the national distribution, and the differences were statistically significant ( $p<0.001$ ). The data were weighted accordingly to adjust for these differences.

**Table 19:** Sample Study: distribution of pharmacies by state compared to national distribution

State	National*		Study participants		Weight (a/b)
	No.	%(a)	No.	%(b)	
TAS	138	2.8	7	6.9	0.407
NSW	1700	34.7	27	26.7	1.300
QLD	1019	20.8	19	18.8	1.107
SA	388	7.9	21	20.8	0.381
VIC	1160	23.7	19	18.8	1.260
WA	488	10.0	8	7.9	1.259
Total	4893	100	101	100	

$$\chi^2_{(5)}=25 \text{ p}=0.0001$$

There were no Pharmacies randomly selected from NT or ACT in the Sample Study

\* Data from CG Berbatis, VB Sunderland, CR Mills and M Bulsara, National Pharmacy Database Project[2].

### 3A.7.2 PHARMACY SALES TURNOVER

There was a difference in the distribution of pharmacies by sales turnover between the Census and the national data with an under-representation of the medium sized pharmacies (turnover \$1.5-2.0 million) in the Census participants. Weights were calculated as below.

**Table 20:** Census: distribution of pharmacies by sales turnover compared to national distribution

State	National*		Study participants		Weight (a/b)
	No.	%(a)	No.	%(b)	
<\$1.5m	227	47.0	411	52.3	0.889
\$1.5m-\$2m	93	20.0	101	12.8	1.484
over \$2m	159	33.0	275	34.9	0.931
Total <sup>1</sup>	4881	100	787	100	

$$\chi^2_{(2)}=20 \text{ p}=0.00006$$

\* Data from CG Berbatis, VB Sunderland, CR Mills and M Bulsara, National Pharmacy Database Project[2].

<sup>1</sup>- Unreported Turnover data removed.

There were insufficient numbers of pharmacies in the Sample Study to examine or adjust for differences in pharmacy sales turnover

### 3A.7.3 QCPP ACCREDITATION

There was no statistical difference in QCPP accreditation by state in the Census participants and the national data, and this was not adjusted for in the analysis.

**Table 21:** Census: distribution of pharmacy QCPP accreditation by state compared to national figures

State	National*		Study participants	
	No.	%	No.	%
ACT	52	91.0	14	100
NSW	1492	88.0	301	95.9
NT	22	79.0	4	100
QLD	823	86.0	203	97.1
SA	361	93.0	79	98.8
TAS	117	87.0	27	100
VIC	997	86.0	154	96.9
WA	443	91.0	74	98.7
Total	4307		856	100

No difference between the distribution of QCPP accreditation by state

$$\text{Mantel Haenzel } \chi^2_{(1)}= 1.25, \text{ p}=0.2645$$

\* Data obtained from QCPSC

In using the Sample Study to obtain representative data on interventions to pre-empt less severe adverse effects adjustment needs to be made for the over-sampling of accredited high compliance pharmacies and the un-accredited pharmacies (the analysis of interest in the Sample Study), and the under-sampling of the intermediate group.

**Table 22:** Sample Study: distribution of pharmacies by QCCP status compared to national distribution

State	National*		Study participants		Weight (a/b)
	No.	% (a)	No.	% (b)	
Group 1	300	6.1	37	36.6	0.17
Group 2	4019	81.9	42	41.6	1.97
Group 3	591	12.0	22	21.8	0.55
Total	4910	100	101	100	

Group 1: QCCP-accredited "Excellent"

Group 2: QCCP-accredited "Satisfactory", "Unsatisfactory" or untested

Group 3: Non-QCCP-accredited

\* Data obtained from QCPSC .

### 3A.7.4 GEOGRAPHIC ACCESSIBILITY

There was no statistically significant difference in ARIA geographic distribution between pharmacies in the Census and the national distribution, and no adjustment factor was used in the analysis.

**Table 23:** Census: distribution of pharmacies by geographic accessibility compared to national data

Accessibility (ARIA) status	National*		Study participants	
	No.	%	No.	%
Highly Accessible	3998	80.3	727	77.8
Accessible (Group A)	199	4.0	33	3.5
Accessible (Group B)	320	6.4	68	7.3
Moderately Accessible	213	4.3	47	5.0
Remote	182	3.7	49	5.2
Very Remote	69	1.4	10	1.1
Total	4981	100	934	100

$\chi^2_{(5)} = 8.6, p=0.1268$

\* Data from CG Berbatis, VB Sunderland, CR Mills and M Bulsara, National Pharmacy Database Project[2].

There were insufficient numbers of pharmacies in the Sample Study to examine and adjust for differences in accessibility (ARIA) status.

### 3A.7.4 PARTICIPATION

The Census participation rate was 18.8% with variation between the states as shown below. The data for pharmacies by state were inflated by 1/participation rate (as a decimal).

**Table 24:** Census: pharmacy participation rate by state

State	National*	Study participants	Rate %	Weight
ACT	62	14	22.6	4.42
NSW	1700	319	18.8	5.32
NT	26	6	23.1	4.33
QLD	1019	207	20.3	4.93
SA	388	87	22.4	4.46
TAS	138	37	26.8	3.73
VIC	1160	181	15.6	6.41
WA	488	83	17.0	5.88
Total	4981	934	18.8	

\* Data from CG Berbatis, VB Sunderland, CR Mills and M Bulsara, National Pharmacy Database Project[2].

The Sample Study participation rate was 2%, with variation between the states as shown below. The data for pharmacies by state were inflated by 1/participation rate (as a decimal).

**Table 25:** Sample Study: pharmacy participation by state

State	National*	Study participants	Rate %	Weight
TAS	138	7	5.07	19.72
NSW	1700	27	1.59	62.89
QLD	1019	19	1.86	53.76
SA	388	21	5.41	18.48
VIC	1160	19	1.64	60.98
WA	488	8	1.64	60.98
Total	4893	101	2.06	48.54

\* Data from CG Berbatis, VB Sunderland, CR Mills and M Bulsara, National Pharmacy Database Project.[2].

### 3A.7.5 PERIOD

All data in both Census and Sample Study were collected over a two-week period. Interventions were multiplied by 26 to produce an annual estimate.

### 3A.7.6 SUB-SAMPLING FOR PANEL CODING

For logistic reasons, interventions were sampled for expert panel coding. In the Census, which was designed to detect interventions to pre-empt infrequent but serious adverse events, the intention was to panel code all interventions that appeared to be life threatening on preliminary coding, and a sample of those considered to require hospital treatment on preliminary coding. In the Census, 90% of the interventions for life threatening conditions were sent for coding, and 11% of the interventions for conditions requiring hospitalisation. This yielded weight factors of 1.105 for interventions for life threatening conditions and 8.857 for interventions for conditions requiring hospitalisation.

In the Sample Study, which was used for interventions to pre-empt frequent but less serious adverse effects, the intention was to panel code a sample of interventions that were a consequence of adverse effects that would lead to medical attention or to a mild/moderate (not requiring medical attention) on preliminary coding. In the Sample Study, the sampling fraction for coding of around 25% generated weights of 4.403 for interventions for adverse effects that would lead to medical attention, and 4.122 for interventions for mild/moderate conditions (not requiring medical attention) on preliminary coding.

### 3A.7.7 ADJUSTING FOR PHARMACIST ONLY (S3) AND PHARMACY MEDICINES (S2) UNDER-DESIGNATION

In some instances, insufficient information was available on the medication involved in the intervention for the product to be properly coded to a Schedule classification. In the Census, some products were coded as S2/S3 or as S2/US (unscheduled) because there was insufficient information to designate Pharmacist Only (S3) or Pharmacy Medicines (S2). In the Sample Study, some products were coded as UKN (unknown) because there was insufficient information to code them as US (unscheduled medicines), S2, S3, or S4 (prescription medicines).

If the S2/S3, S2/US or UKN are excluded, there would be an under-enumeration of interventions associated with Pharmacist Only (S3) and Pharmacy Medicine (S2) products. The numbers of interventions associated with S2/S3, S2/US and UKN were redistributed back into the data assuming the same distribution scheduled products as occurred for the known coded data. From the adjusted distribution of scheduled products an inflation factor was derived to apply to recorded Pharmacist Only (S3) and Pharmacy Medicines (S2) products associated with interventions to adjust for this under-enumeration. This process was undertaken separately for the Census and Sample Study, and within each severity category, for interventions involving up to two medication products. Individual products associated with interventions that were originally classified as S2/S3, S2/US or UKN were not re-classified, and were ignored in the analyses.

**Table 26:** Census: weights to adjust for Pharmacist Only (S3) and Pharmacy Medicines (S2) under-designation

Schedule and severity	Census weights	
	Product 1	Product 2
S2 Hospitalisation	1.33	2.63
S2 Life threatening	1.51	1.00
S3 Hospitalisation	1.17	2.20
S3 Life threatening	1.18	1.00

**Table 27:** Sample Study: weights to adjust for Pharmacist Only (S3) and Pharmacy Medicines (S2) under-designation

Schedule and severity	Sample Study weights	
	Product 1	Product 2
S2 Mild / moderate	1.35	1.05
S2 Medical attention	1.38	1.00
S3 Mild / moderate	1.35	-*
S3 Medical attention	1.38	-*

\* No S3 for product 2

### 3A.7.8 PROBABILITY OF AN ADVERSE EFFECT

The expert panel assigned a probability of occurrence to each of the possible adverse events that prompted an intervention using a combination of an arithmetic scale (between 0.1-1), a logarithmic (Base 10) scale (below 0.1) and an open-ended scale (Appendix 32). The interventions were also weighted by this probability in some analyses to derive actual cases avoided.

## 3A.8 CALCULATION OF INTERVENTION RATES

For purposes of comparing levels of professional intervention, rates were calculated. All rates were calculated according to the generic formula:

$$\text{Intervention rate} = \frac{\text{Interventions/year}}{\text{Total Purchases/year}}$$

This results in a 'number of interventions per unit' rate.

The only pharmacy purchase data available to the research group was from IMS Health. The data represent purchases in the individual consenting pharmacies. These data have been sourced from pharmaceutical wholesalers (representing over 98% coverage of the Australian market) and companies' direct sales to pharmacies.

Confidence Intervals (CIs) were calculated according to the Poisson method using the conventional 95% level. Values outside these limits could occur by chance in 1 in 20 instances. The upper and lower 95% CIs of the counts of interventions were obtained from Poisson tables (Ciba-Geigy), and the upper and lower 95% CIs of rates were then calculated by division of each by the denominator. 95% CIs that do not overlap indicate statistical significance at  $p < 0.05$ . The 95% Poisson confidence intervals were based on the actual counts of interventions recorded in the census and sample surveys, and pro-rated to provide CIs for the extrapolated annual counts and rates for Australia.

### 3A.8.1 CENSUS INTERVENTION RATES

Numerator values were calculated from weighted clinical panel data, according to the nature of the rate being calculated. The denominator value (annual units) was calculated from IMS Health derived data. Annual wholesale unit data of the

Australian pharmacy non-prescription market were sourced from IMS Health for the year June 2002-May 2003.

**Table 28: IMS Health data**

IMS Unit Data	S2	S3
May-03	5953607	1771682
Apr-03	6012579	1808077
Mar-03	6273788	1710642
Feb-03	4795735	1456053
Jan-03	3881672	1372450
Dec-02	4813635	1697611
Nov-02	5123575	1577193
Oct-02	5432609	1598112
Sep-02	5581544	1730183
Aug-02	6015474	1810297
Jul-02	6713906	1895223
Jun-02	5240402	1616401
Total	65838526	20043924

### 3A.8.2 SAMPLE STUDY INTERVENTION RATES

Out of the 101 pharmacies participating, 84 pharmacies gave their consent for the researchers to access their sales data (non-prescription unit data were sourced from IMS Health for October 2002 - September 2004. These data were used to calculate the denominator in determining intervention rates. The value of the numerator was sourced from unweighted Sample Study data.

### 3A.8.3 HAWTHORNE EFFECT ON INTERVENTION RATES

Since it was anticipated that the results of the study might be questioned with respect to a potential increased pharmacy performance, the research team considered approaches to deal with this issue. The Hawthorne Effect refers to the phenomenon of subjects performing better when under study observation. The research team developed a proposal for testing the presence of a Hawthorne Effect by using pseudo-patient testing during and outside of the study observation period to see if there were significant changes in the results of interventions, however, the proposal was not accepted by the EAG as it was felt that the **magnitude of the effect could be accounted for by sensitivity analyses** (Appendix 34).

There is always a possibility of the results being influenced by a Hawthorne Effect in empirical studies. However, from the review of the data, it appears to be unlikely that this has had any significant effect on the results of this study. It appears that under-reporting is more of a concern than over-reporting by observation of the recording rates and by the qualitative feedback provided by participants. It is important to note that where the term ‘intervention rate’ is stated in this study, what is essentially being analysed is the recording rate of pharmacy staff of the interventions that they perform. Often they may be the same figure if the pharmacy staff record all the interventions that they perform. However, there is the suggestion that pharmacy staff may not be recording all of the interventions performed in their pharmacies. Evidence was provided in the pilot study. In both the pilot and the Sample Study, pharmacies were



asked to record all of their interventions, yet the pilot study recorded a mean of 10.8 interventions over the two-week study period (Section 3A.1.2 Pilot Study), while the Sample Study recorded a mean of 8.8 interventions (Section 3B.1 Census Results). Even with this difference, qualitative interviews with pilot study pharmacies found that most felt that they had only recorded 50-80% of interventions actually performed. Reasons given for this included all staff not being aware of the study, staff members not having enough time to record interventions in busy periods or staff members forgetting to record the intervention. The limited timeframe and sample size of the pilot study allowed for analysis of recording rates by day and week, which suggested there were differences between days and weeks (Section 3A.1.2 Pilot Study).

## 3B EPIDEMIOLOGY STAGE - RESULTS

The Study of Professional Interventions was completed to satisfy Tender Requirements 7.1 and 7.3. The Epidemiology Stage of the Study of Professional Interventions involved two separate field collection studies: a census to determine the incidence rates for ‘highly significant’ yet low incidence interventions relating to non-prescription medicines (Stage 1) and a sample study (Stage 2/3) to collect data on the less significant non-prescription interventions and examine pharmacy performance according to QCPP accreditation. The methodology for the Study of Professional Interventions was developed to assess the current baseline practice of pharmacies in Australia with data collection taking place from November 2003 – September 2004.

### 3B.1 CENSUS

For the Census, pharmacies were asked to collect all significant (“averted routine medical treatment”), very significant (“averted emergency medical treatment”) or potentially life-saving interventions for non-prescription medicines (refer to Section 3A.5.2 Operational Definitions of Clinical Interventions). This was to ensure that all the high significance interventions, namely, interventions that were very significant (“averted emergency medical treatment”) or potentially life-saving interventions were collected.

Of the (n=4981) pharmacies contacted, the Census recruited 1574 respondents, 934 of whom completed the study. A total of 6463 intervention forms were received (range 0-45) from 934 pharmacies with the mean of 6.9 intervention forms received per pharmacy per two-week period. Of the n=6463 interventions forms received, n=4917 were coded as interventions meeting the criteria of the present study.

**Table 29: Intervention Coding (Census)**

Intervention Coding	No. of Intervention Forms Received
NOT an intervention	1484
Intervention	4917
Not enough information	62
Total	6463

About three-quarters of the interventions arose from customers directly requesting a product. About one in ten interventions arose from symptom presentation (Table 30).

**Table 30: Origin of intervention (Census)**

Origin of the Intervention	No. of Intervention Forms Received	% of Intervention Forms Received
Direct Product Request	3743	76.1
Symptom Presentation	544	11.1
Not Recorded	514	10.4
Other	116	2.4
Total	4917	100.0

Of the n=4917 interventions, pharmacists were involved in n=3904 for an average estimate of 6.12 (s.d.=4.1) minutes/intervention. Pharmacy assistants were involved in n=2177 interventions for an average of 4.48 (s.d.=3.5) minutes/intervention. Pharmacist and pharmacy assistant involvement in interventions is not mutually exclusive, as more than one staff member could be involved in any intervention.

**Table 31: Staff involvement in Census-recorded interventions**

Pharmacy staff member	Total reported no. of staff involved in interventions	Avg. mins/ intervention	Std. dev. (mins/ intervention)
Pharmacist	3904	6.12	4.1
Pharmacy Assistant	2177	4.48	3.5

About half of the interventions in the Census were dealt by pharmacists alone with about one in six interventions being dealt by pharmacy assistants alone. The level of referral from assistant to pharmacist can be inferred from the number of cases where both a pharmacist and an assistant was involved (29.5%).

**Table 32: Staff interaction in Census-recorded interventions**

Pharmacy staff member	Total reported no. of staff involved in interventions	% of total interventions
Pharmacist alone	2453	49.9
Assistant alone	726	14.8
Both Pharmacist and Assistant	1451	29.5
Neither Pharmacist nor Assistant*	287	5.8
Total	4917	100.0

\*This includes pre-registration graduates.

**Table 33: Staff Involvement by Schedule in Census-recorded interventions**

Schedule		Frequency	Percent
S2	Pharmacist alone	463	48.3
	Assistant alone	179	18.7
	Both Pharmacist and Assistant	260	27.1
	Neither Pharmacist nor Assistant*	57	5.9
	Total	959	100
S3	Pharmacist alone	232	59.5
	Assistant alone	32	8.2
	Both Pharmacist and Assistant	111	28.5
	Neither Pharmacist nor Assistant*	15	3.8
	Total	390	100

\*This includes pre-registration graduates.

The most common problem identified in Census interventions was 'Inappropriate/suboptimal drug/product choice' (82.5%), with the most likely cause 'Drug-condition contraindications/use with caution/warnings' (40%). 'Therapeutic duplication' (14.8%) and 'Untreated/undertreated indications' (13.4%) were other common causes.

**Table 34: Problem identified for Census interventions (by frequency)**

Problem Identified	Frequency	Percent
Inappropriate/suboptimal drug/product choice	4056	82.5
Untreated/undertreated indications	187	3.8
Incorrect dose	110	2.2
Therapeutic duplication	100	2.0
Treatment of drug-induced symptoms	68	1.4
Incorrect dosing schedule	58	1.2
Drug-drug interaction	58	1.2
Drug-condition contraindications/use with caution/warnings	55	1.1
Incorrect duration of therapy	47	1.0
Adverse drug reaction	45	0.9
Possible abuse or misuse	41	0.8
Other	27	0.5
Dosing problems, e.g. spacing, food	21	0.4
Drug used without indication	11	0.2
Missing	11	0.4
Incorrect dosage form or route	10	0.2
Drug allergy	7	0.1
Incorrect strength	5	0.1
Total	4917	100.0

**Table 35: Cause of Problem for Census interventions (by frequency)**

Cause of this Problem	Frequency	Percent
Drug-condition contraindications/use with caution/warnings	1969	40.0
Therapeutic duplication	726	14.8
Untreated/undertreated indications	659	13.4
Drug-drug interaction	368	7.5
No cause/not applicable	277	5.6
Drug used without indication	238	4.8
Inappropriate/suboptimal drug/product choice	120	2.4
Adverse drug reaction	100	2.0
Incorrect duration of therapy	85	1.7
Drug allergy	78	1.6
Incorrect dose	65	1.3
Other	61	1.2
Possible abuse or misuse	51	1.0
Incorrect dosing schedule	42	0.9
Incorrect dosage form or route	22	0.4
Dosing problems, e.g. spacing, food	18	0.4
Treatment of drug-induced symptoms	13	0.3
Missing	13	0.5
Incorrect strength	12	0.2
Total	4917	100.0

Census interventions were most likely to involve medications belonging to either '11(a) Expectorants, antitussives, mucolytics, decongestants - Respiratory System' or '5(a) Non-steroidal anti-inflammatory agents - Musculoskeletal System' MIMS category. Analgesics ('4(c) Combination simple analgesics – Analgesia', and '4(a) Narcotic analgesics – Analgesia') were next most common, along with '12(a) Antihistamines - Allergic Disorders' (Appendix 34).

**Table 36: Most common medications involved in Census-recorded interventions**

MIMS Category	Recorded Census Frequency	Estimated annual interventions in Australia*
11(a) Expectorants, antitussives, mucolytics, decongestants - Respiratory System	1284	118359
5(a) Non-steroidal anti-inflammatory agents - Musculoskeletal System	763	153083
4(a) Narcotic analgesics - Analgesia	269	10364
4(c) Combination simple analgesics - Analgesia	246	49666
4(b) Simple analgesics and antipyretics - Analgesia	224	37075
12(a) Antihistamines - Allergic Disorders	190	26065
11(c) Bronchodilator aerosols and inhalations - Respiratory System	133	22141
1(a) Hyperacidity, reflux and ulcers - Alimentary System	106	13508
13(b) Topical nasopharyngeal medication - Ear, Nose and Oropharynx	92	4384

\* These are weighted frequencies that were calculated using a systematic weightings procedure which can be found in Data Integration, Representativeness of Samples and Weighting (Section 3A.7).

Once the clinical panels had assessed the interventions, a medical coder who had experience with ICD-09 codes (as this was the code system that was able to be linked to the Mathers report [3]) coded the adverse consequences. This was then weighted to reflect the estimated frequency of annual interventions in Australia (Section 3A.7). The clinical panel assessed probability of the intervention avoiding the adverse effect and this was applied to the estimated frequency of annual interventions in Australia to determine estimated annual cases avoided. The clinical panel also assessed each intervention form for clinical significance. The most common estimated annual cases avoided were asthma, peptic ulcers, hypertension and unspecified adverse effects of drugs (Table 38), which suggests that the high risk groups were patients with those underlying diseases.

**Table 37: Clinical Significance of Census recorded interventions**

Clinical Significance*	Frequency	Percent
Minor	18	5.8
Significant	105	33.9
Very Significant	135	43.5
Potentially Life-Saving	27	8.7
No Effect	25	8.1
Total	310	100

\* Assessed by the clinical panels

**Table 38: Most common adverse health consequences avoided in Census interventions**

ICD-09 Code	Description	Recorded Census frequency	Estimated annual interventions in Australia *	Estimated annual cases avoided †
965.4	Poisoning by aromatic analgesics, not elsewhere classified	46	51103	372
995.2	Unspecified adverse effect of drug, medicinal and biological substance	27	9776	2462
533.9	Peptic ulcer, unspecified as acute or chronic, without mention of haemorrhage	18	17982	4876
239.9	Neoplasms of unspecified nature, site unspecified‡	17	7311	228
493.9	Asthma, unspecified	17	17256	4996
333.99	Other and unspecified extra pyramidal diseases and abnormal movement disorders	15	15136	19
578.9	Haemorrhage of gastrointestinal tract, unspecified	12	4559	197
401.9	Essential hypertension, unspecified	11	10840	2555

\* These are weighted frequencies that were calculated using a systematic weightings procedure which can be found in Data Integration, Representativeness of Samples and Weighting (Section 3A.7).

† Estimated cases avoided = estimated frequency of annual Australian interventions x probability of the adverse health consequence resulting had the intervention not taken place (calculated from a mean of clinical panel members using a combination of an arithmetic scale (between 0.1-1, a logarithmic (Base 10) scale (below 0.1) and an open-ended scale).

‡ These descriptions come directly from the ICD-09. The nature of the ICD-09 classification system results in some of these disease descriptions being general. An example of this set is expanded in the case studies (3B.7.3), please see C147.

## 3B.2 SAMPLE STUDY

In the Sample Study, pharmacies were asked to record *all* of their interventions for non-prescription medicines: this included minor ('interventions that averted minor

harm'), significant ('interventions averted routine medical attention'), very significant ('interventions potentially averted emergency medical attention or serious harm') and potentially life-saving interventions (refer to Section 3A.5.2 for definition) in order to collect data on the less significant (minor – significant) non-prescription interventions and examine pharmacy performance according to QCPP accreditation

A total of n=888 intervention forms were received (range 0-55) from 101 pharmacies with overall mean of 8.8 intervention forms per pharmacy per two-week period. Of the n=888 intervention forms received, n=469 were coded as interventions meeting the criteria of the present study. Of these, most interventions (71.4%) were as the result of a direct product request.

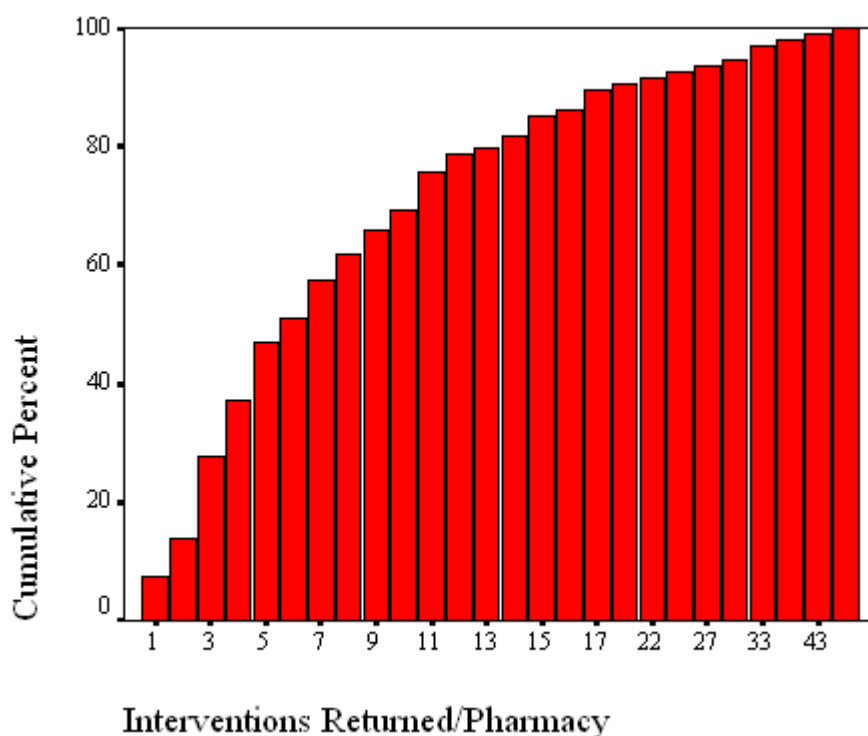
**Table 39: Intervention Coding (Sample Study)**

Intervention Coding	No. of Intervention Forms Received
NOT an intervention	228
Intervention	469
Insufficient information	191
Total	888

**Table 40: Origin of intervention (Sample Study)**

Origin of the Intervention	No. of Intervention Forms Received	% of Intervention Forms Received
Direct Product Request	335	71.4
Symptom Presentation	74	15.8
Other	60	12.8
Total	469	100.0

**Figure 5: Cumulative Percent of Interventions Returned per Pharmacy**



**Table 41:** Interventions recorded per pharmacy by quartiles (Sample Study)

Quartile	Interventions/Pharmacy
25%	3
50%	6
75%	11

75% of pharmacies returned 11 or fewer interventions across the fortnight of collection (Table 41), however, there were a number of pharmacies who performed above this 75% percentile.

Pharmacists were involved in 359 interventions for an average of 4.73 (s.d.=3.7) minutes/intervention. Pharmacy assistants were involved in 212 interventions for an average of 3.65 (s.d.=4.0) minutes/intervention. Pharmacist and pharmacy assistant involvement in interventions is not mutually exclusive, as more than one staff member could be involved in any intervention. The level of referral from assistant to pharmacist can be inferred from the number of cases where both a pharmacist and an assistant were involved (27.3%).

**Table 42:** Staff involvement in Sample Study-recorded interventions

Pharmacy staff member	Total reported no. of staff involved in interventions	Av mins/ intervention	Std. dev. (mins/ intervention)
Pharmacist	359	4.73	3.7
Pharmacy Assistant	212	3.65	4.0

**Table 43:** Staff involvement for Sample Study-recorded interventions

Pharmacy staff member	Total reported no. of staff involved in interventions	% of total interventions
Pharmacist alone	231	49.3
Assistant alone	84	17.9
Both Pharmacist and Assistant	128	27.3
Neither Pharmacist or Assistant*	26	5.5
Total	469	100.0

\*This includes pre-registration graduates.

**Table 44:** Staff involvement by Schedule in Sample Study-recorded interventions

Schedule		Frequency	Percent
S2	Pharmacist alone	163	43.0
	Assistant alone	83	21.9
	Both Pharmacist and Assistant	106	28.0
	Neither Pharmacist or Assistant*	27	7.1
	Total	379	100.0
S3	Pharmacist alone	63	55.3
	Assistant alone	9	7.9
	Both Pharmacist and Assistant	37	32.5
	Neither Pharmacist or Assistant*	5	4.4
	Total	114	100.0

\*This includes pre-registration graduates.



The most common problem identified in Sample Study interventions was 'Inappropriate/suboptimal drug/product choice' (72.3%), most likely caused by 'Drug-condition contraindications/use with caution/warnings' (35.4%). 'Untreated/undertreated indications' (14.9%), and 'Therapeutic duplication' (9.2%) were also common causes.

**Table 45:** Problem identified for Sample Study-recorded interventions (by frequency)

Problem Identified	Frequency	Percent
Inappropriate/suboptimal drug/product choice	339	72.3
Untreated/undertreated indications	31	6.6
Missing	16	3.2
Incorrect duration of therapy	12	2.6
Therapeutic duplication	12	2.6
Treatment of drug-induced symptoms	11	2.3
Drug-condition contraindications/use with caution/warnings	8	1.7
Incorrect dose	7	1.5
Incorrect dosing schedule	5	1.1
Adverse drug reaction	5	1.1
Other	5	1.1
Incorrect dosage form or route	4	0.9
Drug used without indication	4	0.9
Drug-drug interaction	4	0.9
Possible abuse or misuse	3	0.6
Incorrect strength	1	0.2
Dosing problems, e.g. spacing, food	1	0.2
Drug allergy	1	0.2
Total	469	100.0

**Table 46:** Cause of this problem for Sample Study-recorded interventions (by frequency)

Cause of this Problem	Frequency	Percent
Drug-condition contraindications/use with caution/warnings	166	35.4
Untreated/undertreated indications	70	14.9
Therapeutic duplication	43	9.2
No cause/not applicable	42	9
Drug-drug interaction	26	5.5
Drug used without indication	24	5.1
Adverse drug reaction	17	3.6
Drug allergy	17	3.6
Inappropriate/suboptimal drug/product choice	16	3.4
Missing	16	3.6
Incorrect duration of therapy	10	2.1
Other	8	1.7
Incorrect dosing schedule	5	1.1
Incorrect strength	2	0.4
Incorrect dosage form or route	2	0.4
Treatment of drug-induced symptoms	2	0.4
Possible abuse or misuse	2	0.4
Incorrect dose	1	0.2
Total	469	100.0

Sample Study interventions, as with the interventions recorded in the Census, were most likely to involve medications belonging to either '11(a) Expectorants, antitussives, mucolytics, decongestants - Respiratory System' or '5(a) Non-steroidal anti-inflammatory agents - Musculoskeletal System' MIMS category. Analgesics ('4(c) Combination simple analgesics – Analgesia', and '4(a) Narcotic analgesics – Analgesia') were next most common, along with '12(a) Antihistamines - Allergic Disorders' (see Appendix 35).

**Table 47:** Most common medications involved in Sample Study interventions

MIMS Category	Recorded Sample Study frequency	Estimated annual interventions in Australia*
11(a) Expectorants, antitussives, mucolytics, decongestants - Respiratory System	242	1441634
5(a) Non-steroidal anti-inflammatory agents - Musculoskeletal System	73	463184
4(a) Narcotic analgesics - Analgesia	38	181339
4(c) Combination simple analgesics - Analgesia	38	116251
12(a) Antihistamines - Allergic Disorders	31	142129
15(g) Topical antifungals - Skin	21	102470
4(b) Simple analgesics and antipyretics - Analgesia	21	25993
13(b) Topical nasopharyngeal medication - Ear, Nose and Oropharynx	13	106880

\* These are weighted frequencies that were calculated using a systematic weightings procedure which can be found in Data Integration, Representativeness of Samples and Weighting (Section 3A.7).

Once the clinical panels had assessed the intervention form, a medical coder who had experience with ICD-09 codes (as this was the code system that was able to be linked to the Mathers report [3]) coded the adverse consequences. This was then weighted to reflect the estimated frequency of annual interventions in Australia (Section 3A.7). The clinical panel assessed probability of the intervention avoiding the adverse effect and this was applied to the estimated frequency of annual interventions in Australia to determine estimated annual cases avoided. The clinical panel also assessed each intervention form for clinical significance. Please note that the rank for Sample Study interventions varies from the ranked Census interventions, however, the same groups of patients appear to be at risk.

**Table 48: Clinical Significance of Sample Study recorded interventions**

Clinical Significance*	Frequency	Percent
Minor	36	19.0
Significant	56	29.6
Very Significant	36	19.0
Potentially Life-Saving	3	1.6
No Effect	58	30.7
Total	189	100.0

\* Assessed by the clinical panels

**Table 49: Most common adverse health consequences avoided in Sample Study recorded interventions**

ICD-09 Code	Description	Recorded Sample Study frequency	Estimated annual interventions in Australia*	Estimated annual cases avoided †
401.9	Essential hypertension, unspecified	28	124017	13640
995.2	Unspecified adverse effect of drug, medicinal and biological substance	9	71707	21850
372.3	Conjunctivitis, unspecified	6	18500	17883
333.99	Other and unspecified extra pyramidal diseases and abnormal movement disorders	5	2199	44
493.9	Asthma, unspecified	5	15619	1195
998.1	Haemorrhage or haematoma complicating a procedure	4	30151	1508
54.9	Herpes simplex without mention of complication	3	2033	1964

\* These are weighted frequencies that were calculated using a systematic weightings procedure which can be found in Data Integration, Representativeness of Samples and Weighting (Section 3A.7).

† Estimated cases avoided = estimated frequency of annual Australian interventions x probability of the adverse health consequence resulting had the intervention not taken place (calculated from a mean of clinical panel members using a combination of an arithmetic scale (between 0.1-1, a logarithmic (Base 10) scale (below 0.1) and an open-ended scale)

### 3B.3 CENSUS AND SAMPLE STUDY - INTEGRATED RESULTS

Patients were most likely to be aged 13-64 years (73.3% in the Census and 73% in the Sample Study) and female (58.3% in the Census and 59.3% in the Sample Study).

**Table 50: Patient age group by schedule of product (Census)\***

Schedule	Age	Frequency	Percent
S2	0-2 years	36	4.3
	3-12 years	48	5.7
	13-64 years	609	72.2
	65+ years	140	16.6
	Not Recorded	11	1.3
	Total	844	100.0
S3	0-2 years	30	9.5
	3-12 years	20	6.3
	13-64 years	239	75.4
	65+ years	25	7.9
	Not Recorded	3	0.9
	Total	317	100.0

\* There were a number of interventions where a product was not directly requested

**Table 51: Patient age group by schedule of product (Sample Study)\***

Schedule	Age	Frequency	Percent
S2	0-2 years	8	3.1
	3-12 years	15	5.9
	13-64 years	192	75.3
	65+ years	34	13.3
	Total	249	97.6
	Not Recorded	6	2.4
S3	Total	255	100.0
	0-2 years	10	13
	3-12 years	5	6.5
	13-64 years	55	71.4
	65+ years	6	7.8
	Total	76	98.7
	Not Recorded	1	1.3
	Total	77	100.0

\* There were a number of interventions where a product was not directly requested

Hypertension was the most commonly reported pre-existing medical condition, accounting for one in five of the patients in the Census and Sample Study. Asthma, the second most reported known pre-existing condition, accounted for approximately one in ten of the patients in both the Census and the Sample Study. A number of pre-existing conditions featured in greater percentages in the Census where pharmacy staff were asked to record more significant interventions (Table 52).

**Table 52: Medical history of Census and Sample Study patients**

Medical History	Frequency (Census)	Frequency (Sample)	% (Census)	% (Sample)
Hypertension	1276	188	19.7	21.2
Other	892	142	13.8	16.0
Asthma	595	65	9.2	7.3
Heartburn/Ulcer	505	40	7.8	4.5
Arthritis	490	45	7.6	5.1
Heart Disease	474	53	7.3	6.0
Diabetes	325	47	5	5.3
Pregnancy	309	26	4.8	2.9

\* Pre-existing conditions are not mutually exclusive, so row and column totals do not apply

For each of the pre-existing medical conditions, there is a distribution across most levels of clinical significance (Table 53). If ‘Very Significant’ and ‘Potentially Life-Saving’ interventions are grouped with the underlying condition of the patient, interestingly, pregnancy is ranked the highest (n=25), followed by hypertension and heart disease.

**Table 53: Medical history of consumers vs. clinical significance (Census and Sample Study)**

Clinical Significance*	Hypertension	Heart Disease	Heartburn/Ulcer	Diabetes	Arthritis	Asthma	Pregnancy
Minor Significance			1	1	1	1	
Significant	17	8	10	5	8	9	3
Very Significant	14	9	8	3	6	7	20
Pot. Life-Saving	2	2	1		1	3	5
Total†	33	19	20	9	16	20	28

\* Minor (‘interventions that averted minor harm’), significant (‘interventions averted routine medical attention’), very significant (‘interventions potentially averted emergency medical attention or serious harm’) and potentially life-saving interventions (refer to Section 3A.5.2 for full definitions).

† Pre-existing conditions are not mutually exclusive, so row and column totals do not apply.

As expected, pharmacists account for the highest number of interventions when ‘Very Significant’ and ‘Potentially Life-saving’ interventions are grouped (86). Interestingly, about half the pharmacy assistant interventions in the Census data were assessed to be ‘Very Significant’ or ‘Potentially Life-saving’, however, there was a predominance of referral of these higher significance interventions from the pharmacy assistant to the pharmacist.

**Table 54: Pharmacy staff involvement vs. clinical significance (Census clinical panel)**

Clinical Significance*	Pharmacist alone	Assistant alone	Both	Other	Total
Minor Significance	6	4	5	3	18
Significant	51	17	30	7	105
Very Significant	74	20	33	8	135
Pot. Life-Saving	12	4	8	3	27
Total†	143	45	76	21	285

\* Minor (‘interventions that averted minor harm’), significant (‘interventions averted routine medical attention’), very significant (‘interventions potentially averted emergency medical attention or serious harm’) and potentially life-saving interventions (refer to Section 3A.5.2 for full definitions).

† Cases where staff input was not recorded have been omitted from analysis

### 3B.4 INTERVENTION RATES

For purposes of comparing levels of professional intervention, rates were calculated. All rates were calculated according to the generic formula:

$$\text{Intervention rate} = \frac{\text{Interventions/year}}{\text{Total units/year}}$$

This results in a 'number of interventions per unit' rate. The denominator value (annual units) was calculated from IMS Health data (June 2002-May 2003).

**Table 55: IMS Health data**

IMS Unit Data	S2	S3
May-03	5953607	1771682
Apr-03	6012579	1808077
Mar-03	6273788	1710642
Feb-03	4795735	1456053
Jan-03	3881672	1372450
Dec-02	4813635	1697611
Nov-02	5123575	1577193
Oct-02	5432609	1598112
Sep-02	5581544	1730183
Aug-02	6015474	1810297
Jul-02	6713906	1895223
Jun-02	5240402	1616401
Total	65838526	20043924

Numerator values were calculated from weighted clinical panel data, according to the nature of the rate being calculated. Annual levels of professional intervention are required to acquire numerator data before rates can be calculated

#### 3B.4.1 INTERVENTION RATES

Addition of intervention totals across the Census and Sample Study allowed for the calculation of a total rate, and rates for both Pharmacist Only (S3) and Pharmacy Medicines (S2), ranging in significance from 'minor' to 'potentially life-saving'. Interventions that had no effect were not used in the calculation.

The rate of professional intervention that currently occurs in Australia for Pharmacist Only (S3) and Pharmacy Medicines (S2) is 5.66/1000 (Lower 95% CI: 4.79, Upper 95% CI: 6.64). These figures have been obtained using weighted data from the Census (high significance interventions; coded as 6/7) and Sample Study (minor-significant interventions; coded as 4-5) clinical panels to reflect annual figures for the Australian population.

**Table 56:** Total non-prescription medicine intervention rates by significance

Significance of interventions*	Recorded Interventions in Census or Sample	Estimated annual interventions in Australia	Annual Unit Purchases in Australia	Intervention rate per 1000 Units		
				Rate	Lower 95% CIs	Upper 95% CIs
High Significance Intervention	101	101324	85882450	1.18	0.96	1.43
Minor-Significant Intervention	50	384588	85882450	4.48	3.32	5.90
Total Interventions	151	485912	85882450	5.66	4.79	6.64

\* High Significance Interventions = very significant ('interventions potentially averted emergency medical attention or serious harm') and potentially life-saving interventions. Minor-Significant Intervention = minor ('interventions that averted minor harm'), significant ('interventions averted routine medical attention') (refer to Section 3A.5.2 for full definitions). Interventions that had no effect were not used in the above calculation.

The total rate above can be subdivided by schedule with the Pharmacy Medicines (S2) intervention rate being of greater magnitude than the Pharmacist Only (S3) Medicines rate, even though overlapping CIs suggest this difference does not reach statistical significance. Differences of magnitude are also observed in the rates for Pharmacist Only (S3) and Pharmacy Medicines (S2) if subdivided by higher and minor-significant significance (See 3B.4.2 and 3B.4.3).

**Table 57:** Pharmacy Medicines (S2) intervention rate, by significance

Significance of interventions*	Recorded Interventions in Census or Sample	Estimated annual interventions in Australia	Annual Unit Purchases in Australia	Intervention rate per 1000 Units		
				Rate	Lower 95% CIs	Upper 95% CIs
High Significance S2 Interventions	74	73871	65838526	1.12	0.88	1.41
Minor-Significant S2 Interventions	39	305073	65838526	4.63	3.30	6.33
Total S2 Interventions	113	378944	65838526	5.76	4.74	6.92

\* High Significance Interventions = very significant ('interventions potentially averted emergency medical attention or serious harm') and potentially life-saving interventions. Minor-Significant Intervention = minor ('interventions that averted minor harm'), significant ('interventions averted routine medical attention') (refer to Section 3A.5.2 for full definitions). Interventions that had no effect were not used in the above calculation.

**Table 58:** Pharmacist Only (S3) Medicines intervention rates, by significance

Significance of interventions*	Recorded Interventions in Census or Sample	Estimated annual interventions in Australia	Annual Unit Purchases in Australia	Intervention rate per 1000 Units		
				Rate	Lower 95% CIs	Upper 95% CIs
High Significance S3 Intervention	27	27453	20043924	1.37	0.90	1.99
Minor-Significant S3 Intervention	11	79515	20043924	3.97	1.98	7.10
Total S3 Intervention	38	106968	20043924	5.34	3.78	7.33

\* High Significance Interventions = very significant ('interventions potentially averted emergency medical attention or serious harm') and potentially life-saving interventions. Minor-Significant Intervention = Minor ('interventions that averted minor harm'), significant ('interventions averted routine medical attention') (refer to Section 3A.5.2 for full definitions). Interventions that had no effect were not used in the above calculation.

### 3B.4.2 HIGH SIGNIFICANCE INTERVENTIONS

Rates calculated from Census data focused on comparing levels of professional intervention for Pharmacist Only (S3) and Pharmacy Medicines (S2). Only those interventions with clinical significance of ‘Very Significant’ or ‘Potentially Life Saving’, and involving Pharmacist Only (S3) or Pharmacy Medicines (S2) medications were included. There are differences of magnitude in the rates for high significant interventions by schedule. Pharmacist Only (S3) Medicines has reported a rate of 1.37 interventions per thousand units, and Pharmacy Medicines (S2), 1.12 per thousand.

**Table 59:** Comparison of high significance interventions by schedule

Significance of interventions*	Recorded Interventions in Census or Sample	Estimated annual interventions in Australia	Annual Unit Purchases in Australia	Intervention rate per 1000 Units		
				Rate	Lower 95% CIs	Upper 95% CIs
High Significance S2 Interventions	74	73871	65838526	1.12	0.88	1.41
High Significance S3 Interventions	27	27453	20043924	1.37	0.90	1.99
Total High Significance	101	101324	85882450	1.18	0.96	1.43

\* High Significance Interventions = very significant (‘interventions potentially averted emergency medical attention or serious harm’) and potentially life-saving interventions (refer to Section 3A.5.2 for full definitions). Interventions that had no effect were not used in the above calculation.

### 3B.4.3 MINOR-SIGNIFICANT INTERVENTIONS

Rates calculated from Sample Study data focused on comparing levels of professional intervention for Pharmacist Only (S3) and Pharmacy Medicines (S2) products. Only those interventions with clinical significance of ‘Minor’ or ‘Significant’, and involving Pharmacist Only (S3) and Pharmacy Medicines (S2) medications were included.

**Table 60:** Comparison of Minor-Significant Interventions by Schedule

Significance of interventions*	Recorded Interventions in Census or Sample	Estimated annual interventions in Australia	Annual Unit Purchases in Australia	Intervention rate per 1000 Units		
				Rate	Lower 95% CIs	Upper 95% CIs
Minor-Significant S2 Interventions	39	305073	65838526	4.63	3.30	6.33
Minor-Significant S3 Interventions	11	79515	20043924	3.97	1.98	7.10
Total Minor-Significant	50	384588	85882450	4.48	3.32	5.90

\* Minor-Significant Intervention = Minor (‘interventions that averted minor harm’) or significant (‘interventions averted routine medical attention’) (refer to Section 3A.5.2 for full definitions). Interventions that had no effect were not used in the above calculation.



### 3B.4.4 INTERVENTION RATE BY QCPP GROUP

Purchase data (units/fortnight) were made available for 84 of the 101 participating pharmacies from the Sample Study, allowing for a comparison of intervention rates by QCPP group. The numbers of interventions were taken from researcher-coded intervention data (n=469). Thus this rate was calculated in a slightly different form from that of the clinical panel data, the major difference being that it did not exclude interventions with no clinical effect.

**Table 61:** Total Interventions recorded and intervention rates by QCPP group and schedule

Group-Schedule*	Total Interv. recorded†	Interv/ fortnight	Units purchased/ fortnight	Units Purchased	Rate	Intervention rate per 1000 Units		
						Rate	Lower 95% CIs	Upper 95% CIs
Group 1 (S2)	91	2.46	337.07	12472	0.0073	7.30	5.87	8.96
Group 1 (S3)	30	0.81	61.1	2261	0.0133	13.27	8.95	18.94
Group 1 (Total)	121	3.27	398.17	14732	0.0082	8.21	6.82	9.81
Group 2 (S2)	118	2.81	384.79	16161	0.0073	7.30	6.04	8.74
Group 2 (S3)	25	0.6	63.67	2674	0.0093	9.35	6.05	13.80
Group 2 (Total)	143	3.4	448.46	18835	0.0076	7.59	6.40	8.94
Group 3 (S2)	46	2.09	334.71	7364	0.0062	6.25	4.57	8.33
Group 3 (S3)	22	1	55.42	1219	0.018	18.04	11.31	27.32
Group 3 (Total)	68	3.09	390.13	8583	0.0079	7.92	6.15	10.04

\* Group 1 = 'Excellent' QCPP Accreditation (n=37); Group 2 = 'Satisfactory' - 'Unsatisfactory' QCPP accreditation and QCPP-accredited but untested (n=42); Group 3 = Not QCPP-accredited (n=22).

† This total includes only interventions where there was an S2 or S3 product requested and does not include interventions where no product was requested or could be determined.

The table above provides the rate for Pharmacist Only (S3) and Pharmacy Medicines (S2) across the three study groups. The rates (per thousand) vary from 3.83 to 18.04. This large variation may be due to a number of factors, including the availability of only purchase data not sales data or inherent variability in the way that pharmacies practice. The lack of any significant differences between intervention rates could represent a beta error resulting from insufficient statistical power.

### 3B.4.5 CONSEQUENCES OF AMALGAMATION

The following calculations were performed to determine the effects of amalgamating the two schedules. The assumptions used are discussed in Section 1.3 (Assumptions of an Amalgamated Schedule).

#### Total Model

**Table 62:** Total intervention rates by schedule

Schedule	Rate	Rate/1000
S2	0.0058	5.8
S3	0.0053	5.3

If Pharmacist Only (S3) Medicines were to move to a Pharmacy Medicines (S2) type schedule, Pharmacist Only (S3) interventions would be subject to an increased rate. This factor would be the ratio:

$$S2rate:S3rate=0.0058/0.0053=1.08$$

Thus, when this factor is applied to the 106968 Pharmacist Only (S3) Medicines interventions, the result is 115366, or an additional 8398 interventions. Conversely, if Pharmacy Medicines (S2) were to move to a Pharmacist Only (S3) Medicines type schedule, Pharmacy Medicines (S2) interventions would be subject to a reduced rate. This factor would be the ratio:

$$S3rate:S2rate=0.0053/0.0058=0.93$$

Thus, when this factor is applied to the 378944 Pharmacy Medicines (S2) interventions, the result is 351359, or 27585 fewer interventions.

### High Significance Model

**Table 63:** High significance intervention rates by schedule

Schedule	Rate	Rate/1000
S2	0.0011	1.12
S3	0.0014	1.37

If Pharmacist Only (S3) Medicines were to move to a Pharmacy Medicines (S2) type schedule, Pharmacist Only (S3) Medicines interventions may be subject to a reduced rate. This factor would be the ratio:

$$S2rate:S3rate=0.0011/0.0014=0.82$$

Thus, when this factor is applied to the 27453 high significance Pharmacist Only (S3) Medicines interventions, the result is 22489, or 4964 fewer high significance interventions. Conversely, if Pharmacy Medicines (S2) were to move to a Pharmacist Only (S3) Medicines type schedule, Pharmacy Medicines (S2) interventions may be subject to an increased rate. This factor would be the ratio:

$$S3rate:S2rate=0.0014/0.0011=1.22$$

Thus, when this factor is applied to the 73871 high significance Pharmacy Medicines (S2) interventions, the result is 90175, or an additional 16304 high significance interventions.

### Minor-Significant Model

**Table 64:** Minor-significant intervention rates by schedule

Schedule	Rate	Rate/1000
S2	0.0046	4.63
S3	0.0040	3.97

If Pharmacist Only (S3) Medicines were to move to a Pharmacy Medicines (S2) type schedule, Pharmacist Only (S3) Medicines interventions may be subject to an increased rate. This factor would be the ratio:

$$S2rate:S3rate = 0.0046/0.0040 = 1.17$$

Thus, when this factor is applied to the 79515 minor-significant Pharmacist Only (S3) Medicines interventions, the result is 92877, or an additional 13362 minor-significant interventions. Conversely, if Pharmacy Medicines (S2) were to move to a Pharmacist Only (S3) Medicines type schedule, Pharmacy Medicines (S2) interventions may be subject to a reduced rate. This factor would be the ratio:

$$S3rate:S2rate = 0.0040/0.0046 = 0.86$$

Thus, when this factor is applied to the 305073 minor-significant Pharmacy Medicines (S2) interventions, the result is 261184, or 43889 fewer minor-significant interventions.

### 3B.5 EVALUATION OF SOCIAL AND HEALTH IMPACTS

The weighted frequencies were adjusted by applying the probabilities from the individual probabilities assigned by the clinical panel to each specific intervention under each code.

The main health impact appears to be in avoiding urgent GP visits, followed by avoidance of regular GP visits and accident and emergency treatment. The additional impact in the hospital system appears to be avoiding the health impacts of using a standard ward in hospital followed by a number of patients avoiding intensive care.

**Table 65:** Healthcare avoided from total interventions (Census and Sample Study integrated)

Healthcare	Recorded study frequency	% of Healthcare reported	Estimated annual interventions in Australia *	Estimated annual cases avoided †
Intensive care in hospital	15	3.69	13668	76
Standard ward in hospital	21	5.17	13134	1161
Accident and Emergency	140	34.48	172584	30808
Urgent GP	122	30.05	229995	84650
Next regular GP	57	14.04	133837	35783
Self-care	36	8.87	39135	6074
Other	15	3.69	55431	13106
Total	406	100	657784	171658
Not reported	93		149926	5806
<b>TOTAL</b>	<b>499</b>		<b>807710</b>	<b>177464</b>

\* These are weighted frequencies that were calculated using a systematic weightings procedure, which can be found in Data Integration, Representativeness of Samples and Weighting (Section 3A.7).

† Estimated cases avoided = estimated freq of annual Australian interventions x probability of the adverse health consequence resulting had the intervention not taken place (calculated from a mean of clinical panel members using a combination of an arithmetic scale (between 0.1-1, a logarithmic (Base 10) scale (below 0.1) and an open-ended scale).

The social effects that result from patients avoiding the above forms of healthcare were not investigated in depth as part of this study, but one would obviously expect that there would be a social impact on patients and their families associated with admittance to accident and emergency units or intensive care in hospitals. Even the referral of a patient for urgent GP consultation may be seen as detrimental in social and behavioural terms.

### 3B.6 POST-MARKETING SURVEILLANCE RESULTS

Pharmacy staff advice was reportedly well accepted by most consumers (90.3% in the Census and 86.8% in the Sample Study). A number of consumers (3.9% in the Census and 6.2% in the Sample Study) were reported to have rejected the advice (Table 66).

**Table 66:** Patient response for Census and Sample Study.

Patient Response	Frequency (Census)	Percent (Census)	Frequency (Sample)	Percent (Sample)
Accepted Advice	4441	90.3	407	86.8
Rejected Advice	194	3.9	29	6.2
Unknown	99	2.0	33	7.0
Missing	183	3.8	0	0
Total	4917	100.0	469	100.0

4550 PMS Questionnaire forms were distributed to the 182 respondent pharmacies (pharmacies that agreed to participate in the study). Of these, 118 questionnaires were distributed by pharmacy staff in 41 pharmacies, 57 (48.3%) consumer follow-up questionnaires were returned to the research centre and 43 could be linked with the corresponding intervention forms. Humanistic outcomes were measured by the patient's perceived resolution of the problem and satisfaction with the advice received in the pharmacy. The outcome of the problem was either not known or missing in six cases. Twenty-one of the remaining 51 patients (41.2%) reported partial resolution of the problem, while 29 reported complete resolution (56.9%). One patient reported that her problem had been 'not at all resolved', but commented that she had a long-standing problem with back pain. Twelve of the 57 respondents (21.1%) used further medical services within a week of visiting their pharmacy, upon recommendation by pharmacy staff. There were no cases of pharmacy staff making an urgent referral that was subsequently ignored by the patient. This suggests the integrity with which pharmacy staff are viewed by the general public. Supporting this is the high level of satisfaction with the pharmacy advice that was reported by these patients.

**Table 67:** Humanistic outcomes of the intervention

Resolution	Very Satisfied	Satisfied	Not at all Satisfied	Missing	Total
Complete	27	2	0	0	29
Partial	18	3	0	0	21
Missing	3	3	0	1	6
Total	48	8	0	1	57

Many positive comments were volunteered about respect for their pharmacists and assistants. For example: "Have always received excellent advice from local

pharmacy”; “I find the staff at the pharmacy very friendly and helpful and the advice very practical”; “The pharmacist was dealing with me very well and understood what situation I was in. He was a great help”.

### **3B.7 CASE STUDIES FROM CENSUS AND SAMPLE STUDY**

A number of case studies have been included to illustrate the range of intervention types and levels of significance recorded in the Census and Sample Study.

#### **3B.7.1 EXAMPLES OF SIGNIFICANCE RATING**

The following cases studies illustrate the different levels of significance attached to interventions by the clinical panels.

##### **Potentially Life-Saving Interventions**

C3796: An adult male requested Product A (loratadine) from a pharmacist. On questioning, the pharmacist discovered that the patient had a severe allergy to wasps and was stung an hour ago. The pharmacist also noted that the patient’s face had severe swelling and he had breathing difficulties. The pharmacist realised that stronger treatment than loratadine was required, administered 2 x 25mg tablets of promethazine hydrochloride and had his wife drive him to hospital immediately. The clinical panel felt that there was a 100% chance that anaphylaxis was prevented, which was life-saving.

C1828: An adult female requested cough and cold medication for a cold. On questioning, the pharmacist discovered that the patient had extreme conditions including photophobia, stiff neck and could not touch her chest, and had an all-round bad “flu” feeling. The pharmacist explained that the symptoms could be serious and she needed to see the doctor immediately. The pharmacist contacted the patient’s doctor but the surgery was fully booked, and subsequently arranged for her friend to take her to a doctor. The patient eventually returned to inform the pharmacist that she was diagnosed with meningitis and had been prescribed antibiotics. The clinical panel felt there was a 40% chance that the intervention prevented permanent harm and was potentially life-saving.

C914: A male patient adult patient came into the pharmacy asking for a packet of Product B (promethazine hydrochloride) tablets. The pharmacist assistant, on questioning, asked some questions and found out that the patient had been vomiting blood. The assistant referred the patient to the pharmacist, who contacted the patient’s doctor and recommended an immediate visit. The patient accepted the recommendation. The clinical panel felt there was a 60% chance that this prevented the ulcer from going untreated with the result that it could be potentially fatal. Most likely healthcare needed to treat this was Accident and Emergency, or secondly, a standard ward in hospital.

C1070: A mother requested Product E (aspirin) for her male child under 12 years. The child had chicken pox and paracetamol was not helping. The pharmacy assistant advised that aspirin was not recommended for use in children and suggested using Product F (ibuprofen) instead. The clinical panel thought there was a 0.1% chance that the potentially fatal Reye’s Syndrome was avoided which was potentially fatal, along with permanent damage and intensive care in hospital.

C1111: A pregnant woman asked the pharmacy assistant for Cold and Flu Product G (containing pseudoephedrine). She was asked if she had any blood pressure problems or any medical conditions, she replied that she was four months' pregnant. She was unaware that she was not meant to be taking cold and flu preps through pregnancy. The assistant recommended paracetamol for the aches/pains. The clinical panel felt that there was a 1% chance that this intervention prevented hypertension in pregnancy, which if eventuated, could be potentially life threatening.

### **Very Significant Interventions (“Averted Emergency Treatment”)**

C29: An adult female requested both Product H (paracetamol/codeine) and Product I (paracetamol) and was informed that taking both medications simultaneously could result in a possible paracetamol overdose. She had been unaware that both medications contained paracetamol and that the maximum dosage was eight tablets combined in 24 hours. The clinical panel felt that there was 0.5% chance that the patient would have suffered a very significant paracetamol overdose. The healthcare that would have been required was treatment at Accident and Emergency, or secondly, intensive care in hospital.

C260: An adult male with a history of heart disease requested Product J (ibuprofen) for treatment of his gout from a pharmacist as this was the product that a friend recommended. The pharmacist discovered that the patient was currently taking warfarin sodium, and so highlighted the contraindication and recommended a paracetamol/codeine combination instead. A review of the patient's medications subsequently took place, with the pharmacist giving advice on appropriate usage of other medications that the patient had at home. The clinical panel felt that there was a 1% chance that a gastrointestinal bleed was avoided, with Accident and Emergency, or secondly, intensive care in hospital being the most likely treatments that would have been needed

### **Significant Interventions (“Averted Routine Medical Treatment”)**

S393: An adult female requested Product O (ranitidine hydrochloride). On questioning, the pharmacist discovered that the patient had recently returned from Thailand. The symptoms included stomach cramps, diarrhoea and vomiting and were reoccurring. The pharmacist suggested that the patient may have contracted giardia and advised on a visit to the doctor. The clinical panel felt that there was a 40% chance that the patient avoided further symptoms of gastroenteritis. The most likely treatment would have been an urgent GP visit.

C4905: An adult female requested Product P (sodium citrotartrate). On questioning, the pharmacy assistant discovered that the patient had urinary tract symptoms for a long time. The pharmacy assistant advised that the sodium citrotartrate was not an appropriate product for a urinary tract infection and that the patient needed to see a doctor immediately. The clinical panel felt that there was 30% chance that a prolonged urinary tract infection was avoided by the intervention. The most likely treatment would have been an urgent GP visit.

### **Minor Interventions (“Averted Minor Harm”)**

S406: An adult Female requested Product K (codeine/ibuprofen) and Product L (codeine phosphate/paracetamol/pseudoephedrine hydrochloride) from a pharmacist. The pharmacist informed the patient that they both contain codeine and are not to be taken at the same time. The clinical panel felt that there was a 70% chance that the

pharmacist prevented the patient from suffering constipation. The clinical panel felt that the most likely healthcare needed to treat this would have been a regular GP visit.

S409: An adult female requested Product M (cetirizine hydrochloride). On questioning, the pharmacist discovered that this product had not been working effectively and that the patient was a hay fever sufferer who needed treatment daily. The pharmacist recommended Product N (fluticasone propionate) instead as a better treatment for daily use. The clinical panel felt that there was a 97% chance that the continuation of the symptoms of allergic rhinitis were avoided, with a regular GP visit being the most likely level of health care avoided.

### **3B.7.2 EXAMPLES OF DRUG-CONDITION CONTRAINDICATIONS**

The following case studies are examples of interventions involving common drug-condition contraindications

#### **Patient with pre-existing hypertension and heart disease**

S31: An adult female requested a cold and flu mixture containing pseudoephedrine from a pharmacy assistant, who checked for pre-existing conditions and medications. On discovering that the patient suffered from hypertension and heart disease and was taking blood pressure medication, the case was referred to the pharmacist, who recommended a mixture without pseudoephedrine. The clinical panel felt that there was a 10% chance that the avoided outcome was a hypertensive crisis, with Accident and Emergency being the most likely treatment that would have been needed, had there been no intervention.

#### **Patient with pre-existing asthma**

S11: An adult male came into the pharmacy requesting a suspension for fever and pain containing ibuprofen. The pharmacist knew that the patient was asthmatic and taking several medications to control the symptoms, and recommended that he take a paracetamol mixture instead. The clinical panel found that there was a 6% chance that the intervention avoided exacerbating the patient's asthma's symptoms, with a visit to Accident and Emergency being the most likely level of health care needed if the intervention had not taken place.

### **3B.7.3 EXAMPLES OF UNTREATED/UNDERTREATED INDICATIONS**

The following case studies are examples of interventions involving untreated/undertreated indications.

C147: An adult male asked for Product AB (combination gel) for a sore on his lip that was not healing. The pharmacist examined it and felt that it needed to be seen by a doctor immediately, rather than being treated with an OTC gel. No product was sold. The patient returned to inform the pharmacist that the sore was cancerous. The clinical panel felt that there was a 100% chance the pharmacist prevented the cancer from worsening.

C2154: Son of the patient, a 70-year-old female, asked for Product X (paracetamol and codeine). A pre-registration graduate questioned him and found out that the patient had a history of heart disease and hypertension and was prescribed anti-hypertensive medication and warfarin. She had had a fall the day before and had severe pain in her leg and could not walk. Her son had given her six Product Y

(paracetamol) tablets in four hours, with no effect. The pre-registration graduate explained to the son that it may be very serious. The pre-registration graduate also explained that she should only be given one to two paracetamol tablets every four hours with a maximum of eight per day. If they couldn't find a doctor immediately, the son should call an ambulance. The patient accepted the advice. The clinical panel felt that there was a 10% chance that the intervention was potentially life-saving.

C253: An adult woman requested Product Z (ibuprofen). She was asked by the pharmacist about its intended use, and reported that it was to treat pain radiating down her left arm. The pharmacist thought it could be a possible coronary incident and referred to the doctor immediately. The Clinical Panel believed that there was a 60% chance that an acute coronary syndrome was avoided, which would have involved Accident and Emergency care and a Coronary Care unit.



### 3C EPIDEMIOLOGY STAGE - DISCUSSION

No other studies of a similar nature were found in the published or grey literature. It appears that decisions relating to the promulgation of various scheduling arrangements for non-prescription medications internationally are made on grounds other than on research data. The lack of a previous conceptual and/or theoretical approach presented a major challenge to the research team. The overview of the research, as outlined in Figure 2 therefore represents an innovative and possibly a seminal approach to future international studies.

An issue which created a major obstacle was that of pharmacy recruitment. Both in the Census and Sample Study, extensive efforts and resources had to be made available to recruit community pharmacists. The reasons for this reluctance to participate in the study must inevitably be multi-factorial. Community pharmacists and their staff serve the community in a professional manner and simultaneously operate commercially in a retail environment. By their nature, they are not predisposed to document activities unless it is a by-product of their normal activities. In addition, there a number of research projects being undertaken in community pharmacy, which may be excessively impinging on day-to-day activities of community pharmacists and their staff. It is surprising that a study of this type, despite the major efforts of the researchers and pharmacy professional organisations, and which could affect the very professional and commercial future of the profession of pharmacy, did not attract more participation.

Nevertheless, the sample sizes of about 19% (934) of the total population of approximately 4900 for the Census and 101 pharmacies for the Sample Study that were achieved led to the conclusion that this study is the largest in Australian community pharmacy research, and possibly internationally, that has documented clinical interventions in the area of non-prescription medicines. Furthermore, the samples were broadly representative on a number of factors and were adjusted by weighting where this was not the case. It is also apparent that if clinical interventions made by community pharmacy need to be documented in a longitudinal manner, an optimal system of documenting this process needs to be developed, trialled, evaluated and implemented.

#### **Recommendation 8:**

That a national system for tracking clinical interventions on Pharmacist Only (S3) and Pharmacy Medicines (S2) be instituted as part of a quality assurance and improvement system. The system should include the ability to report on individual products and patient characteristics.

This system should provide data down to the product level, and should meet a number of requirements so that the information generated could be utilised by a number of organisations, including government, statutory bodies, NDPSC, professional organisations, educators, pharmaceutical manufacturers and community pharmacy. Clearly such a system would report on 'at-risk' patients and produce risk levels for

active ingredients and branded products, thus directly addressing the conceptual approach suggested by the Galbally report. The system would also be used to track switched products from prescription to Pharmacist Only (S3) and Pharmacist Only (S3) to Pharmacy Medicines (S2).

**Recommendation 9:**

That a post-switching (from prescription to Pharmacist Only (S3) Medicines and Pharmacist Only (S3) Medicines to Pharmacy Medicines (S2)) a pharmaco-vigilance system be developed and implemented on a national basis to assist in the analysis and management of risk.

**Staffing input into interventions**

Although legislation does not require pharmacists to be involved in clinical interventions associated with Pharmacy Medicines (S2), it was interesting to note that pharmacists were involved in about half the interventions recorded (alone in 49% of cases in both studies or including a pharmacy assistant, 79% and 77% of the time in the Census and Sample Study respectively). In the interventions recorded, pharmacy assistants were more likely to refer customers to the pharmacist in the Census, where higher significance interventions were asked to be recorded, than the Sample Study (67% of Census interventions where a pharmacy assistant was involved, compared to 60% in the Sample Study, and 29.5% compared to 27.3% of the total interventions in the Census and Sample Study respectively). The approximately 25% referral rate suggests that pharmacist assistants recognise that they have a limited capacity to deal with certain types of interventions. Pharmacists were involved in interventions with a higher clinical significance – 20 of the 27 potentially life-saving in the two week period of the Census and Sample Study. However, pharmacy assistants' interventions were documented across a spectrum of clinical significance.

The importance of pharmacy staff is further highlighted by the rate of interventions conducted by this group with 14.8 percent of Census interventions and 17.9% of interventions in the Sample Study being performed by pharmacy assistants alone. However, currently there exists no legislative requirement that pharmacy assistants be formally trained nor are they legally required to meet any competency standards. Although we do not have data on the number of pre-registration graduates in the population as a whole it is noteworthy that they seemed to be a particularly active group, accounting for about 5% of the interventions. Although not analysed for this report, the researchers had the impression from processing the data that pharmacists and pharmacy staff have a set of behavioural practice patterns that may be unique to an individual pharmacy or group of pharmacies. The implication is that there is a need to promulgate the breadth of application of clinical intervention knowledge to community pharmacy. A number of recommendations arise from these data.

**Recommendation 10:**

That the competency statement for pharmacists be reviewed to explicitly include a core competency for performing clinical interventions for Pharmacist Only (S3) and Pharmacy Medicines (S2).

**Recommendation 11:**

That a national program be instituted to increase the clinical intervention rate for Pharmacist Only (S3) and Pharmacy Medicines (S2).

**Recommendation 12:**

That national policy and protocols should be developed, concentrating on when and how pharmacy assistants should refer at-risk patients to pharmacists. These policies should be incorporated in the 'Standards for the Provision of *Pharmacist Only* and *Pharmacy Medicines* in Community Pharmacy'.

**Recommendation 13:**

That all universities and pre-registration programs should incorporate clinical intervention education on Pharmacist Only (S3) and Pharmacy Medicines (S2) as part of their curricula.

**Recommendation 14:**

That there be a formal requirement for those pharmacy staff members who are not pharmacists to have a formal qualification for handling Pharmacist Only (S3) and Pharmacy Medicines (S2).

**Differences in the number of interventions and the way in which Schedule 2 and Schedule 3 medicines are supplied within the community practice setting**

Ideally, the calculation of rates of interventions would be based on actual sales from pharmacy. However, no such data were available to the research team. IMS Health provided national and individual pharmacy purchase data as a surrogate for sales data. These data are considered to be of a very high integrity, and are used by the pharmaceutical industry as a whole. The other limitation in determining the intervention rate is the concept of under-reporting or over-reporting of interventions. The evidence available suggests that, on balance, there has been under-reporting. The counter-balance to the under-reporting could be that participating pharmacies may be biased to high performers than non-participants.

The estimated annual Australian intervention rate was found to be 5.66 interventions per 1000 units for all non-prescription medicine products, with the Pharmacy Medicines (S2) rate being 5.76 per 1000 units and Pharmacist Only (S3) Medicines rate being 5.34 per 1000. Although there is no statistically significant difference observed between rates (as analysed by overlap between CIs), an examination of the rates of intervention for Pharmacy Medicines and Pharmacy Only Medicines show that there are differences in magnitude between the rates, and as such, differentiation in how the two schedules are supplied. While there was a higher rate of intervention overall on Pharmacy Medicines (S2), this is due to the fact that there were more interventions made of minor significance undertaken for Pharmacy Medicines (S2) than Pharmacist Only (S3) Medicines. When the high significance interventions are separated, there was a higher rate for Pharmacist Only (S3) Medicines than Pharmacy

Medicines (S2). The result provides epidemiological evidence on the different nature of the medicines in the two schedules. The overall higher rate of intervention on Pharmacy Medicines (S2) products may be explained partly by the inherent properties of the products classified as Pharmacy Medicines (S2) and their availability, while Pharmacist Only (S3) Medicines are kept behind the counter and must be processed by a pharmacist. There may also be more consumer awareness of Pharmacy Medicines (S2), and they may be more likely to be asked for directly. There are also differences in rates in the significance of the interventions, with Pharmacist Only (S3) Medicines having a higher rate of high significance interventions (1.37 per 100 units 95%CI 0.9 to 1.99). This suggests that Pharmacist Only (S3) Medicines have more capacity for harm and a higher risk than Pharmacy Medicines (S2) products (1.12 per 1000 units 95%CI 0.88 to 1.41), and thus, benefit from being provided by a professional with extensive health training rather than an assistant. The epidemiological data support the notion of separate Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules, and led to the corresponding recommendation.

The consequences of modelling for an amalgamated schedule indicate that, in essence, the number of interventions would increase if the amalgamated model mimicked the current Pharmacy Medicines (S2) schedule. Pharmacist Only (S3) Medicines would be subjected to a total higher rate. By contrast, if the amalgamated model mimicked the current Pharmacist Only (S3) Medicines schedule then the total intervention rate would decrease since Pharmacy Medicines (S2) products would be subjected to the lower intervention rate for Pharmacist Only (S3) Medicines. However if one amalgamated schedule were to be adopted, taking into account the type of significance associated with the intervention, an amalgamation to the Pharmacist Only (S3) Medicines type amalgamated model would be preferred, since the rate for high significance interventions is lower with Pharmacy Medicines (S2) than Pharmacist Only (S3) Medicines.

Nonetheless, it is important to note that while placing all Pharmacy Medicines (S2) under the mandatory supervision of pharmacists would ensure that these medicines were provided with the highest level of care, this level of care may be unnecessary due to the lower risk and may also result in negative implications for the consumer. Placement of less dangerous medicines behind-the-counter may leave consumers less aware that there are treatments available to them. The Cost Benefit Analysis (Section 4) has shown that amalgamating non-prescription medicines in a Pharmacist Only (S3) Medicines type schedule would require far greater labour and training costs that could be passed on to the consumer. This may have clinical implications if certain customers were then not able to afford helpful medication. Overall, the researchers conclude that the current dual non-prescription schedules result in a balance of appropriate care for product risk, making less dangerous medications more accessible, but retaining the provision of extra care in dispensing necessary but more dangerous medications.

**Recommendation 15:**

That, due to the clinical benefits provided by the current non-prescription medicine scheduling system, separate Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules be retained.

### **The level of professional intervention that currently occurs and the types of conditions and the specific products involved**

The range of types of interventions identifies 'at-risk' consumers. 'At-risk' consumers were identified as a large number of patients with underlying diseases who were found to request Pharmacist Only (S3) and Pharmacy Medicines (S2). Patients with diseases such as hypertension, heart disease, ulcers, diabetes, arthritis and asthma appeared to be most at risk. Surprisingly, in practice, pregnant women were also shown to be an at-risk group. The results of the study show that pharmacy is well placed to encourage the appropriate use of non-prescription medicines and prevent harm to the consumer. The most common interventions involved consumers who were unaware that their pre-existing conditions may have relevance to the medications that they requested. The most common pre-existing condition which required an intervention was hypertension. For example, consumers attempted to purchase cold and flu or anti-histamine medications that contained pseudoephedrine and were unaware that this could exacerbate their condition. The second most commonly identified pre-existing condition was asthma. For example, a number of asthmatic patients were not aware that they might have allergies to non-steroidal anti-inflammatory agents, which could trigger an asthmatic attack, or they were not controlling their condition adequately. It is difficult to assign risk according to age. It appears that in both the Census and Sample Study about one in five or six patients purchasing non-prescription medications were over 65. One would expect that with age, the number of underlying disease and number of medications prescribed would increase. The most frequently documented patient involved in an intervention was an adult (aged 13-64) female. In both the Census and Sample Study, older people seemed to be more involved in Pharmacy Medicines (S2) interventions, and children were more involved in Pharmacist Only (S3) Medicines interventions.

The case studies illustrate the spectrum of issues raised by direct product request in pharmacy. The specific cases provide examples where patients with underlying diseases were inappropriately requesting non-prescription medications. The most common problems that pharmacies were detecting in non-prescription medicine interventions, in both the Sample and the Census studies, were drug-condition contraindications, therapeutic duplications and untreated/under treated indications. The most common products involved in both the Census and the Sample Study were cold and flu medications, non-steroidal anti-inflammatory agents, combination simple analgesics, narcotic analgesics and antihistamines. While only 4.8% of interventions in the Census and 2.9% in the Sample Study involved pregnant women, they were involved in 18% of high significance interventions. This indicates that not enough pregnant women were firstly reading adequately or understanding product labels, or were actively seeking the required pharmacy staff advice on their medicine purchases. These data show that the common types of adverse health outcomes prevented were exacerbation of asthma, essential hypertension and peptic ulcer.

#### **Recommendation 16:**

That a national training program for community pharmacy on Pharmacist Only (S3) and Pharmacy Medicines (S2) be developed, emphasising clinical interventions in high-risk patients with underlying conditions, age and specific products identified in this report.

**Recommendation 17:**

That existing patient education leaflets be revised to address problems associated with Pharmacist Only (S3) and Pharmacy Medicines (S2) specific for patients with underlying conditions identified at-risk in this report. These leaflets are to be circulated through patient support groups, general medical practitioners and community pharmacy.

Other types of consumer behaviour are also apparent, with cases of therapeutic duplications and overdosing, e.g. consumers were either at risk of overdosing using one product or through using a combination of products with the same active ingredient. Even where the instructions on the pack are clearly indicated, many patients appeared not to be aware of the maximum daily dose of commonly available ingredients such as paracetamol. Pharmacies also reported undiagnosed or misdiagnosed problems in consumers. While it is possible that the problems may eventually be detected by other healthcare professionals, it is also probable that they may not be detected until the problem becomes significant or life-threatening. A doctor's visit may be seen by consumers as more expensive or time consuming than visiting a pharmacy. Research into the area of patients' willingness to see one type of healthcare professional over another may be useful in determining how to best detect latent significant problems earlier, when treatment may be less costly and/or effective. What is interesting to note is the prevalence of analgesics, either singly or in combination, involved in interventions where there was a discovery of an undiagnosed problem. This study suggests that use of pain-killers may be masking potentially serious problems. Further research is needed to examine the attitudes that consumers have towards pain and analgesics, and the prevalence of misdiagnoses of serious ailments due to the use of these products.

**Recommendation 18:**

That a review of labelling requirements for Pharmacist Only (S3) and Pharmacy Medicines (S2) be undertaken, as this study has shown that currently a significant number of at-risk consumers are not complying with labelling instructions.

Cough and cold products, classified as per MIMS classification as 'Respiratory', provided the highest number of interventions, closely followed by non-steroidal anti-inflammatory and other analgesics. NSAIDs were the second most common types of products involved in the interventions. A proportion of these cases involved ibuprofen, in particular with patients with pre-existing conditions of asthma, ulcers or pregnancy. This study suggests that there may be considerable risks inherent with the provision of ibuprofen without any screening. As smaller packs of ibuprofen are currently available in an unscheduled and unregulated environment in Australia, it is suggested that further research be undertaken on the incidents and consequences of inappropriate use of the drug from products sold in supermarkets.

**Recommendation 19:**

That further analysis of data collected as part of the Study of Professional Interventions includes interventions performed on unscheduled medicines and further analysis take place on the data collected in the Study of Professional Interventions at the product level to determine the relative risk of products.

**Recommendation 20:**

That a study investigate the incidence and outcomes of inappropriate use of unscheduled medications sold in non-pharmacy outlets (e.g. supermarkets).

As previously mentioned, it is important to note that the identification and predominance of certain types of pre-existing medical conditions or products in interventions may be a result of the focus of practice in individual pharmacies. For example, one pharmacy may be better at detecting contraindications with hypertension and pseudo-ephedrine or paracetamol overdosing, but may be missing other types of interventions.

**Recommendation 21:**

That research be conducted into the nature of clinical interventions reported in this study to identify practice behaviour patterns of pharmacists and pharmacy staff.

**The Effect of QCPP Accreditation**

The limitations of the stratification by QCPP have been outlined in the methodology and therefore caution needs to be exercised when interpreting these results. There appears to be no significant difference found between the three groups, with total intervention rates on non-prescription medicines of 8.2 (Group 1- 'Excellent' QCPP Accreditation), 7.6 (Group 2 – 'Low' – 'Medium' QCPP accreditation and QCPP-accredited but untested ) and 7.9 (Group 3 - Not QCPP-accredited) interventions per 1000 units purchased. However in actual numbers, Group 1 ('Excellent' QCPP-Accreditation) outperformed the other two groups. By contrast, Group 3 (Not QCPP-Accredited) showed a higher Pharmacist Only (S3) Medicines rate (18 interventions per 1000 units purchased) than any other group. On these data, it would be inappropriate to comment on the effect of QCPP. Similarly, no conclusive evidence is available with regards to the increased intervention rates as a result of the dissemination of the *Standards*.

**Recommendation 22:**

That an investigative study of pharmacies with higher intervention rates be conducted to identify factors contributing to the higher rate, and these incorporated into national training programs.

**Potential of the intervention to encourage appropriate use of non-prescription medicines and prevent harm – evaluation of social and health impacts**

This study has provided data and demonstrated how community pharmacy encourages appropriate use of non-prescription medicines and prevents harm through intervening

at the point of sale or supply. It was estimated that Australian pharmacies perform 485,912 interventions per annum in the process of dealing with non-prescription medicines, with 101,324 per annum being high significance interventions (averting emergency medical attention, serious harm or being potentially life saving). When the probability of the pharmacy intervention preventing the adverse event (assigned by the clinical panel) is taken into account to derive a count of annual cases avoided by pharmacy interventions, it is estimated that pharmacy staff prevent an annual 30,808 visits to hospital Accident and Emergency, 76 visits to an intensive care unit and 84,650 urgent visits to a general medical practitioner. This is based on the current rate of intervention. If there were an improvement in the intervention rate of 10% (i.e., an intervention rate of 0.0062), this would result in an additional 48,591 interventions being made each year.

➡ Please see Recommendation 11

### **Monitoring of consumers' health, other outcomes and satisfaction post-intervention**

The number of responses for the post-marketing stage of this study was significantly less than predicted due to a number of compounding factors. This post-marketing surveillance questionnaire and method of distribution had been adopted from previous published research. However, this is the first known study in which pharmacy staff were asked to perform dual research duties: both recording of the intervention and recruitment of the consumer. While the offer for reimbursement for each recruited patient was appreciated by the pharmacies, the time involvement may have been a disincentive. Time and resource restraints did not allow adequate follow-up of both pharmacies (for recruitment) and patients (for return of questionnaires). Pharmacy staff also reported difficulties in recruiting consumers which led to low motivation on part of the staff to continue to attempt recruitment. While there was the offer for reimbursement to the pharmacy for each recruited patient, there was not a direct incentive for the consumer. The 57 returned questionnaires have offered a preliminary insight into consumer behaviour during the week following the intervention undertaken in their pharmacy. Future research could experiment with providing more incentive for consumer recruitment, refining the procedure for coordinating data from both pharmacies and consumers, and providing researcher involvement in pharmacies for recruitment so to relieve the staffing burden and to minimise the discrepancies between the intervention rate and the reporting rate. Future research may also consider targeting consumers independent of interventions, post-purchase of medications in order to assess the rates of misuse of non-prescription medicines in the community. For approximately 4,848 of 5,386 interventions (90% of interventions), the customer accepted the advice of the pharmacist or pharmacy staff at the time of intervention, through either purchasing alternative (more) appropriate products or indicating that they would seek medical attention either immediately or at the next time of an appointment. The case studies in the Post-Marketing Surveillance Study provide detailed evidence on the health impact of clinical interventions undertaken by community pharmacy through monitoring the actual behaviour of the consumer..

In conclusion, the data collected provided a rich source of information on many issues over and above the tender requirements and thus can sustain further analysis not



possible due to the time constraints in reporting. The two following recommendations are examples of the type of analyses that could be undertaken.

➡ **Please see Recommendation 19**

➡ **Please see Recommendation 21**

## **SECTION 4**

### **COST BENEFIT ANALYSIS REPORT**

**A cost benefit analysis to consider the merging of Pharmacist Only (S3) and Pharmacy Medicines (S2) pharmacy schedules in Australia**

## **A COST BENEFIT ANALYSIS TO CONSIDER THE MERGING OF PHARMACIST ONLY (S3) AND PHARMACY MEDICINES (S2) PHARMACY SCHEDULES IN AUSTRALIA**

This report examines the economic implications of merging the Pharmacist Only (S3) and Pharmacy Medicines (S2) pharmacy schedules in Australia. Please note that any use of this analysis to make new policy decisions that will impact on the provision of health services in Australia should be made with extreme caution, due to the degree of uncertainty in the underlying estimates. In addition, a range of assumptions was required to fill several key data gaps, reducing the robustness of the results. Nevertheless, a number of conclusions can be drawn from the analysis, which enhances our general understanding of the costs and benefits of Pharmacist Only (S3) and Pharmacy Medicines (S2) scheduling.

## 4.1 BACKGROUND

The Commonwealth regulates the supply of Pharmacist Only (S3) and Pharmacy Medicines (S2) pharmaceuticals through the *Therapeutic Goods Act 1989*, and the States and Territories do so through parallel provisions in State and Territory medicines and poisons legislation. These regulations have periodically been assessed to determine their efficiency (Industry Commission [13], 1996; Productivity Commission, 1999 [19]; Ballenden, 2000 [3]; Galbally, 2001[9]).<sup>2</sup> Scheduling was originally introduced, primarily in the interests of consumers, to assist in the quality use of medicines by reducing medicinal misadventure, and to contribute to the appropriate selection and effective use of medicines.

This analysis examines the economic implications of merging the Pharmacist Only (S3) and Pharmacy Medicines (S2) pharmacy schedules in Australia. Two different approaches to the analysis were considered.

A revealed preference approach was considered. This approach compares sales of Pharmacist Only (S3) and Pharmacy Medicines (S2) products in the pharmacy and products in the open market. Price differences are assumed to represent the consumer value gained by purchasing products within a pharmacy, such as additional information and advice. Examination of supply and demand curves in these markets is used to calculate consumer and producer surpluses, and profit gains and losses.

The revealed preference approach was rejected on the grounds that health care markets are not perfect markets and are subject to substantial market failure. Furthermore, consumers are not expected to act rationally within these markets. For example, consumers do not fully understand the risk reduction associated with clinical advice. If consumers did fully understand this value, all health care markets would be deregulated. Similarly, price differences in unscheduled markets would not capture the likely increased gains from advice received for higher risk drugs in Pharmacy Medicines (S2) / Pharmacist Only (S3) Medicines. There is also a lack of evidence regarding the impact of high-risk Pharmacist Only (S3) Medicines becoming amalgamated in S4 (prescription), if Pharmacist Only (S3) Medicines were to be merged with Pharmacy Medicines (S2) as a single schedule.

An epidemiological approach was also considered. This estimates the clinical gains and economic implications of pharmacy interventions (advice affecting consumer behaviour) in the sale of Pharmacist Only (S3) and Pharmacy Medicines (S2) products. There are a number of shortcomings with this approach, but it has the major benefit of addressing the central issue in health care regulation, which is the estimation of health gains under alternative scheduling systems. These health gains are expressed as monetary values. Production costs – pharmacy staff time – are

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<sup>2</sup>The Commonwealth controls the number of pharmacies entitled to dispense PBS prescriptions under the *National Health Act 1953*. Entry barriers to community pharmacy were reaffirmed by recommendations of the National Competition Review of Pharmacy (Wilkinson, 2000) and further secured pursuant to the *Third Community Pharmacy Agreement* in 2000.

subtracted from these health gains to obtain a measure of net monetary benefit. Repeating this analysis for each scheduling option enables a cost-benefit analysis to be performed, in which these options are compared using the same units (dollars). For these reasons, this approach was preferable and was used in the analysis.

It should be noted that data were not available to calculate costs or health benefits for the possible scenarios where Pharmacy Medicines (S2) are de-scheduled or Pharmacist Only (S3) Medicines are re-scheduled to prescription (S4). This was beyond the scope of the data collection exercise. In the absence of data it was not possible to estimate the effects of these scenarios.

## 4.2 METHODS

### 4.2.1 BENEFITS

Using epidemiological data collected in the course of this project, we have directly estimated the economic benefit of pharmacy interventions associated with the sale or pharmacy customer requests for Pharmacist Only (S3) or Pharmacy Medicines (S2). The impact of interventions in avoiding diseases in a 12-month period was estimated by extrapolation of data collected in a survey of pharmacy interventions consisting of:

- a census of 4981 pharmacies conducted in two branches in late 2003 and early 2004, to capture rare and possibly life-saving interventions; and
- a sample study of 1238 pharmacies in late 2004 to capture more common interventions.

Of the 4981 pharmacies contacted, there were 934 participant pharmacies in the Census. In the Sample Study, there were 101 participants out of the 1238 pharmacies approached. Full details of the survey methods, response rate and extrapolation of results to develop our data on national pharmacy intervention behaviour are set out in Section 3A.7. Our extrapolation is subject to 95% confidence intervals created using raw and weighted frequencies according to the Poisson method, with reference to the Poisson table.

In the course of selling Pharmacist Only (S3) and Pharmacy Medicines (S2) products to the value of approximately \$1 billion, involving some 90 million transactions, in the year ended April 2003, our central estimate is that Australia's 4981 pharmacies delivered some 156,000 interventions. These were weighted on a scale of 0–1 according to the probability that they caused pharmacy customers to avoid disease and/or injury (see Appendix 36 and Section 3A.7). Approximately 115,000 of such interventions were attributable to Pharmacy Medicines (S2), and 41,000 to Pharmacist Only (S3) Medicines.

The diseases or injuries avoided were identified from a review of documentation on each intervention by an expert clinical panel. The panel assessed the health consequences that might have ensued without the intervention of a pharmacist and/or pharmacy assistant. Allowance was made for some pharmacy interventions having a negative impact on health.<sup>3</sup> All interventions were coded, via the International Classification of Diseases, Ninth Revision (ICD-9), to selected three-digit disease categories used by Mathers *et al.* (1999) [16] in their Australian burden of disease study.

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<sup>3</sup> Data on positive and negative interventions were amalgamated. This was done by subtracting negative interventions from the respective positive interventions. Deaths were also netted out. In the case of one disease (depression), there was in fact negative benefit.

The reason for adopting the disease categories used by Mathers *et al.* [16] was to develop a systematic framework in which standard disease costings could be employed. Accordingly, we found that interventions could be described in terms of 33 disease categories, as set out in Appendix 36. Our central estimate of the number of cases of disease or injury avoided corresponds to the weighted number of interventions. We then calculated the total annual benefit of avoided diseases at 2000/01 prices. This was carried out with reference to the sum of the costs associated with each of the diseases avoided, according to the disease category to which they had been coded. Our method is described in the next section.

#### 4.2.2 DISEASE COSTING

For each disease category, we collected information on:

- annual expenditure on disease management at 2000/01 prices (the most recent year for which such data are available), including medical, hospital, pharmaceutical, allied health, long-term care costs, etc. (from the Australian Institute of Health and Welfare)
- its disability weight (from Mathers *et al.* [1999], Annex Table B [16])
- the mean duration of disability with which the disease category was associated (from survey)
- the number of individuals (cases) in whom the disability was avoided (from survey)
- number of deaths avoided and survival times (from survey)
- the value of life (from literature, see below).

From the above information set, we calculated the various elements of the cost per case for each of the diseases avoided, consisting of:

- the annual cost of treatment per case per disease category, which under Australia's Medicare arrangements, would have mainly been a cost to government
- the cost of disability, which is essentially a private cost that may be thought in terms of what people might be willing to pay in order to avoid a disability
- the cost of death – a valuation that may be based either on private willingness-to-pay or the value of human capital associated with the economic cost of productivity loss.

Each of these costs is described below.

##### **Cost of treatment**

The annual case cost for each disease category was obtained by dividing overall annual expenditure by incidence/prevalence as appropriate. The treatment cost per case was obtained by applying the mean duration of the disease to the annual case cost. For example, for disease category A2d (Other STD), the mean duration per case was 4.43 days and the annual case cost was \$5,827. Therefore, the treatment cost per case was estimated to be \$71 ( $= \$5827 \times [4.43/365]$ ). Many of the diseases avoided were self-limiting and of no more than a few days' duration. Total treatment costs

avoided were obtained by multiplying treatment cost per case (Appendix 36) by the number of cases avoided.

### **Cost of disability**

In order to ascribe an economic valuation to disability, we derived the value of a healthy life-year from the value of life. There are different approaches to the valuation of life. The human capital approach calculates the present value of an individual's discounted anticipated stream of future earnings. The willingness-to-pay method estimates the value of life from the amounts that individuals are prepared to pay to reduce risks to their lives (Viscusi, 1993 [22]). The willingness-to-pay approach generally results in higher values than the human capital approach.

There is comparatively little Australian literature on the value of life. A recent study measuring the returns on investment in public health in the early 2000s valued a life at \$1 million (Applied Economics, 2003 [2]). This was reported as being a conservative valuation of the estimated willingness-to-pay. A study by the Bureau of Transport and Regional Economics (Amoako *et al.*, 2003 [1]) used a human capital approach to measure the cost of pollution-induced deaths associated with transport emissions. This was a derivative of the estimated cost of \$1.9 million attributable to each life lost in transport accidents, and yielded an actual valuation of \$1.3 million. The downward valuation adjustment reflected the older age distribution of the population most susceptible to pollution.

We believe that this older age group may be more representative of risk-averse persons who are more likely to seek and be receptive to pharmacy interventions and for whom risks associated with exposure to inappropriate OTC medication may be greater. We have therefore used \$1.3 million as the value of a statistical life (VOSL) in this study. From this it follows that the value of a healthy year of life, or statistical life-year (VOSLY) is \$76,000, assuming 40 years of survival at a discount rate of 5%.<sup>4</sup> The impact of the choice of value is tested in a sensitivity analysis, where the unadjusted VOSL of \$1.9 million is used.

A disability weight may be applied to the VOSLY to develop a money metric for the cost of disability. A disability weight of zero represents perfect health, while a disability weight of 1 represents death (Mathers *et al.*, 1999 [16]). For example, an endocrine/metabolic disorder (category I4, Appendix 36) has a disability weight of 0.25, implying that suffering from such a disorder for 4 years is equivalent to losing 1 year of healthy life valued at \$76,000. The cost of disability associated with any category of disease may hence be calculated by multiplying the relevant disability weight by:

- the mean duration of time lived with the disability (Appendix A)
- the number of cases, and
- the VOSLY.

For example, for disease category A2d (Other STD), there is a disability weight of 0.455 and there were 696 cases avoided for Pharmacy Medicines (S2) products.

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<sup>4</sup>  $\$1.3 \text{ million} = \$76,000/1.05 + \$76,000/(1.05)^2 + \dots + \$76,000/(1.05)^{40}$



Therefore, the cost avoided for preventing these disabilities is estimated to be \$292,001 ( $= 696 \times 0.455 \times [4.433/365] \times \$76,000$ ).

### **4.2.3 COST OF DEATH**

As previously indicated, the majority of diseases avoided were relatively minor, typically lasting a few days. There were, nevertheless, a number of more serious diseases avoided that could have resulted in death. To obtain the value of lives saved, we multiplied the estimated total number of deaths avoided by the VOSL (\$1.3 million). Where death occurred after the year of disease attribution, costs were discounted to their net present values at an annual rate of 5%, in line with Australian guidelines.

For example, for disease category A6 (Meningitis), there are zero survival years (death is immediate) and there were 125 deaths avoided for Pharmacy Medicines (S2) products. Therefore, the cost avoided for preventing these disabilities is estimated to be \$162,500,000 ( $= 125 \times \$1,300,000$ ).

### **4.2.4 PRODUCER COSTS**

Producer costs are the costs of staff time required to produce the benefits (avoided diseases and deaths) estimated above. These include the costs of both the pharmacist's and pharmacist assistant's time involved in dispensing products in the Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules. These costs are a product of the following factors:

- the number of items supplied on the Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules
- the probability of involvement
- the duration of involvement (minutes)
- the hourly cost of staff time.

The producer costs include staff time spent supplying all items, with or without a positive intervention. However, in the Census and Sample Study, data on the numbers of staff involved and the duration of their involvement were collected only for sales accompanied by a positive intervention (minor or significant intervention in the Sample, and very significant or potentially life-saving intervention in the Census). Therefore, in sales not accompanied by a positive intervention, the types of staff involved and the durations of their involvement were assumed. 0.72% of Pharmacy Medicines (S2) item sales and 0.81% of Pharmacist Only (S3) Medicines item sales were accompanied by a positive intervention (note that these rates take into account the probability of the intervention preventing the adverse effect, therefore weighted probability data have been used to determine the number of cases). Therefore, the producer costs are largely driven by our assumptions and should be regarded with caution.

For positive interventions, the probabilities of a particular staff member's (pharmacist or assistant) involvement and the mean duration of involvement are presented below.

**Table 68:** Probabilities of staff member involvement and the mean duration

Staff member	S2	S3
<b><i>Pharmacist</i></b>		
Probability of involvement	0.7933	0.7402
Mean time involved (minutes)	6.079	4.431
<b><i>Pharmacy assistant</i></b>		
Probability of involvement	0.6850	0.4920
Mean time involved (minutes)	3.299	2.378

Several interesting points can be noted from the above data. Although law requires only that a pharmacist be involved in Pharmacist Only (S3) Medicines product sales and a pharmacist assistant be involved in Pharmacy Medicines (S2) product sales, it appears that both staff members were involved in many of the sales that were accompanied by a positive intervention. A pharmacist assistant was involved in almost half of the positive interventions for Pharmacist Only (S3) Medicines, and almost 70% of the positive interventions for Pharmacy Medicines (S2) products. Therefore, it is likely that in many transactions, the assistant follows the protocol for the schedules and following a preliminary assessment refers to the pharmacist in the intervention. A combination of advice from both staff members might lead to the avoidance of a temporary disability or death. It appears that more time is spent in the intervention for Pharmacy Medicines (S2) than for Pharmacist Only (S3) Medicines.

For sales not accompanied by a positive intervention, simplifying assumptions were made regarding the level of staff involvement. To assume a zero producer cost for an intervention that results in no impact or harm would have potentially underestimated total producer cost to a substantial degree. It was also considered logical to assume that the time for an intervention that results in no impact or harm would not exceed the time for positive interventions, since an intervention that results in no impact or harm is likely to take less time to convey than advice classed as a positive intervention. Following this logic, the most conservative assumption (i.e., leading to the highest estimate of producer cost and lowest estimate of net benefit) is that the time involved is identical for all types of interventions.

Therefore, it was assumed that for Pharmacy Medicines (S2) products, only a pharmacist assistant would be involved, and for Pharmacist Only (S3) Medicines only a pharmacist was involved. This would appear reasonable given that, from the above data, positive interventions appear to be associated with the involvement of both staff members. The mean time spent for the involved staff member was assumed to be equivalent to that required for that staff member in a positive intervention (given above).

Hourly staff costs were estimated to be \$35.33 for pharmacists and \$22.18 for pharmacy assistants [24]. These include a 25% on-cost to cover annual holidays, public holidays, sick leave, long-service leave and employer superannuation contributions.

The staff hours required to dispense all Pharmacist Only (S3) and Pharmacy Medicines (S2) products examined in the analysis were calculated by dividing total

staff costs by the hourly wage rates. The annual number of pharmacists required was calculated by dividing pharmacist hours by the estimated number of hours that a pharmacist would work per year (1760 hours, assuming 220 eight-hour days).

#### **4.2.5 EFFECTS OF SCHEDULE MERGING**

The methods above outline the estimation of costs for the current situation in Australia where the Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules are separate and distinct. We required a method whereby these costs could be estimated under two hypothetical scenarios: a merger of the schedules into either Pharmacy Medicines (S2) (eliminating Pharmacist Only (S3)) or Pharmacist Only (S3) (eliminating Pharmacy Medicines (S2)).

We assumed that if Pharmacy Medicines (S2) were eliminated, the sale of products previously in Pharmacy Medicines (S2) would be subject to the same degree of pharmacy staff intervention as current Pharmacist Only (S3) Medicines. Likewise, it was assumed that if the Pharmacist Only (S3) Medicines schedule were eliminated, the sale of products previously in Pharmacist Only (S3) Medicines would be subject to the same degree of pharmacy staff intervention as current Pharmacy Medicines (S2) products. Therefore, for the scenario in which Pharmacy Medicines (S2) is eliminated, cases of temporary disability and deaths avoided from interventions in the sale of Pharmacy Medicines (S2) products were adjusted to reflect a differential rate of intervention in the Pharmacist Only (S3) Medicines market. This was carried out by multiplying cases of temporary disability and deaths by the ratio of the probabilities of intervention for current Pharmacist Only (S3) and Pharmacy Medicines (S2) sales.

The estimations of the probabilities of a positive impact per unit sale are presented below for minor, significant, very significant, or potentially life-saving interventions. The annual intervention frequencies were previously calculated using a systematic weightings procedure, which can be found in Data Integration, Representativeness of Samples and Weighting (Section 3A.7). The estimated cases avoided through these interventions were calculated using probabilities that the intervention avoided the adverse outcome as assessed by the clinical panels (Section 3A.6).<sup>5</sup> To estimate the probability of each type of intervention having a positive impact per unit purchased, the number of estimated cases avoided was divided by the estimated annual number of units purchased on that schedule in Australia.

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<sup>5</sup> Estimated cases avoided = estimated frequency of annual Australian interventions x probability of the adverse health consequence resulting had the intervention not taken place (calculated from a mean of clinical panel members using a combination of an arithmetic scale (between 0.1-1, a logarithmic (Base 10) scale (below 0.1) and an open-ended scale).

**Table 69:** Probabilities that the interventions would have a positive impact, by significance and schedule<sup>6</sup>

	Probability of positive impact of intervention	
	S2	S3
Minor impact	0.0019	0.0024
Significant impact	0.0036	0.0029
Very significant impact	0.0016	0.0027
Potentially life-saving impact	0.0001	0.0001
All	0.0072	0.0081

Based on these data, the ratio applied to Pharmacy Medicines (S2) products in the ‘S3 only’ scenario was 1.1268 ( $= 0.0081/0.0072$ ), and the ratio applied to Pharmacist Only (S3) products in the ‘S2 only’ scenario was 0.8875 ( $= 0.0072/0.0081$ ).<sup>7</sup>

In summary, for the scenarios in which the schedules are merged (Pharmacist Only (S3) or Pharmacy Medicines (S2) is eliminated), producer costs were estimated by assuming that, for example, sales of products previously in Pharmacy Medicines (S2) and now in Pharmacist Only (S3) Medicines are subject to the same levels of staff involvement as products that were in Pharmacist Only (S3) Medicines before the merger. Hence, the assumption was made that the level of staff involvement depends on the schedule under which the product is supplied under and not necessarily the risk profile of the product.

It is important to note that the overall number of transactions is higher in Pharmacy Medicines (S2), because there are more products listed on Pharmacy Medicines (S2) than on Pharmacist Only (S3) Medicines. However, as shown in Table 69, the probability of a positive intervention is higher in Pharmacist Only (S3) Medicines transactions. The probabilities that a staff member would be involved in a transaction were presented in Table 68 for positive interventions only.

Therefore, although the probabilities of each staff member being involved in a positive intervention were higher for Pharmacy Medicines (S2) products, these probabilities were applied to a lower probability of positive interventions than for Pharmacist Only (S3) Medicines products.

<sup>6</sup> These figures differ from those in Tables 53 and 54, as they refer to probabilities of adverse outcomes avoided as a result of interventions; the latter refers to rates of pharmacy staff intervening.

<sup>7</sup> These quotients appear inaccurate since the numbers have been rounded to four decimal places for presentation in this report. However, the accuracy in the model can be demonstrated by presenting the numbers to six decimal places, since  $0.008093/0.007183 = 1.126772$ , and  $0.007183/0.008093 = 0.887491$ .

#### 4.2.6 OTHER COSTS

Other costs of changing the current scheduling arrangements were also estimated, including:

- the cost to manufacturers/industry of relabelling products
- the cost to pharmacy of any changes to the physical layout of their store
- the cost to pharmacy of any changes to their software system
- the cost to pharmacy of returning stock to wholesalers.

These costs were estimated through consultation with seven pharmacies based in different regions of Australia.

The cost of relabelling products was estimated by first estimating the number of items that would need relabelling. One pharmacy reported that they had 12 turnovers per year, or one month to sell current stock. This was assumed to be representative of the average turnover rate for pharmacies throughout Australia. The number of Pharmacy Medicines (S2) items that would require relabelling if the schedules were merged into Pharmacist Only (S3) Medicines was estimated as one-twelfth of the annual number of Pharmacy Medicines (S2) units sold. This provides the estimated number of Pharmacy Medicines (S2) units in all Australian pharmacies at any point in time.

The cost of relabelling was derived from a TGA-approved contractor dealing in the labelling of both Pharmacy Medicines (S2) and Pharmacist Only (S3) Medicines products. The contractor stated that relabelling costs between \$0.13 and \$0.20 per unit. The upper limit of \$0.20 was used in this analysis to enable a more conservative estimate of the net benefit of changing the current scheduling arrangements. Higher relabelling costs lead to higher cost offsets against the net benefit of merging the schedules.

If the schedules are merged into Pharmacist Only (S3) Medicines, the cost of relabelling is estimated to be over three times as high as if the schedules are merged into Pharmacy Medicines (S2), due to a greater annual number of Pharmacy Medicines (S2) sales.

**Table 70:** Cost of relabelling items within pharmacies

Scenario	Units per year	Units relabelled	Cost of relabelling
Merge into S2	20,043,924 (S3 items)	1,670,327	\$334,065
Merge into S3	65,838,526 (S2 items)	5,486,544	\$1,097,309

Three of the seven pharmacies reported that no change would be required to the pharmacy layout if Pharmacy Medicines (S2) were eliminated, and three pharmacies reported that no change would be required to the pharmacy layout if Pharmacist Only (S3) Medicines were eliminated. Pharmacies reporting that a change to the layout would be required, estimated this at between half a day's work for one staff member and a major refit totalling \$100,000. Some pharmacies reported a higher cost if Pharmacy Medicines (S2) were eliminated, and some reported a higher cost if Pharmacist Only (S3) Medicines were eliminated. Therefore, there was no clear evidence to enable precise costs to be calculated. An appropriate average based on this data was considered to be one week of pharmacist time for half of all pharmacies in

Australia. Based on a cost per pharmacist hour of \$35.33 and an eight-hour working day, the cost was estimated to be \$703,915 ( $= \$35.33 \times 8 \times 4981 \times [1/2]$ ) for either of the schedule merging arrangements.

Only one pharmacy reported that software changes would be required if Pharmacy Medicines (S2) were eliminated, and only one pharmacy reported that software changes would be required if Pharmacist Only (S3) Medicines were eliminated. Both pharmacies estimated that software changes would require at most one day of pharmacist time. Therefore, the cost of a software change is estimated to be \$282.64 ( $= \$35.33 \times 8$ ). Since only one of seven pharmacies reported a software change was necessary on eliminating a schedule, the Australia-wide cost under either of the two schedule merging arrangements was estimated to be \$201,119 ( $= \$282.64 \times 4981 \times [1/7]$ ).

Three of the seven pharmacies reported that no costs of returning stock for relabelling etc would be incurred if Pharmacy Medicines (S2) were eliminated, and three reported that no costs would be incurred if Pharmacist Only (S3) Medicines were eliminated. For pharmacies reporting that costs would be incurred two reported that this would be one week of pharmacy assistant time for each schedule merging scenario. The other two pharmacies reported that between three hours' and two days' work would be required. Therefore, the cost of sending back stock was estimated using an approximate midpoint of these estimates - five days work for four in seven pharmacies. Based on a cost per pharmacist hour of \$22.18, this cost was estimated to be \$2,525,224 ( $= \$22.18 \times 8 \times 5 \times 4981 \times [4/7]$ ).

The total of other costs is \$1,239,099 where the schedules are merged into Pharmacy Medicines (S2), and \$2,002,343 where the schedules are merged into Pharmacist Only (S3) Medicines.

**Table 71:** Total of Other Costs in Merged Schedules

	Merge into S2	Merge into S3
Relabelling	\$334,065	\$1,097,309
Pharmacy layout changes	\$703,915	\$703,915
Software changes	\$201,119	\$201,119
Sending back stock	\$2,525,224	\$2,525,224
Total	\$1,239,099	\$2,002,343

These costs are one-off costs, which would not likely be incurred beyond the first few months following a change in scheduling. Therefore, these costs cannot be generalised over time. Changes to software and sending back stock might only occur in the first week following a change in regulations. The pharmacies contacted expressed a range of estimates for the work required, ranging from no change to several weeks. Depending on the stock held in a pharmacy, it might be more cost-efficient to discard current stock rather than return it to the manufacturer and/or relabel it. Similarly, changes to the pharmacy layout would depend on the current store configuration.

These other costs are expected to be higher if the schedules are merged into Pharmacist Only (S3) Medicines. Since there are more Pharmacy Medicines (S2) items than Pharmacist Only (S3) Medicines items the cost of relabelling would be greater. Changes to the store layout might also be greater under this scenario. A

pharmacy might have less space behind the counter than in front of the counter. In this case, the pharmacy might incur greater reconfiguration costs if the schedules were merged into Pharmacist Only (S3) Medicines and the Pharmacy Medicines (S2) items had to be moved, since the space behind the counter might need expanding. If the schedules were merged into Pharmacy Medicines (S2), there might already be sufficient floor space to accommodate the items previously listed on Pharmacist Only (S3) Medicines.

The annual net benefits calculated in Section 4.3 have been adjusted to account for these costs, although it is important to note that this adjustment would not apply beyond the year of the analysis (the first year following a change in scheduling). The impact of including these costs is low, since these are one-off costs that would only be incurred by some pharmacies.

## 4.3 RESULTS

Annual costs and benefits were estimated for each of the following scenarios

- the Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules are kept separate (the current situation)
- the schedules are merged by eliminating Pharmacist Only (S3) ('S2 only')
- the schedules are merged by eliminating Pharmacy Medicines (S2) ('S3 only').

The results for each of these scenarios are presented below.

### 4.3.1 KEEP THE SCHEDULES SEPARATE

The table below shows the central estimate and confidence limits of the monetary benefits from avoiding temporary disabilities and deaths through positive pharmacy staff interventions. An estimated \$2.75 billion benefit is achieved by avoiding 155,613 cases of temporary disability (114,679 in Pharmacy Medicines (S2), and 40,934 in Pharmacist Only (S3) Medicines) and 2216 deaths (1265 in Pharmacy Medicines (S2), and 951 in Pharmacist Only (S3) Medicines). It is noted that more temporary disabilities and deaths are prevented from intervening in the sale of Pharmacy Medicines (S2) than in the sale of Pharmacist Only (S3) Medicines. Furthermore, \$2.68 billion benefit is attributed to preventing deaths, whilst only a small proportion of the benefit comes from preventing temporary disability.

**Table 72:** Central estimate and confidence limits of the monetary benefits from avoiding temporary disabilities and deaths through positive pharmacy staff interventions

	Central estimate	Lower 95% confidence interval	Upper 95% confidence interval
S2	\$1,576,609,989	\$118,638,364	\$7,312,662,173
S3	\$1,170,716,694	\$33,226,726	\$6,379,055,258
Total	\$2,747,326,683	\$151,865,090	\$13,691,717,431

Producer costs are presented in the table below. The annual cost of staff time for pharmacists and pharmacist assistants is estimated to be \$134 million, equating to 5.1 million staff hours. These are the costs involved in dispensing all Pharmacist Only (S3) and Pharmacy Medicines (S2) products – only a small proportion of those sales were accompanied by positive interventions generating the benefits above.

**Table 73:** Producer costs by schedule

	Staff costs	Staff hours	Pharmacist hours	Equivalent number of pharmacists
S2	\$81,434,990	3,649,839	38,009	22
S3	\$52,249,817	1,480,295	1,477,131	839
Total	\$133,684,807	5,130,134	1,515,140	861



The calculation of net benefit is presented in Table 74. This shows that under the current situation of separate schedules, the monetary benefits from avoiding temporary disabilities and deaths far outweigh production costs. The central estimate is that a producer cost of \$134 million generates \$2.75 billion benefit, or a net benefit of \$2.61 billion.

**Table 74:** Calculation of net benefit

	Producer costs	Benefits	Net benefits
S2	\$81,434,990	\$1,576,609,989	\$1,495,174,999
S3	\$52,249,817	\$1,170,716,694	\$1,118,466,878
Total	\$133,684,807	\$2,747,326,683	\$2,613,641,877

#### 4.3.2 MERGE INTO PHARMACY MEDICINES (S2)

It is estimated that if the schedules are merged into Pharmacy Medicines (S2) (Pharmacist Only (S3) Medicines schedule is eliminated), then an estimated \$2.62 billion benefit is achieved from avoiding 151,008 cases of temporary disability (114,679 from current Pharmacy Medicines (S2) products, and 36,329 from Pharmacist Only (S3) Medicines products shifting into Pharmacy Medicines (S2)) and 2109 deaths (1265 from current Pharmacy Medicines (S2) products, and 844 from Pharmacist Only (S3) Medicines products shifting into Pharmacy Medicines (S2)). Of this benefit, \$2.55 billion is attributed to preventing deaths.

These benefits represent a reduction in the numbers of cases of temporary disability and deaths avoided relative to current scheduling arrangements (4605 disabilities and 107 deaths, respectively). Therefore, all other factors held equal, merging the schedules into a single Pharmacy Medicines (S2) schedule is predicted to reduce population health.

**Table 75:** Central estimate and confidence limits of the monetary benefits from avoiding temporary disabilities and deaths through positive pharmacy staff interventions

	Central estimate	Lower 95% confidence interval	Upper 95% confidence interval
S2 items remaining in S2	\$1,576,609,989	\$118,638,364	\$7,312,662,173
S3 items shifting to S2	\$1,042,403,619	\$29,488,432	\$5,661,356,316
Total	\$2,619,013,608	\$148,126,796	\$12,974,018,489

When Pharmacist Only (S3) Medicines products merge into the Pharmacy Medicines (S2) schedule there are two effects that reduce producer costs. First, the probability of a positive intervention falls for these products (products sold on the Pharmacy Medicines (S2) schedule are associated with a lower rate of positive intervention). Second, the cost of staff time for non-positive interventions falls for these products since the time of involvement per pharmacist assistant in a Pharmacy Medicines (S2) product sale (3.299 minutes  $\times$  \$22.18 per hour = \$1.22) is 53% lower than for a pharmacist in a Pharmacist Only (S3) Medicines product sale (4.431 minutes  $\times$  \$35.33 per hour = \$2.61).

Producer costs are presented in Table 76. The annual cost of staff time for pharmacists and pharmacist assistants is estimated to be \$106 million, equating to 4.8 million staff hours. This is equivalent to a producer cost decrease of \$27 million, or 833 fewer pharmacists.

**Table 76:** Producer costs by Schedule

	Staff costs	Staff hours	Pharmacist hours	Equivalent number of pharmacists
S2 items remaining in S2	\$81,434,990	3,649,839	38,009	22
S3 items shifting to S2	\$24,792,122	1,111,159	11,571	7
Total	\$106,227,112	4,760,998	49,580	28

The calculation of net benefit is presented in Table 77. The reduced numbers of temporary disabilities and deaths avoided are accounted for as a reduction in benefits (the monetary valuation of health gains). Under a situation where Pharmacist Only (S3) is eliminated and merged into Pharmacy Medicines (S2), a production cost of \$106 million generates \$2.62 billion benefit, or a net benefit of \$2.51 billion. Compared with the current system of separate schedules, this represents a reduction of \$100.9 million in net benefit (a 3.9% decrease).

**Table 77:** Calculation of net benefit

	Production costs	Benefits	Net benefits
S2 items remaining in S2	\$81,434,990	\$1,576,609,989	\$1,495,174,999
S3 items shifting to S2	\$24,792,122	\$1,042,403,619	\$1,017,611,498
Total	\$106,227,112	\$2,619,013,608	\$2,512,786,497

If the other costs estimated in Section 4.2.6 are taken into account, this has a small effect of reducing the net benefits by \$1,239,099 to \$2,511,547,398.

### **4.3.3 MERGE INTO PHARMACIST ONLY (S3) MEDICINES**

It is estimated that if the schedules are merged into Pharmacist Only (S3) Medicines (Pharmacy Medicines (S2) is eliminated), then an estimated \$2.95 billion benefit is achieved from avoiding 170,151 cases of temporary disability (129,217 from Pharmacy Medicines (S2) products shifting into Pharmacist Only (S3) Medicines, and 40,934 from current Pharmacist Only (S3) Medicines products) and 2376 deaths (1425 from Pharmacy Medicines (S2) products shifting into Pharmacist Only (S3) Medicines, and 951 from current Pharmacist Only (S3) Medicines products) (Table 78). Of this benefit, \$2.87 billion is attributed to preventing deaths.

These benefits represent an increase in the numbers of cases of temporary disability and deaths avoided relative to current scheduling arrangements (14,538 disabilities and 160 deaths, respectively). Therefore, all other factors held equal, merging the

schedules into a single Pharmacist Only (S3) Medicines schedule is predicted to increase population health.

**Table 78:** Central estimate and confidence limits of the monetary benefits from avoiding temporary disabilities and deaths through positive pharmacy staff interventions

	Central estimate	Lower 95% confidence interval	Upper 95% confidence interval
S2 items shifting to S3	\$1,776,479,289	\$133,678,334	\$8,239,699,725
S3 items remaining in S3	\$1,174,550,747	\$33,226,726	\$6,379,055,258
Total	\$2,951,030,036	\$166,905,060	\$14,618,754,983

When Pharmacy Medicines (S2) merge into Pharmacist Only (S3) Medicines, there are two effects that increase producer costs. First, the probability of a positive intervention increases for these products (products sold on the Pharmacist Only (S3) Medicines schedule are associated with a higher rate of positive intervention). Second, the cost of staff time for non-positive interventions increases for these products, since the time of involvement per pharmacist in a Pharmacist Only (S3) Medicines product sale is 114% higher than for a pharmacist assistant in an Pharmacy Medicines (S2) product sale.

Production costs are presented in Table 79. The annual cost of staff time for pharmacists and pharmacist assistants is estimated to be \$224 million, equating to 6.3 million staff hours. This is equivalent to a producer cost increase of \$90 million, or 2735 additional pharmacists.

**Table 79:** Producer costs by Schedule

	Staff costs	Staff hours	Pharmacist hours	Equivalent number of pharmacists
S2 items shifting to S3	\$171,625,621	4,862,343	4,851,952	2,757
S3 items remaining in S3	\$52,249,817	1,480,295	1,477,131	839
Total	\$223,875,437	6,342,638	6,329,083	3,596

The calculation of net benefit is presented Table 80. The reduced numbers of temporary disabilities and deaths avoided are accounted for as a reduction in benefits (the monetary valuation of health gains). Under a situation where Pharmacy Medicines (S2) is eliminated and merged into Pharmacist Only (S3) Medicines, a production cost of \$224 million generates \$2.95 billion benefit, or a net benefit of \$2.73 billion. Compared with the current system of separate schedules, this represents an increase of \$113.5 million in net benefit (a 4.3% increase).

**Table 80:** Calculation of net benefit

	Production costs	Benefits	Net benefits
S2 items shifting to S3	\$171,625,621	\$1,776,479,289	\$1,604,853,668
S3 items remaining in S3	\$52,249,817	\$1,174,550,747	\$1,122,300,930
Total	\$223,875,438	\$2,951,030,036	\$2,727,154,598

If the other costs estimated in Section 4.2.6 are taken into account, this has a small effect of reducing the net benefits by \$2,002,343 to \$2,725,152,255. The net benefits still remain greater than under the current schedules or in the scenario where the schedules are merged into Pharmacy Medicines (S2).

#### 4.3.4 LIMITATIONS AND SENSITIVITY ANALYSIS

It is important to set out the limitations of this analysis, so that it can be properly assessed by the reader. These limitations are as follows:

- There is no analysis of what would happen if Pharmacist Only (S3) Medicines products were to shift into an S4 market.
- There is no analysis of what would happen if Pharmacy Medicines (S2) products were to shift into an open-seller market.
- There are limited data available to calculate producer time costs.
- There are limitations relating to the epidemiological study, which have been discussed elsewhere.
- The benefits are highly dependent on the calculation of a statistical life. This value can arguably vary widely and is dependent on the source used.
- The benefits associated with preventing illicit drug use were not collected in this project and are therefore not included in the cost-benefit analysis.

Several of these limitations have been tested in sensitivity analyses. The impact of using the value of a statistical life before any age adjustment (\$1.9 million) has been tested. The impact of varying the estimated staff time involved in all sales not accompanied by a positive intervention has also been tested. In the sensitivity analyses, this is assumed to be either zero or the same as for positive interventions. These analyses enable lower and upper limits of producer cost impact to be calculated.

A sensitivity analysis on producer cost using a more complex method for estimating the time per intervention has also been included. In the year ending April 2003, 85,882,450 transactions were performed (an average of 235,294 transaction per day) in Australia's 4981 pharmacies. Assuming that the average pharmacy is open for 12 hours per day and that there is a constant stream of transactions (this might overestimate the estimated intervention time), the estimated intervention time per sale is 4 minutes ( $= 235,294 / [4981 \times 12]$ ). This estimate is applied to all non-positive interventions. The assumption that only pharmacy assistants engage in Pharmacy Medicines (S2) sales and only pharmacists engage in Pharmacist Only (S3) Medicines sales is maintained (Table 81).

**Table 81:** Results of the sensitivity analysis

	<b>Producer costs</b>	<b>Benefits</b>	<b>Net benefits</b>	<b>Impact</b>
<b>Base case</b>				
Keep schedules separate	\$133,684,807	\$2,747,326,683	\$2,613,641,877	
Merge into S2	\$106,227,112	\$2,619,013,609	\$2,512,786,497	-\$100,855,380
Merge into S3	\$223,875,437	\$2,951,030,035	\$2,727,154,598	\$113,512,721
<b>VOSL = \$1.9m</b>				
Keep schedules separate	\$133,684,807	\$3,983,156,615	\$3,849,471,809	
Merge into S2	\$106,227,112	\$3,795,698,275	\$3,689,471,163	-\$160,000,645
Merge into S3	\$223,875,437	\$4,276,884,846	\$4,053,009,409	\$203,537,600
<b>Staff time for non-positive interventions</b>				
<b>No staff time</b>				
Keep schedules separate	\$2,121,007	\$2,747,326,683	\$2,745,205,676	
Merge into S2	\$2,266,599	\$2,619,013,609	\$2,616,747,010	-\$128,458,666
Merge into S3	\$1,642,777	\$2,951,030,035	\$2,949,387,258	\$204,181,582
<b>Staff time equivalent to positive interventions</b>				
Keep schedules separate	\$289,284,171	\$2,747,326,683	\$2,458,042,512	
Merge into S2	\$315,559,297	\$2,619,013,609	\$2,303,454,312	-\$154,588,200
Merge into S3	\$202,977,936	\$2,951,030,035	\$2,748,052,099	\$290,009,587
<b>Alternative method</b>				
Keep schedules separate	\$145,574,589	\$2,747,326,683	\$2,601,752,094	
Merge into S2	\$128,317,539	\$2,619,013,609	\$2,490,696,070	-\$111,056,025
Merge into S3	\$202,259,036	\$2,951,030,035	\$2,748,771,000	\$147,018,905

The sensitivity analysis shows that for larger values of a statistical life, there is a greater decrease in the net benefit from eliminating Pharmacist Only (S3) Medicines (or a greater increase in net benefit from eliminating Pharmacy Medicines (S2)). It is also noted that the base case assumed staff time in sales not accompanied by a positive intervention lead to more conservative estimates of the effect of merging schedules than the three alternatives presented in the sensitivity analysis. The reduction in net benefit if Pharmacist Only (S3) Medicines were eliminated (or improvement in net benefit if Pharmacy Medicines (S2) were eliminated) is lowest in the base case analysis presented in this report. The impacts of merging the schedules are greatest when staff time is assumed to be equivalent to positive interventions.

No data were collected to enable an analysis of what would happen if Pharmacy Medicines (S2) products were to shift into an open-seller market. However, it is likely that if Pharmacy Medicines (S2) were eliminated then, to the extent that shifts into an open-seller market did occur, producer costs would be lower than those presented in this report. In an efficient system producer costs would be zero, since no advice has to be provided with the sale. However, where these products are associated with some

health risk, there would be a reduction in benefits from the change in scheduling. The net effect is ambiguous and cannot be estimated without additional data.

Similarly, no data were collected to enable an analysis of what would happen if Pharmacist Only (S3) Medicines products were to shift into the Prescription Medicines (S4) market. However, it is likely that if Pharmacist Only (S3) Medicines were eliminated then, to the extent that shifts into the prescription (S4) market did occur, both the producer costs and benefits would be higher than those presented in this report. Costs would increase since more detailed advice might have to be provided within the pharmacy, and there would be an additional cost of a GP visit for be given the prescription. There would also be a likely increase in benefit, since advice would be provided to the individual at the GP and pharmacy levels, increasing the likelihood of a positive intervention. Again, the net effect is ambiguous, and additional data would be required to estimate this.

The benefits of scheduling arrangements associated with preventing illicit drug use have not been considered in this report. Pseudoephedrine-containing products, such as OTC oral decongestants used in the relief of cold and flu and allergic symptoms, can be used for the production of methylamphetamine (more commonly known as 'speed'). The current listing of these products in the Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules is likely to limit their purchase, compared to if they were not scheduled and were more widely available (ie, in supermarkets). Current scheduling arrangements are proposed to limit the availability of methylamphetamine, and there are likely to be health benefits from this.

The impact of these health benefits from merging the schedules is less clear. Lower regulation of these products is likely to increase the volume of pseudoephedrine products purchased for illicit diversion and the availability of methylamphetamine. Merging the schedules into Pharmacist Only (S3) Medicines might lead to greater health benefits than estimated in this report. There would likely be a reduction in methylamphetamine availability and use (and an increase in cost) if pseudoephedrine products listed on Pharmacy Medicines (S2) shifted into Pharmacist Only (S3) Medicines. However, as previously stated, some Pharmacy Medicines (S2) products might be descheduled if Pharmacy Medicines (S2) were eliminated. Although data were not available to consider the subsequent health impact, this would be likely to at least partly offset any increase in health benefits.

Merging the schedules into Pharmacy Medicines (S2) (eliminating Pharmacist Only (S3) Medicines) would reduce health benefits if lower regulation increased the volume of pseudoephedrine products purchased and subsequent availability of methylamphetamine. This would be at least partly offset by some of these products being instead listed on prescription (S4), requiring a doctor's prescription and thus limiting their purchase.

## 4.4 CONCLUSION

Under the current situation in which the Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules are separate and distinct, our epidemiological model suggests a central estimate of some \$2.75 billion in benefit annually, with a lower-bound estimate of \$152 million and an upper-bound estimate of \$13.69 billion. This is the benefit derived from preventing cases of temporary disability and death. This outweighs the costs required to deliver these benefits in terms of the pharmacy staff time involved in providing positive interventions. Our central estimate of current net benefit per year is \$2.61 billion.

We examined the situations in which the Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules are merged into a single schedule. In the situation in which the Pharmacist Only (S3) schedule is eliminated, Pharmacist Only (S3) products become Pharmacy Medicines (S2) and net benefits are predicted to decrease by \$100.9 million to \$2.51 billion. In the situation in which the Pharmacy Medicines (S2) schedule is eliminated, Pharmacy Medicines (S2) products become Pharmacist Only (S3), and net benefit is predicted to increase by \$113.5 million to \$2.73 billion. It would therefore appear that, given the evidence available, merging the two schedules by eliminating Pharmacy Medicines (S2) would confer the greatest net benefit. However, it is estimated that in achieving this net benefit, producer costs will increase by \$90 million. This increase in within-pharmacy activity would require an additional 2735 pharmacists in Australia. Any decision on changing the Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules would therefore require consideration of potential manpower constraints.

There are a number of qualifications to the analyses. First, it must be kept in mind that the epidemiological evidence was self-reported and that pharmacies participating in the survey may have contributed to a pro-selective bias for which it would have been impossible to control in weighting the results of the survey (see Section 3A.7, c.f. Section 3A.8.3 Hawthorne Effect).

Second, there is a lack of evidence for the impact of Pharmacist Only (S3) and Pharmacy Medicines (S2) products shifting into the unscheduled or S4 market following a merger. We assumed that if Pharmacy Medicines (S2) were eliminated, all Pharmacy Medicines (S2) products would shift into the Pharmacist Only (S3) schedule. However, it is possible that some might become open sellers. Likewise, if the Pharmacist Only (S3) schedule were eliminated, some high-risk products might shift to the Prescription Medicines (S4) schedule. Therefore, our net benefit estimates are subject to some degree of uncertainty.

Third, limited data were available to calculate producer time costs. Therefore, simplifying assumptions were made regarding the extent of staff involvement in sales not accompanied by a positive intervention.

Fourth, gross and net benefit estimates are dependent on the value of a statistical life and the assumptions required to generate from this the value of a statistical life-year.

There are a variety of estimates in the literature. Depending on which of these is selected, the estimates of benefit will differ.

For these reasons, any use of this analysis to make policy decisions that will impact on the provision of health services in Australia should be made with extreme caution.

The analysis suggests that there would be a small positive gain from eliminating the Pharmacy Medicines (S2) schedule. However, given the limitations of the analysis and the potential requirement for a large increase in the number of pharmacists to cope with this change in legislation, we recommend that there should be no change to scheduling at the current time.

Instead, it is recommended that the impact of rescheduling products as Prescription Medicines (S4) or unscheduled products, the increase in the demand for pharmacists, and the impact on within-pharmacy resources be further explored to determine whether such a change would truly confer an improvement in the cost-effectiveness of the scheduling of pharmaceuticals in Australia.

**Recommendation 23:**

That, from a cost-benefit perspective, there be no change to the current scheduling arrangements.



## **SECTION 5**

### **RISK MANAGEMENT ASSESSMENT REPORT**

***Are the Standards Drawn Up in a Way  
that Reflects Risk Management?***

## 5.1 BACKGROUND

### 5.1.1 THE STANDARDS

In 1999, the Pharmaceutical Society of Australia published ‘Standards for the Provision of *Pharmacist Only* and *Pharmacy Medicines* in Community Pharmacy’ (“*Standards*”). These *Standards* were developed following a recommendation by the Industry Commission in its 1996 Report on the Pharmaceutical Industry regarding retention of current scheduling for relevant products *pending further research into the role of pharmacist counselling in ensuring health outcomes* [2]. In response to this recommendation the Commonwealth Department of Health and Family Services commissioned research, *inter alia*, to develop a model to optimise pharmacy practices and to ensure that all community pharmacies provide appropriate and consistent professional advice.

The *Standards* were developed, tested and implemented in consultation with pharmacists and their staff, regulatory authorities, the Council of Pharmacy Registering Authorities, the Consumers Health Forum and Pharmacy professional organisations. An advisory board with representation from all of the above stakeholder groups had oversight of all aspects of the project. Although at the time of the development of the *Standards*, the theoretical framework associated with the general area of risk had not been conceived, nevertheless, the *Standards* may reflect the overall medicines risk-management structure elucidated in Australia’s National Medicines Policy and its National Strategy for Quality Use of Medicines. The intention, therefore, was to provide pharmacists and their staff with an assessment tool that took risk-management into account. This tool guided communication and consultation with consumers and patients with the ability to assess medical and pharmaceutical risk. The tool also assisted pharmacy staff to understand the medicine, consumer, pharmacist and health environment components of medication appropriate use and misadventure assessing certain components of risk. The protocols were provided as tools to enable appropriate risk assessment and to direct referral to relevant pharmacy or medical expertise depending on the risk evaluation. The strategy took into account that costs to the healthcare system through an unnecessary referral to medical practitioners or the unnecessary purchase of a medicine needed to be balanced and with the associated higher level of professional pharmacy services.

### 5.1.2 COMPETITION POLICY

Community pharmacies operate in a commercial environment where they are required to continually balance the often competing needs of commercial exigencies and consumer demands. Competition policy is relevant to this debate as it provides an understanding from a policy perspective of those competing economic needs and how they are viewed from a government policy position.

At about the same time as the Industry Commission’s work, in response to obligations under the Competition Principles Agreement of 1995, all Heads of Government

agreed to a review legislation governing drugs, poisons and controlled substances chaired by Ms Rhonda Galbally. Under this review, an options paper was published in February 2000, and final reports were published in January 2001 [1].

In her 2000 options paper, Galbally said *inter alia*:

Given the wide and increasing range of OTC medicines and the potential for harm, appropriate counselling and advice has the potential to prevent some significant hospital and medical costs which could result from inappropriate selection and use of medicines or drug interactions. However, despite a number of standards on the way in which counselling should be delivered, there appears to be considerable disparity in the level of counselling delivered. Further, such counselling is often initiated by the consumer which could lead one to conclude that there is no need to mandate that supply only be permitted where that counselling is available (pp xii-xiii).

The two key reasons for restricting access to OTC medicines are to improve outcomes by redressing the information asymmetry between consumers and professions; and to prevent abuse or diversion of products to the illicit market. While restrictions on access so that counselling can be provided can also affect the level of accidental poisoning, this is more likely to be influenced by packaging and labelling controls. With a few exceptions (most notably paracetamol) the toxicity of OTC medicines is generally not such as to lead to their involvement in successful suicides. Therefore whether there are one or two levels of restrictions on access for OTC medicines is likely to have only minimal impact on deliberate poisonings... the restrictions on access are intended to complement requirements of the Pharmacy Acts to provide a mechanism to redress consumers' information and understanding deficit in relation to OTC medicines. However, counselling does not always occur when it 'should'. This is in part because counselling is mandated to occur when the risk may be low. This dilutes the effectiveness and so it becomes cost-ineffective and possibly ineffective altogether.

A risk-based code of practice which would be developed in consultation with all stakeholders and supported by ongoing training, could ensure more effective counselling is provided when necessary across all Pharmacist Only (S3) or Pharmacy Medicines (S2) sales, not because they are Pharmacy Medicines (S2) or Pharmacist Only (S3) Medicines but because, for that consumer, the risk-based triggers were activated (p 37).

It should be possible to focus counselling on situations which are higher risk than others. Indicators of risk would be specific to the product type or situation and could be defined for each product group or situation. They might include the drug newly switched to OTC use; side effects which may be problematic in certain groups, e.g. pseudoephedrine in middle aged males, or loperamide in children; accelerating use in a client; the consumer is not known to the staff; the consumer is known to be taking prescribed medicines containing the same active ingredient or ingredients which have similar pharmacological actions. There may be identifiable risk factors which makes counselling particularly important and likely to be effective. These could include a recent admission to

hospital during which medications might have been changed; the age of the patient and the number of drugs they are taking; recently accelerating (or cessation of) drug use, perhaps without having returned to the doctor; therapy with drugs that are known to be problematic, e.g. anticonvulsants; and purchase of an OTC medicine which is contraindicated. This risk-based approach would blur the boundary between Pharmacist Only (S3) and Pharmacy Medicines (S2). Both will give rise to counselling when risk factors warrant it (p 136).

In her 2001 final reports, Galbally recommended *inter alia*:

That all Commonwealth, State and Territory governments agree

... that funds be allocated... to commission... 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

... that the National Co-ordinating Committee on Therapeutic Goods present the Australian Health Ministers Council with a report by the end of July 2004 [that] 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 system for meeting the objectives of restricting access to OTC medicines ... (Part A, Recommendation 5).

Further, in her 2001 final reports Galbally said *inter alia*:

The Review noted that the Industry Commission questioned the need for two OTC schedules and recommended that Pharmacist Only (S3) Pharmacy Medicines (S2) only be retained pending further research into the role of pharmacy counselling in ensuring improved health outcomes. The Review was similarly hampered by lack of data, which would have enabled it to assess the net benefit to the community as a whole of retaining both OTC schedules...

... the Review considered that the triggers which should elicit pharmacist intervention should focus more on the particular consumer than on the substance... that a single OTC schedule would enable pharmacists' professional judgement and expertise to be more validly used in establishing the level of risk associated with a consumer's use of a particular product than the present system of two OTC schedules... The system would rely on a pharmacists risk-based assessment of the nature and extent of the professional intervention needed to support the safe and effective use of medicines by particular consumers... The Review considered it would be desirable to move away from this 'two schedule approach' in which risk, in the first instance, is presumed based on substance characteristics... This would reduce the current level of regulation associated with Pharmacist Only (S3) Pharmacy Medicines (S2) which, at present, is non-discretionary (Part A, pp 34- ).

... in 1996, the Industry Commission, in its Review of the Pharmaceutical Industry, found difficulty in supporting the retention of both Pharmacist Only (S3) or Pharmacy Medicines (S2) schedules. The Commission recommended that

*“... both Schedule 2 Pharmacy only and Schedule 3 Pharmacists only be retained, pending further research into the role of pharmacist counselling in ensuring improved health outcomes and monitoring the extent of such counselling...”*

The Review is concerned to note that while some effort has been made to examine the extent to which counselling occurs, no effort has been made to undertake any research to evaluate the effectiveness of counselling in delivering improved health outcomes...

The Review noted that the Third Community Pharmacy Agreement provides that, after a phase-in period, a financial incentive will be paid to pharmacies which comply with the recently developed Pharmacy Guild Quality of Care Standards... These standards are based on a limited risk-based approach, which relies heavily on Schedules 2 and 3 to identify the level of risk for OTC medicines, and thus the extent to which counselling is required... Evaluation of the extent to which this initiative improves health outcomes should provide the basis on which to establish whether there is a net benefit to the community as a whole in retaining both Schedules 2 and 3.

The Review believed that an evaluation strategy (including collection of baseline data) should be put in place immediately to establish the extent to which these standards, their associated incentives and the legislative controls deliver improved health outcomes. (Part B, pp 56- )

It is clear that both the Industry Commission and Galbally were concerned about the lack of information available regarding improved health outcomes resulting from the restriction of distribution methods. There is also a consistent view that there should be mandated counselling for certain OTC medicines.

## 5.2 RISK MANAGEMENT

### 5.2.1 BACKGROUND

There have been countless definitions of what the term ‘risk-management’ means. A common attribute that tends to be encapsulated in its meaning, however formally defined, is a focus on maximising positive outcomes and limiting adverse effects. Additionally, a risk-management process requires a need to be systematic in the way that an organisation goes about managing its risk.

The Australian/New Zealand Risk Management Standard AS/NZS 4360:2004 will be used to determine the best-practice aspects of an effective risk-management plan [3].

‘Risk’ itself should be broadly defined to include anything that will have an impact on the objectives of the organisation [3, 4].

A number of significant advantages have been identified where an organisation has adopted a risk-management process and where the culture of the organisation is clearly reflected through its risk-management system. These include:

- a more confident and rigorous basis for decision making and planning
- a more clear identification of opportunities and threats
- having a greater understanding of how to interpret variability and uncertainty
- reinforcement of the advantages of a proactive management approach
- more effective allocation and use of resources
- improved incident management
- greater stakeholder confidence and trust
- improved compliance with legislative frameworks; and
- better corporate governance.

What should a good risk-management process include? There are a number of key elements that should exist in any effective risk-management process. There should be evidence of the following:

#### **Communication and consultation**

The system should provide evidence that communication and consultation occurs at each step in the risk-management process and concerning the process as a whole.

#### **Context within which risk is managed**

An understanding of the external and internal environments enables an organisation to clarify its objectives and to prioritise the elements for structuring risk identification and assessment processes. The requirements of the organisation and the key stakeholders are used to derive a set of criteria for the analysis.

### **Identifying risks**

It is important that an effective risk-management process demonstrates an understanding of the components that might make up a relevant risk. These could include sources, consequences or causes of a particular risk. By using the elements identified while establishing the context, it provides the organisation with confidence that risk identification has most likely been thorough. Finally, in order to identify risks effectively, the process needs to articulate by what methods information will be collected about the risks.

### **Analysing risks**

An effective risk-management process should demonstrate for example, that low-impact risks are excluded or similar risks are combined before proceeding to a more sophisticated risk assessment. In the case of community pharmacy, for example, a qualitative analysis is most appropriate (informed by factual information and data where available).

Another component of an effective risk-analysis system is evidence that key questions have been tested as part of the risk-management process. For example, does the system measure the consequences of undesirable risks, positive outcomes, likelihood of occurrence of risks, factors that might increase or decrease those likelihoods, how confident can the 'expert' (that is, pharmacist or pharmacy assistant) be in their judgement?

Good systems have processes in place to document the risk-analysis. The focus here is on quality information summary rather than any particular level of detail. In fact detailed documentation may not be required for very low risks, although there should be a documented framework of the rationale for screening very low risks.

### **Risk evaluation**

There should be evidence that where qualitative risk-analysis sources need to be relied upon more strongly, priorities are clearly defined. There should be evidence that the risk-management process sets treatment on the level of risk. It is often the case that different levels of risk define different actions required

A relevant concept that should be incorporated into a best evidence risk-management process is that of 'intolerable' risk rather than considering risks as either 'acceptable' or "unacceptable". Risks should be evaluated by some method that allows categories to be observed involving intolerable risk, as low as is reasonably possible, and negligible risk.

The evaluation process needs to demonstrate that risk-evaluation decisions are also linked to the resource implication. For example, when risk is close to the intolerable level, the expectation is that risk will be reduced unless the cost of reducing the risk is grossly disproportionate to the benefits gained. When risks are close to the negligible level then action may only be taken to reduce risk where benefits exceed the cost of reduction [4].

The evaluation should be informed by case studies for example, that assist the process.

### **Risk treatment**

An effective risk-management process should provide evidence of how the decision to treat a risk in a particular way was arrived at. For example, in relation to community pharmacy, the assessment of risk-treatment options should balance the costs (in its broadest meaning) associated with implementing an option against the benefits derived from it. Once again, in community pharmacy, an integral component to the risk assessment and treatment decision making in regard to appropriate choice of a Pharmacy Medicines (S2)/ Pharmacist Only (S3) Medicines product is that rare but severe risks may play a far more important part in the decision making process than in other (non-pharmacy) examples of risk assessment and treatment.

Evidence should be available to demonstrate that decisions have taken into account the need to consider carefully rare but severe risks that may warrant risk treatment actions that are not justifiable on strictly economic grounds. Legal and social responsibility requirements may override simple financial cost benefit analyses.

### **Monitoring and review**

Monitoring requires routine surveillance of actual performance for comparison with expected or required performance [4]. Review involves periodic investigation of the current situation, usually with a specific focus.

Monitoring and review are an integral part of an effective risk-management process. By this is meant a process by which the risk-management plan and system as a whole is monitored to assess the effectiveness and appropriateness of the strategies and management systems set up to implement risk treatments.

Risk management can take the form of a continuous monitoring process, a periodic line management review or a third party external audit. A good system will have developed performance indicators that allow quantitative measures of the level of performance of a given activity or item. Performance indicators should reflect the relative importance of risk-management actions, with the greatest effort and focus applied to the highest risks and those processes with the greatest potential for improvements in efficiency.

### **Documentation**

Evidence of a record of the risk-management process is an essential component of an effective system. Without it the opportunities to learn from the collated information quickly diminishes. The benefits that flow include:

- to demonstrate to stakeholders that the process has been conducted properly
- to provide evidence of a systematic approach to risk identification and analysis
- to enable decisions and processes to be reviewed
- to provide a record of risks and to develop the organisation's knowledge database
- to provide decision makers with a risk-management plan for approval and subsequent implementation
- to provide an accountability mechanism and tool
- to facilitate continuing monitoring and review
- to provide an audit trail; and
- to share and communicate information [4].



### 5.2.2 METHODOLOGY

The researchers at the University of South Australia used information collected in Section 2 of this Review (p29) to suggest a number of changes to the ‘Standards for the Provision of *Pharmacist Only* and *Pharmacy Medicines* in Community Pharmacy’ (Appendix 4). This Risk Management Assessment Report was commissioned in order to assess the *Standards* in specific relation to risk-management best-practice and is to be taken in addition to those findings.

A qualitative analysis of the ‘Standards for the Provision of *Pharmacist Only* and *Pharmacy Medicines* in Community Pharmacy’ (“*Standards*”) was undertaken using, as the comparative framework, the Australian/New Zealand Standard on Risk Management AS/NZS 4360:2004. Additionally, the Census and Sample Study data from this current Review were used to provide any relevant commentary on the *Standards*. Finally, the programs offered by the Quality Care Pharmacy Program (The Pharmacy Guild of Australia and Pharmaceutical Society of Australia) and the Quality Care Pharmacy Support Centre (The University of Sydney) were examined in the context of their role in implementing the *Standards* in community pharmacy.

### 5.3 STANDARDS FOR THE PROVISION OF PHARMACIST ONLY AND PHARMACY MEDICINES IN COMMUNITY PHARMACY

#### 5.3.1 COMPONENTS OF THE STANDARDS

The *Standards* consist of four key Standards:

- Resource Management
- Professional Practice
- Pharmacy Design and Environment; and
- Rights and Needs of Customers.

Two of the Standards are further divided into parts:

Professional Practice into:

- Customer Care and Advice
- Indirect Supply; and
- Documentation.

Pharmacy Design and Environment into:

- Display and Storage; and
- Customer Consultation.

The *Standards* are claimed to be designed as a self assessment tool and an educative resource for community pharmacists [6]. They intend to define and describe what professional activities are required in the provision of Pharmacist Only (S3) and Pharmacy Medicines (S2).

The introduction to the *Standards* provides the following commentary to their structure and intent:

“The standards are followed by criteria, which are clearly defined process guides describing how each standard is achieved in practice. They describe key components of the standard and specify the appropriate level of performance required by expressing what a competent professional would do in terms of observable ‘outputs’. Except where marked ‘desirable’, all criteria are to be regarded as minimum standards, and must be met in order to achieve the required level of practice.

Each criterion is followed by a number of indicators which will assist in deciding the degree to which an individual criterion has been met. These are of central importance and describe the processes (inputs) which, when delivered consistently, indicate the achievement of a criterion.

The footnotes (Guidelines) are a tool to assist pharmacy staff interpret and implement the standards..... [6, p5].”

The *Standards* also provide detailed Standard Operating Procedures for Standards 1 (Resource Management), 2.1 (Customer Care and Advice) and 2.2 (Indirect Supply). These operating procedures spell out in a step-by-step process what actions a pharmacy assistant and pharmacist should undertake to meet the criterion under the Standard.

Finally, the *Standards* provide Protocols (see Appendix 4 of the *Standards*) for both pharmacists and pharmacy assistants as a flow-chart guide to assist pharmacist staff deliver appropriate and consistent professional service and advice to customers who seek treatment for symptoms or to self medicate with Pharmacist Only (S3) or Pharmacy Medicines (S2).

## 5.4 QUALITY CARE PHARMACY PROGRAM

The Quality Care Pharmacy Program ('the Program') operated by The Pharmacy Guild of Australia and supported by the Pharmaceutical Society of Australia aims to raise the standard of customer service and care in individual community pharmacies in Australia.

Standards under the Program focus on (a) Pharmacy Standards and (b) Team Standards. Pharmacy Standards are further broken down into standards focussing on:

- Professional Services
- Retail Skills
- Business Management; and
- Loss Prevention.

Team Standards focus on customer standards to be achieved by pharmacy assistants, although they are applicable to all pharmacy staff.

Community pharmacies approach The Pharmacy Guild of Australia to participate in a voluntary Pharmacy Accreditation Audit which involves trained assessors undertaking a third-party audit of the community pharmacy based on the abovementioned standards. Approximately 90% of Australian community pharmacies participate in the voluntary accreditation Program. That is, approximately 4300 pharmacies in Australia are involved. An external accreditation audit takes place approximately once in every three years. Between external audits, the community pharmacy is expected to use the standards within the Program to maintain the standards to their appropriate levels.

For those parties that participate in the accreditation Program, The Pharmacy Guild of Australia has delegated to The University of Sydney the assessment and monitoring of that part of the Professional Services standards that focus on the provision of Pharmacist Only (S3) and Pharmacy Medicines (S2). As previously mentioned, this component is separately covered under the *Standards* described in 5.3 above.

The Quality Care Pharmacy Support Centre (QCPSC) of The University of Sydney coordinates the national monitoring of the *Standards* in community pharmacies. Via a 'mystery shopper' program, community pharmacies are visited approximately once per year to be assessed on compliance with the *Standards* in respect of a request for a sale of a Pharmacist Only (S3) or Pharmacy Medicine (S2). The community pharmacy is given notice that some time within the following four weeks a mystery shopper will visit the pharmacy. The pharmacy is aware that this person is sent by the QCPSC as a part of the assessment of compliance with the *Standards*.

The mystery shopper may present a scenario that reflects a symptom-based approach for the need for a Pharmacist Only (S3) or Pharmacy Medicine (S2), or it may be a direct request to purchase a Pharmacist Only (S3) or Pharmacy Medicine (S2). The

intervention ('counselling') assessed may involve a pharmacy assistant or a pharmacist or both.

## 5.5 ASSESSMENT OF THE STANDARDS

The *Standards* form part of a quality improvement process that is inherent in all health practices. It may be useful to review the essential elements of a best-practice risk-management process and comment on whether the *Standards* meet these elements. In doing so, it is important to distinguish between the uses of the term "risk-management" in the context of the *Standards* as a "process" and not confuse that broader assessment with the elemental component of risk assessment where a pharmacist or pharmacy assistant focuses on a customer request as an intervention within the broader risk-management framework.

### **Communication and consultation**

A significant number of the *Standards* focus on this element. Note in particular, criteria 2.1.1, 2.1.2, 2.1.3, 2.1.6, 3.2.1, 4.1 and 4.2. Additionally, the standard operating procedures provide further guidance for this element in 2.1.1, 2.1.2, 2.1.3, and 2.1.6.

### **Context within which risk is managed**

An understanding of the external and internal environments is particularly reflected in Standards 1, 2.1, 2.2, and 4. A component that could usefully gain from a greater focus from the assessment of environments is the development of a more clearly defined set of criteria upon which risk is to be evaluated. The risk criteria must correspond to the type of risks and the way in which risk levels are expressed. This could occur more effectively in respect of Standards 2.1 and 4.

This could encapsulate the issues raised by Galbally [2] in her comments regarding a need for counselling to focus more on the customer risks than on the product sale. It is suggested that Galbally's comments can be accommodated within the current framework. If a system can be established whereby pharmacists and pharmacy assistants can easily tap into information on Pharmacist Only (S3) and Pharmacy Medicine (S2) that identifies high risk user groups, this would enable the counselling intervention to be more focussed to those who would benefit substantially from this risk-management improvement.

### **Identifying risks**

Standards 2 and 3 focus particularly on identifying risks in the context of community pharmacy. The protocols also provide guidance on what methods can be used to collect information. The protocols would benefit from a review to ensure that community pharmacies (via the Standard) can be provided with greater certainty in relation to Standard 2.1 and the protocols. For example, clearer guidance within a revised set of protocols that marry in with the standard operating procedures for Standard 2.1 and the provision of a consistent set of guidelines for community pharmacies for interview formats would assist risk identification.

### **Analysing risks**

It is accepted that the substantial method by which risks are identified and analysed in a community pharmacy is via a qualitative process. The *Standards* acknowledge (via 2.1) that documentation of Pharmacist Only (S3) Medicines interventions should be made subject to the requirements of the law.

In terms of best-practice risk-management, it would be prudent that a simple documentary record for Pharmacist Only (S3) Medicines interventions becomes a part of the risk-management approach to the *Standards*.

In terms of the risk assessment for documentation of Pharmacy Medicines, representatives from community pharmacy, government and consumers would need to decide the acceptable level of risk using qualitative data available from the Census and Sample Study and other sources. It may well be handled by a clearer set of guidelines for pharmacists and pharmacy assistants in the identification of risk information at the counselling intervention. If it was considered that documentation of Pharmacy Medicine interventions was not warranted, it is important that the *Standards* reflect the rationale for this decision and how the *Standards* have dealt with this area.

The Review identified data that reported interventions where counselling was successful in evaluating risk for defined 'highly significant' and 'potentially life threatening' situations (see Tables 54, 59 and 63). The data suggested further that the intervention rates for "highly significant" situations were greater for Pharmacist Only (S3) Medicines than for Pharmacy Medicines (S2).

In 8.2% of Census interventions and 7.9% of Sample Study interventions (Tables 33 and 44), a pharmacy assistant alone was reported as being involved in a Pharmacist Only (S3) Medicines product sale. However, it should be noted these interventions may have occurred under direct supervision of a pharmacist and would have thus met the legislative requirements.

It is noted that Recommendation 8 of this Review goes a long way in dealing with these risks.

### **Risk evaluation**

The changes recommended in 'Identifying risks' and 'Analysing risk' above will satisfy the risk-based evaluation process needed within the *Standards*.

### **Risk treatment**

When the *Standards* were developed the need for documentation as a process to enable risk-analysis, review and treatment was recognised. However the cost of implementing a documentation system was seen as too great in the existing community pharmacy environment. There were also concerns expressed by pharmacists and their staff on the negative impact on workload and business practice.

From a risk-based assessment, the *Standards* would benefit from a review of Standard 2.3 in respect of the documentation that might be necessary for Pharmacist Only (S3)

and Pharmacy Medicines (S2) interventions. It is not suggested that a laborious schemata of documentation is necessary to achieve best-practice in this area.

However, to reduce risk the *Standards* ought to address what type of Pharmacist Only (S3) and/or Pharmacy Medicines (S2) interventions need to be simply documented and what information ought to be collected. This might be achieved via further protocols or additions to the standard operating procedures.

Strategies are in place to develop barcode swipe systems to link medicines recommended to a patients pharmacy record. A best-practice risk-management system would need to capture data on the decision making tree for high risk interventions, related to both Pharmacist Only (S3) and Pharmacy Medicines (S2). Recommendation 8 may address this to a large extent.

### **Monitoring and review**

Discussions with the Chief Investigator, who is also actively involved in the Quality Care Pharmacy Support Centre (QCPSC) of The University of Sydney, has suggested that compliance by community pharmacies is relatively high in respect Standard 3. No data have been sighted for this view.

In respect of Standard 2.1, Benrimoj has reported a decrease over the past 12 months of those community pharmacies scoring in the 'Unsatisfactory' rating on mystery shopper visits. This was for 'direct product requests' interventions. Similarly, and also for 'direct product requests' the data have reflected an improvement in numbers of community pharmacies rated in the 'Excellent' category.

For a best-practice perspective, the *Standards* would benefit from an increased external audit scrutiny. The *Standards* generally comply with a risk-based focus, but are too heavily weighted towards self monitoring. Given the comments about the need to improve the risk-identification and analysis process and the associated documentation, more evidence could be obtained through increased external audits to enable a continuing risk improvement model to be followed.

It is noted that external accreditation review is once every three years. Additionally, a mystery shopper visit occurs on average once per year. It may well be that the an increase in the mystery shopper audit to twice per year may provide better monitoring and review data to enable an improved self assessment process for community pharmacies. External audit should also involve some reporting role to the Pharmacy Boards in each state.

### **Documentation**

Comments have been made above where consideration needs to be given to improved documentation of the *Standards* process to reflect what actually does occur within the risk identification, assessment and evaluation processes.

## 5.6 CONCLUSION

Generally, the *Standards* followed a risk-based process in assessing the approach of a community pharmacy to its activities, decisions and operations. However, a number of issues would need to be addressed to bring the *Standards* in line with best-practice risk-management processes proposed by the Australian/New Zealand Standard on Risk Management AS/NZS 4360:2004. It is recommended that consideration is given to developing further guidelines within the *Standards* to assist community pharmacies in better identifying, assessing and documenting risks. A component that could usefully gain from a greater focus from the assessment of environments is the development of a more clearly defined set of criteria upon which risk is to be evaluated. The risk criteria must correspond to the type of risks and the way in which risk levels are expressed. This could occur more effectively in respect of Standards 2.1 and 4. Standards 2 and 3 focus particularly on identifying risks in the context of community pharmacy. The protocols also provide guidance on what methods can be used to collect information. However, the protocols would benefit from a review to ensure that community pharmacies (via the *Standards*) can be provided with greater certainty in relation to Standard 2.1 and the protocols. It would be prudent that a simple documentary record for Pharmacist Only (S3) Medicines interventions becomes a part of the risk-management approach to the *Standards*. Representatives from community pharmacy, government and consumers would need to decide the acceptable level of risk using qualitative data available from the Census and Sample Study and other sources. It may be that not all non-prescription medicines may need documentation. This might be achieved via further protocols or additions to the standard operating procedures. Furthermore, consideration needs to be given to increasing the external audit component of the monitoring of the *Standards* to provide greater certainty of their effectiveness.

### **Recommendation 24:**

That consideration be given to developing further guidelines within the *Standards* to assist community pharmacies in better identifying, assessing and documenting risks so that the *Standards* appropriately meet best-practice risk-management processes. Further, that consideration be given to increasing the external audit component of the monitoring of the *Standards* to provide greater certainty of their effectiveness.



<p><b>SECTION 6</b></p> <p><b>PROJECT CONCLUSIONS AND RECOMMENDATIONS</b></p>
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## 6.1 CONCLUSIONS

This project brought together a number of individual yet interdependent studies to provide an understanding of community pharmacy, standards of practice, Pharmacist Only (S3) and Pharmacy Medicines (S2) and their social, health and economic impacts. It investigated concepts and answered recommendations that had been proposed by Galbally [1]. This report's major objective was to provide research data so that policy makers would be better informed in responding to the Galbally recommendations [1]. A number of quantitative and qualitative studies were empirically designed to address the tender requirements and research questions. Interestingly, there was no guidance from literature on the conceptual research approach to be taken in addressing the issues associated with scheduling of non-prescription medications. It is hoped that the approach taken in this Australian study will have an international impact, since a large number of countries are faced with similar policy decisions.

The study did not consider 'general counselling' as an intervention, discussion reinforcing correct consumer self-medication practices, nor did it consider the role of community pharmacy in limiting the illicit use of non-prescription medications. The impact of 'general counselling' may be in assisting consumers with their choice of self-care treatment and in providing advice both on products and symptoms being presented by consumers. A comprehensive quantitative study on the incidence of illicit use prevention by pharmacy would involve other factors (for example, the assessment of whether the request was truly illicit) which should be addressed in-depth by a separate study. This study, therefore, may be underestimating the role of community pharmacy in the sale and provision of non-prescription medications.

*The Review of the national and international literature and qualitative study with members of the NDPSC* came to the conclusion, on a qualitative basis, that there were differences in the risk profile of Pharmacy Only (S3) and Pharmacy Medicines (S2). It suggested that in countries with no 'pharmacy only' schedules, medications are more likely held in 'prescription only' schedules, thus restricting consumer access. The current Australian scheduling system was said to provide Australian consumers with a wider range of medicines for self management than in any comparable country. The Australian system provided for efficient allocation of resources by indicating through the scheduling system which medicines required additional intervention by either pharmacist or pharmacy assistants. The role of the pharmacy assistant with the Pharmacy Medicines (S2) schedule allowed for targeting of training to pharmacy assistants to provide advice at an appropriate level and a bridge for consumers who require pharmacist attention. The quantitative study on professional interventions substantiated this position by noting a 25% referral rate. The qualitative interviews with members of the NDPSC come to the conclusion that the current scheduling arrangements provide a workable and usable framework to support the Quality Use of Medicines in Australia. However, some members of the committee were concerned about the application in practice with the suggestion that many pharmacists were not fulfilling their responsibilities. A number of recommendations addressed the voting

process in determining schedules and the evidence required for efficacy in switched submissions.

An epidemiological study on professional interventions by pharmacists and their staff on Pharmacist Only (S3) and Pharmacy Medicines (S2) provided a quantitative analysis of current baseline practice and provided the base for a cost benefit analysis of the schedules. The epidemiological study was carried out in two parts – a Census to document low frequency interventions with high significance, and a Sample Study to document all other types of interventions. The integrated data were extrapolated to a national level using a comprehensive system of weightings. A sample of interventions from the Census and Sample Study was processed through clinical panels to estimate the adverse health outcomes avoided and the probability of avoidance. Rates were calculated by using interventions per year with annual purchase data provided by IMS Health. Sales data would have been preferred; however, there appears to be no national database on sales. Baseline professional practice was found to be 5.66 interventions per 1000 units. When confidence limits of 95% were calculated, no significant difference was found for the rate for Pharmacy Medicines (S2) and Pharmacist Only (S3) Medicines with respective base rates of 5.76 and 5.34 per 1000. Interestingly, there was tendency towards significance in highly significant interventions with Pharmacist Only (S3) Medicines (1.37 per 1000), whilst the Pharmacy Medicines' (S2) rate was 1.12. Analysis with 95% Confidence Intervals showed no significance. Conversely, the Pharmacy Medicines (S2) rate in minor significance also showed a tendency towards significance with the Pharmacy Medicines (S2) rate of 4.63 per 1000 and Pharmacist Only (S3) Medicines rate of 3.97 per 1000. QCPP data and the results of pseudo-patient visits were used to classify different levels of baseline activity. This was used as a surrogate for *Standards* performance. No statistical difference was found between groups of pharmacies practising at different professional levels, but discernible trends were found with the expected ranking, and the 'Excellent' (highly compliant) group performed at a higher rate of intervention of 8.21 interventions per 1000 units. From the results of the Census and Sample Study, there appears to quite a spectrum of activity in community pharmacy, producing a broad range of interventions. Although there was no significant difference found between the Pharmacist Only and Pharmacy Medicine schedules, it was evident that the amalgamation of the two separate non-prescription schedules would not necessarily be of benefit to the Australian community, and thus, the conclusion from the epidemiological study was that the *status quo* of two separate schedules should remain.

Measurement of the healthcare avoided as the result of interventions suggested that community pharmacy is playing a major role in preventing a large number of patients' contact with more costly and higher-level health care services. It was also clear that the major group of consumers who were at risk of adverse effects from the intended use of non-prescription medications were those with underlying diseases such as hypertension and asthma. Pregnant women were also identified as at-risk group. As expected, pharmacists tended to deal with interventions of a higher significance but pharmacy assistants emerged as a group of staff active in interventions. Surprisingly, currently there is no formal requirement in the area of medicine-related advice for this group of staff. Furthermore, there is scope for pharmacy to improve its intervention

rate. An improvement in the intervention rate of 10% (i.e., an intervention rate of 0.0062) would result in an additional 48,591 interventions being made each year.

The cost-benefit analysis results also indicated caution with any merging of the schedules. The epidemiological model suggested a central estimate of \$2.75 billion per year for the monetary benefits from interventions in preventing temporary disabilities and deaths. The estimated lower and upper 95% confidence bounds were \$152 million and \$13.69 billion, respectively. Pharmacy Medicines (S2) monetary benefits had a central limit of \$1.58 billion, lower 95% confidence bound of \$119 million, and upper 95% confidence bound of \$7.31 billion. Pharmacist Only (S3) Medicines monetary benefits had a central limit of \$1.17 billion, lower 95% confidence bound of \$33 million and an upper 95% confidence bound of \$6.38 billion. Producer costs by schedule were also calculated. The central estimate of current net benefit after subtracting producer costs (staff time) from gross benefits was \$2.61 billion annually. It was estimated that if the schedules are merged into S2 then net benefits will fall by \$100.9 million to \$2.51 billion. If the schedules are merged into S3 then net benefits will increase by \$113.5 million to \$2.73 billion. In all scenarios the monetary benefits from avoiding temporary disabilities and deaths far outweigh the production costs. Merging the schedules into S3 appears to confer the greatest benefit. However, such a change in policy might require an additional 2,000 to 3,000 pharmacists. Further, given the data limitations, caution is recommended when considering any change to the schedules.

The 'Standards for the Provision of *Pharmacist Only* and *Pharmacy Medicines* in Community Pharmacy', originally developed by The University of Sydney and the University of South Australia and adopted by the Pharmaceutical Society of Australia in 1999, were qualitatively analysed using the Australian/New Zealand Standard on Risk Management AS/NZS 4306:2004. Generally, the *Standards* followed a risk-based process in assessing the approach of a community pharmacy to its activities, decisions and operations. However, a number of issues would need to be addressed to bring the *Standards* in line with best-practice risk-management processes proposed by the Australian/New Zealand Standard on Risk Management AS/NZS 4360:2004. It is recommended that consideration is given to developing further guidelines within the *Standards* to assist community pharmacies in better identifying, assessing and documenting risks. A component that could usefully gain from a greater focus from the assessment of environments is the development of a more clearly defined set of criteria upon which risk is to be evaluated. The risk criteria must correspond to the type of risks and the way in which risk levels are expressed. This could occur more effectively in respect of Standards 2.1 and 4. Standards 2 and 3 focus particularly on identifying risks in the context of community pharmacy. The protocols also provide guidance on what methods can be used to collect information. However, the protocols would benefit from a review to ensure that community pharmacies (via the *Standards*) can be provided with greater certainty in relation to Standard 2.1 and the protocols.

It would be prudent that a simple documentary record for Pharmacist Only (S3) Medicines interventions becomes a part of the risk-management approach to the *Standards*. Representatives from community pharmacy, government and consumers would need to decide the acceptable level of risk using qualitative data available from the Census and Sample Study and other sources. It may be that not all non-prescription medicines may need documentation. This might be achieved via further

protocols or additions to the standard operating procedures. Furthermore, consideration needs to be given to increasing the external audit component of the monitoring of the *Standards* to provide greater certainty of their effectiveness.

In conclusion, the three studies point in the same direction and answer the essential questions posed by Galbally in a similar vein that the current separation of schedules should remain. A number of recommendations that arose from this research are listed below.

## 6.2 RECOMMENDATIONS

### **Overall Project Recommendation:**

That, from an analysis of Australian and international scheduling arrangements, clinical benefit perspective, cost-benefit and risk-management perspective, the current non-prescription scheduling system be maintained with regards to separate Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules.

### **Recommendation 1:**

That the current system used by the NDPSC be reviewed so that the following issues are taken into account by the Committee in its deliberations: an examination as to the characteristics of the drug, an examination of issues relating to professional practice, and consideration of consumer issues.

### **Recommendation 2:**

That the recommendation 7(a) of the National Competition Review of Drugs, Poisons and Controlled Substances Legislation that the National Drugs and Poisons Schedule Committee be disbanded and replaced with two separate committees – a Medicines Scheduling Committee and a Poisons Scheduling Committee - be supported and moved forward.

### **Recommendation 3:**

That the guidelines for the provision of information by sponsors and expert advisers to the Medicines Scheduling Committee be amended to require all submissions to conform to those described in the Cochrane Library Reviewers' handbook [23].

### **Recommendation 4:**

That provision be made within the processes of the Medicines Scheduling Committee to allow the Committee to have direct dialogue with experts and clinicians who provide opinion to the Committee.

### **Recommendation 5:**

That all Commonwealth, State and Territory governments agree that decisions of the NDPSC (or its equivalent replacement by a Medicines Scheduling Committee) on the scheduling status of medicines shall be made by consensus or, failing consensus, by a two-thirds majority of all members.

**Recommendation 6:**

That the NDPSC (or a Medicines Scheduling Committee) consider whether it should be required for sponsors to produce evidence of efficacy of products for which a schedule switch is sought.

**Recommendation 7:**

That, from qualitative analysis of Australian and international scheduling arrangements, the current non-prescription scheduling system be maintained with regards to separate Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules to encourage the switch of products from prescription to non-prescription.

**Recommendation 8:**

That a national system for tracking clinical interventions on Pharmacist Only (S3) and Pharmacy Medicines (S2) be instituted as part of a quality assurance and improvement system. The system should include the ability to report on individual products and patient characteristics.

**Recommendation 9:**

That a post-switching (from prescription to Pharmacist Only (S3) Medicines and Pharmacist Only (S3) Medicines to Pharmacy Medicines (S2)) a pharmaco-vigilance system be developed and implemented on a national basis to assist in the analysis and management of risk.

**Recommendation 10:**

That the competency statement for pharmacists be reviewed to explicitly include a core competency for performing clinical interventions for Pharmacist Only (S3) and Pharmacy Medicines (S2).

**Recommendation 11:**

That a national program be instituted to increase the clinical intervention rate for Pharmacist Only (S3) and Pharmacy Medicines (S2).

**Recommendation 12:**

That national policy and protocols should be developed, concentrating on when and how pharmacy assistants should refer at-risk patients to pharmacists. These policies should be incorporated in the 'Standards for the Provision of *Pharmacist Only* and *Pharmacy Medicines* in Community Pharmacy'.

**Recommendation 13:**

That all universities and pre-registration programs should incorporate clinical intervention education on Pharmacist Only (S3) and Pharmacy Medicines (S2) as part of their curricula.

**Recommendation 14:**

That there be a formal requirement for those pharmacy staff members who are not pharmacists to have a formal qualification for handling Pharmacist Only (S3) and Pharmacy Medicines (S2).

**Recommendation 15:**

That, due to the clinical benefits provided by the current non-prescription medicine scheduling system, separate Pharmacist Only (S3) and Pharmacy Medicines (S2) schedules be retained.

**Recommendation 16:**

That a national training program for community pharmacy on Pharmacist Only (S3) and Pharmacy Medicines (S2) be developed, emphasising clinical interventions in high-risk patients with underlying conditions, age and specific products identified in this report.

**Recommendation 17:**

That existing patient education leaflets be revised to address problems associated with Pharmacist Only (S3) and Pharmacy Medicines (S2) specific for patients with underlying conditions identified at risk in this report. These leaflets are to be circulated through patient support groups, general medical practitioners and community pharmacy.

**Recommendation 18:**

That a review of labelling requirements for Pharmacist Only (S3) and Pharmacy Medicines (S2) be undertaken, as this study has shown that currently a significant number of at-risk consumers are not complying with labelling instructions.

**Recommendation 19:**

That further analysis of data collected as part of the Study of Professional Interventions includes interventions performed on unscheduled medicines and further analysis take place on the data collected in the Study of Professional Interventions at the product level to determine the relative risk of products.

**Recommendation 20:**

That a study investigate the incidence and outcomes of inappropriate use of unscheduled medications sold in non-pharmacy outlets (e.g. supermarkets).

**Recommendation 21:**

That research be conducted into the nature of clinical interventions reported in this study to identify practice behaviour patterns of pharmacists and pharmacy staff.



**Recommendation 22:**

That an investigative study of pharmacies with higher intervention rates be conducted to identify factors contributing to the higher rate, and these incorporated into national training programs.

**Recommendation 23:**

That, from a cost-benefit perspective, there be no change to the current scheduling arrangements.

**Recommendation 24:**

That consideration be given to developing further guidelines within the *Standards* to assist community pharmacies in better identifying, assessing and documenting risks so that the *Standards* appropriately meet best-practice risk-management processes. Further, that consideration be given to increasing the external audit component of the monitoring of the *Standards* to provide greater certainty of their effectiveness.

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