

## **APPENDICES**

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## APPENDIX 1

### **Examples of comments from Reasons for Decisions, National Drugs and Poisons Schedule Committee, meetings from November 2000 to October 2002 (refer to Table 2 of Section 2)**

- ... on the basis of safety ... appropriately managed by patients with pharmacist advice ... well-characterised side effect profile ... (Clobetasone; February 2002 meeting)
- ... advice and counselling by a pharmacist at point of sale ... essential for safe use ... should assist in avoiding potential adverse reactions ... (Sodium Picosulfate, February 2002 meeting)
- ... [condition] ... requires medical diagnosis and management ... harmonisation with New Zealand ... (Lopinovar , August 2001 meeting)
- ... reduce the problem of diversion ... while maintaining access for legitimate users ... (Pseudoephedrine, June 2002 meeting)
- ... a history of safe use and no significant safety concerns ... (Hyoscine (increased pack size), June 2002 meeting)
- ... safety profile not consistent with Schedule 3 medicines given the wide range of contraindications and potential adverse outcomes ... thorough prescreening and assessment by a medical professional[is] essential ... impart the wrong public health message ... (Orlistat, February 2002 meeting)
- ... low potential for ... adverse effects ... no evidence of abuse or misuse... (Flurbiprofen Lozenges, October 2002 meeting)
- ... safety ... easily diagnosed and treated by consumers ... (Ibuprofen for external use, October 2002 meeting)
- ... should be available without prescription ... with the benefit of professional advice to assist in appropriate management... (Nitrates for angina, November 2000 meeting)
- ... does not constitute a significant risk to public health ... raising awareness [of indications] beneficial to public health ... (advertising of folic acid; February 2001 meeting)

## **APPENDIX 2**

### **Questionnaire for telephone interviews with members of the NDPSC**

A cost-benefit analysis of Pharmacist Only and Pharmacy  
Medicines and Risk-based Evaluation of the Standards:

A Research project of the University of Sydney in conjunction  
with the University of South Australia.

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## Summary of the research

**The research has been designed to address some of the issues raised in recommendation 5: medicine schedules and associated professional support of the Review Of Drugs, Poisons And Controlled Substances (Galbally, 2001). The research report is required to make recommendations on appropriate scheduling model/s and frameworks to support the quality use of medicines in Australia, and will proceed in two parallel but linked projects.**

One project, which is being undertaken by the University of South Australia<sup>1</sup> (Project director: Ass. Prof. AG Gilbert) includes

1. A review of risk assessment in current Australian Scheduling Acts and Regulations using data from available documentation of the risk assessment used by scheduling committees in making scheduling decisions
2. A review of relevant international scheduling arrangements<sup>2</sup>
3. A review of the current *Professional Standards for the supply of Pharmacy Only and Pharmacist Only medicines* as they relate to risk assessment processes
4. Investigation of and recommendations concerning alternative scheduling models for Australia.

The second linked project, to be undertaken by Sydney University (Project director: Prof SI Benrimoj), involves an examination of how risk is assessed in community pharmacies on the sale of scheduled medicines. The research seeks 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 provision of non-prescription medicines be substantially improved with risk-based elements?

As an essential part of our consideration of the research questions, we wish to interview decision-makers about the cognitive processes they use in making scheduling decisions. We are particularly interested in how decisions are made 'at the margins' i.e. between unscheduled and S2; between S2 and S3; and between S3 and S4, and wish to interview decision-makers about these issues. To make this exercise both consistent and stringent, we are seeking your willingness to be interviewed by phone on the issues raised in the attached questionnaire. In order to use time efficiently, we would be grateful if you consider the issues before the phone conversation. Our secretary, Ms Karen O'Callaghan, will contact you to seek your cooperation and arrange a convenient time for the phone interview.

Confidentiality will be assured. The report will refer to group data only and individuals will not be identified. If you would like to receive a copy of the summary of the interviews, please let me know at the end of the interview.

If you have any concerns or questions about the process, please feel free to contact me (via email or Karen on 08 8302 ) to discuss these.

Neil Quintrell

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<sup>1</sup> Ethics approval for the conduct of this research has been given by the University of SA's Ethics Committee.

<sup>2</sup> Including the UK, USA, New Zealand, Europe, Canada and Norway

# Questionnaire on the decision-making process for the scheduling of drugs in Australia

## **Section A: Relative importance of criteria in assessing risk in scheduling decisions**

An analysis of guidelines for the Committee indicates that the following criteria are listed for the guidance of members in making scheduling decisions.

1. *Issues of individual consumer safety, including*
  - Potential for harm from inappropriate use
  - The incidence of serious side effects
  - Contraindications for use
  - Toxicity
  - Level of Therapeutic Index
  - Potential for child poisoning
2. *Public health issues, including*
  - Bioaccumulation
  - Development of resistance
  - Potentiality for abuse or diversion
3. *Issues relating to diagnosis, including*
  - Requirement for medical diagnosis before initiating treatment
  - Risk of masking serious disease states
4. *Issues of management, including*
  - Requirement for medical oversight or management
  - Risk of compromising management of current medical conditions
5. *Other issues*
  - Consistency within Australian schedules
  - Harmonisation with New Zealand
  - Ease of consumer access
  - Cost to consumers

We would like you to consider a recent example in each of the categories overleaf, and reflect on what were, for you, the most important considerations from the guidelines.

1. An application for a shift from S4 to S3.
2. An application for a shift from S3 to S2.
3. An application for a shift from S2 to open sale.
4. Deliberations about the need for a shift to a more restrictive schedule.



## **Section B: Records of reasons:**

Our analysis of the Committee's Record of Reasons given for scheduling decisions across all categories for the past three years has shown the following pattern. Note that this analysis relates to the frequency reasons were mentioned not to any level of importance, and is likely to reflect issues raised when resolving disagreements.

Reasons most frequently cited (accounting for 77% of the 83 reasons analysed) were

- *level of professional management required (24 times)*
- *level of diagnosis required (13)*
- *safety of the drug (16)*
- *presence of side effects/potential adverse effects (11)*

The remaining 23% of reasons cited were

- *patient choice/accessibility (6)*
- *public health issues(6).*
- *harmonisation and achieving scheduling consistency(5)*
- *concerns about abuse or diversion (2).*

Two criteria listed in the Committee's guidelines that were not mentioned in the reasons were *capacity to mask diseases or compromise management* and *breadth of Therapeutic Index*.

We would like to know to what extent you think that this analysis represents a fair picture of the Committee's deliberations. The use of case studies to illustrate any points you make would be most valuable to us to increase our understanding of the risk assessment process, advantages and disadvantages with the present system, and the effects any changes would have on current models of decision-making.

What comments do you have that would help us understand the ways in which risk is assessed?

## **Section C: Schedules 2 and 3**

The Galbally report (2002) found that the scheduling process provides a community benefit that warrants its retention. However, the Report has proposed that Schedules 2 and 3 should be merged unless there is evidence that their retention as separate schedules provides a significant community benefit.

We are interested in your comments on this issue, especially from the perspective of one charged with the scheduling process.

1. What benefits (if any) do you see in the maintenance of the current scheduling arrangements?
2. What problems (if any) do you see with the current scheduling arrangements?

## **Section D: Alternative scheduling models**

The terms of the research require us to consider alternative scheduling models. In comparable countries, the two most common models are

1. A three schedule model consisting of general sale, pharmacy only and prescription only (eg UK)

2. A two-schedule model consisting of general sale and prescription only (eg. USA)

We are interested in your speculations concerning these two models.

1. What advantages (if any) do you see in the UK model (1. above)?
2. What problems (if any) do you see in the UK model (1. above)?
3. What advantages (if any) do you see in the US model (2. above).
4. What problems (if any) do you see in the US model (2 above)?

### **Section E: General comments**

Do you have any general comments, not covered above, that would help us frame recommendations about the benefits and problems relating to the merging (or maintenance) of the current scheduling arrangements for Schedules 2 and 3?

1. Relating to the Committee's task of scheduling.
2. Relating to public health issues in general.
3. Relating to any other issues (eg costs to consumers or government).

Thank you for your time and consideration.

If you wish to receive a copy of the summary report, please let me know and I will forward one. The summary will probably be available in August.

## **APPENDIX 3**

**List of responses from members of the NDPSC (asterisks indicated frequency of responses)**

### **Section A**

#### **1. Issues considered when deciding on an application for shift from S4 to S3**

- Development of resistance (Fluconazole) \*\*
- Risk of masking disease state or compromising treatment (Fluconazole) \*\*\*\*\*
- Consistency of scheduling relative to current products (Fluconazole)
- Importance of clear labelling/directions (Fluconazole)\*\*
- Is prior diagnosis needed (note: female members of panels felt that this was less important) (Fluconazole) \*\*\*\*
- Consumer access (Fluconazole, levonorgestrel) \*\*\*\*\*
- Access to professional advice (levonorgestrel) \*\*\*\*\*
- Low potential for harm (levonorgestrel)
- Limited side effects (levonorgestrel) \*\*
- Medical diagnosis not needed (levonorgestrel) \*\*\*\*\*
- Low abuse potential
- Able to be managed by PhC \*
- TI sufficiently broad \*\*
- Evidence based
- Presence of contraindications
- Toxicity
- Presence of ADR
- Harmonisation (only after evaluation)
- Evidence of safe use in S4

#### **2. Issues considered when deciding on an application for shift from S3 to S2**

- Appropriateness of use (Nicotine Lozenges)
- Consistency of scheduling with similar products (Nicotine Lozenges)
- Toxicity (Nicotine Lozenges) \*\*
- Side effects profile (Nicotine Lozenges) \*\*
- Potential for inappropriate use (Nicotine Lozenges) \*\*
- Consumer access (Nicotine Lozenges) \*\*
- Harmonisation with NZ (Nicotine Lozenges)
- No requirement for medical diagnosis (Budenoside N/Spray)
- Safety in use (Budenoside N/Spray)
- Low requirement for ongoing professional management (Budenoside N/Spray) \*\*\*\*\*
- Advice available if needed (Budenoside N/Spray, Nicotine Lozenges) \*\*\*
- Low abuse potential (Budenoside N/Spray)
- Wide TI (Budenoside N/Spray)
- Suitable for short-term treatment (Budenoside N/Spray)
- History of safe use
- Route of use (eg compare dermal with oral use, eg diclofenac)

- Evidence of safe use (budenoside)

### **3. Issues considered when deciding on an application for shift from S2 to general sale**

#### **(Small packs Ibuprofen)**

- Side effects (small packs Ibuprofen)
- Contraindications (small packs Ibuprofen)
- Low potential for misuse or harm (small packs Ibuprofen) \*\*\*
- Comparison with similar products eg aspirin, paracetamol (small packs Ibuprofen) \*\*\*
- Consumer access (small packs Ibuprofen)\*\*
- Evidence of safe use and/or absence of negative reports (note use in country areas with registered poison sellers), Low incidence ADR in practice (small packs Ibuprofen) \*\*\*\*\*
- Packaging (child-resistant) required (small packs Ibuprofen)
- Low toxicity (small packs Ibuprofen)
- Low abuse potential (small packs Ibuprofen)
- Self-diagnosis and self-management appropriate \*\*\*\*\*
- Adequate labelling essential \*\*\*\*\*
- Balancing increased consumer with need for access to professional advice

### **4. Issues considered when deciding on an application for shift to more restrictive schedule**

- Abuse (pseudoephedrine) \*\*
- Risks in self-management (eg bowel cleansing agents)
- Toxicity
- Political pressure present, but scientific evidence a key factor (pseudoephedrine)
- Consistency in scheduling within Australia (pseudoephedrine)
- Evidence of diversion to illicit use (pseudoephedrine) \*\*\*

## **Section B**

### **Comments on analysis of records of reasons**

- Analysis a fair representation \*\*\*\*\*
- Influenced by factors presented in argument by sponsors \*\*
- Level of diagnosis and management required are key considerations for placement of preparations in schedules \*\*
- Capacity to mask diseases and TI considered even if not mentioned in records
- Evidence-based
- Balancing public safety/public benefit considered
- Committee's fundamental role is the protection of public health; others considerations are of minor importance relative to primary role \*\*
- Even if all reasons not recorded, all guidelines are followed
- External factors are considered (consistent with above) eg evidence from Police etc

## Section C.

### Current scheduling system

The system is a good one.

- It is workable and useable \*\*
- It provides flexibility and offers consumers the possibility of receiving informed and objective advice \*\*\*\*\*
- Provides graded system of access based on safety and level of diagnosis and management required \*\*\*
- Availability of a wider range of professional advice allows a wider range of products to be made available to the public\*\*
- Its application in practice is not yet satisfactory, and there is concern that many pharmacists are not exercising the responsibility that comes with S3 scheduling. \*\*\*\*\*
- Recognition that time and resource pressures place limitations on pharmacy practice
- Need for better training for sales assistants on rationale for and application of schedules. Assistants cannot be expected to have adequate Science background \*\*\*
- Recognition that more schedules place costs on manufacturers
- Provides opportunities for educating consumers
- Provides a clear message that scheduled medicines are not 'ordinary items of commerce'

## Section D

- Comments on alternative models: No advantage is seen in the US model (apart from possible downward pressure on prices) \*\*\*\*\*. Does not fit with Australian QUM model
- If a single pharmacy only schedule was introduced, there would be a tendency to hold preparations in S4 leading to an increase in costs to consumers and a decrease in consumer access as diagnosis and management issues may preclude decisions to approve downward shifts. \*\*\*\*\*
- Note the development of the 'subsidiary prescriber' model in the UK, and the exemptions to S4 (eg nurses and accredited pharmacists can supply levonorgestrel which remains in S4 in NZ; antismoking counsellors can supply Nicotine RT) – a 'pseudo S3' with more restrictions to consumer access than Australia
- Merged schedule may place greater reliance on labelling and written information and less on interaction with pharmacists \*\*
- What would the legislated requirements for a merged schedule be? May need to be more like the current S3? \*\*

## Section E: Other issues

- Costs (consumer, manufacturer, system) are not considered in scheduling decisions
- Concerns that relaxing of schedules may lead to people not seeking advice appropriately

- Would costs of merging S2 and S3 outweigh the benefits (eg changes to all State legislations and all practice guidelines etc)
- Workload of Secretariat and Committee as significantly increased over the past few years, and the work of the committee has necessarily become more legalistic, leading to Committee being continually reactive without time for reflection eg examination of scheduling of drug classes \*\*
- Public health issues are main driving considerations
- Concerns that the processes and information provision (eg listing of search strategies in literature reviews) to the Committee are not sufficiently rigorous
- Concerns re the ability of the Committee to deal with both drugs and poisons. Individuals cannot be expected to have a broad enough range to consider all applications thoroughly. Preference for splitting the committee
- Preference for the ability to have direct dialogue with experts who provide opinion to the Committee
- Concerns that key stakeholders may not always been informed of decisions that affect their members
- Concerns that key government policies (eg on QUM, tobacco) may not have been addressed in information provided

## **APPENDIX 4**

### **Recommended amendments to the Standards for the provision of pharmacy and pharmacist only medicines in Australian community pharmacy.**

**4.1** On the page immediately following the Contents page, add a page that describes the rationale for Schedule 2 and 3 medicines as follows:

#### ***Schedule 2 medicines***

***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.***

Drugs in Schedule 2

- are suitable for self-treatment of a minor ailments or symptoms capable of being monitored by the consumer
- have extremely low abuse potential
- have low potential for harm from appropriate use
- have a low or well-characterised incidence of adverse effects or side effects, and contraindications for which advice or counselling is available
- have low risk of masking or of compromising medical management of a serious disease

Although pharmacist involvement in the sale of Pharmacy Medicines is not required, pharmacy staff must satisfy themselves that they have adequately assessed the level of risk to the individual who will be taking or using the preparation, and refer to the pharmacist if any uncertainties exist.

#### ***Schedule 3 medicines***

***The purpose of Schedule 3 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.***

Drugs in Schedule 3 (pharmacist only medicines) are substantially safe in use but require professional advice or counselling by a pharmacist. They have

- 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
- interactions with commonly used drugs or food or contraindications that can be managed by a pharmacist
- a level of risk of masking a serious disease or compromising medical management of a disease that can be dealt with by a pharmacist

Although pharmacy staff may handle initial requests for pharmacist only medicines it is required, by law, that pharmacists ensure themselves directly that a proper

diagnosis has been made and that a management plan outlining proper treatment and any attendant risks has been clearly communicated to the patient or carer.’

**4.2** Delete the first two paragraphs of the **INTRODUCTION** (as these are now redundant) and amend the final sentence of paragraph 2 of the **Background** to read

‘The purpose of this model is to optimise pharmacy practices in the provision of *pharmacist only* and *pharmacy* medicines to ensure that all community pharmacies **[have appropriate risk assessment practices in place and]** provide appropriate and consistent professional advice.

**4.3** Under **Glossary of terms**

- 1.3.1 delete the descriptions of ‘Pharmacy medicines’ and ‘Pharmacist only medicines’. (This is replaced by 4.1 above).
- 1.3.2 under ‘Protocols’ delete *[Outline the process to be followed]* and amend to read **[Outline a sample process to be followed]**
- 1.3.3 after ‘is provided.’ add **[Protocols are to be applied flexibly, but provide a guide to an interview process that ensures that an appropriate needs analysis and risk assessment has been carried out before any recommendation is made.]**

**4.4** Under the guidelines to Criterion 1.1.2, delete the dot point before ‘Subscriptions to journals such as ‘Current Therapeutics’ ...

**4.5** Under the guidelines to Criterion 2.1.2. amend the second sentence to read

Pharmacists have been authorised to supply these items on the understanding that they accept responsibility **[for making an full assessment of risk factors that relate to the patient’s condition and/or medication use and ensure safe and effective use of any recommended medications].**

**4.6** Under the Guidelines to Criterion 2.1.3 amend the third sentence to read

The purpose of these procedures and protocols is to provide a filter to ensure that **[an adequate assessment of risk factors that relate to the patient’s condition and/or medication is undertaken and]** that products provided are appropriate to customer needs, and give the pharmacist the opportunity to refer to a medical practitioner when indicated.

**4.7** Delete the Guidelines under Criterion 2.1.5 and replace with

**[All staff who handle pharmacist only or pharmacy medicines must have received training in the philosophies that underpin the scheduling of medicines, in assessing patient risk relating to pharmacist only and pharmacy medicines, and in understanding their limitations in relation to these medicines. Pharmacy assistants who are involved with the sale of pharmacy medicines must have completed, or have been formally assessed to have a level of competence equal to, the Australian National Training Authority Certificate Level II: Working effectively within the Pharmacy Industry.]**



**4.8** Amend the Guidelines of Criterion 2.2.1 to read

When supply of pharmacist only and pharmacy medicines is made by post or delivery, pharmacists must fulfil their legal and professional responsibilities to ensure that **[an adequate risk assessment has been made and that]** customers are provided ...

**4.9** Amend the third sentence in the Guidelines under Criterion 2.2.2 to read

...pharmacy staff must take all reasonable steps to ensure that **[an adequate risk assessment has been made and]** that the information ...

**4.10** Amend the sixth sentence of the Guidelines under Criterion 2.3.3 to read

‘Inappropriate use’ means medicines being taken for the wrong purpose, consistent use of medicines that may indicate the presence of other untreated medical conditions, **[medicines purchased to divert for criminal purposes]** and medicines taken solely to support dependency.

**4.11** Amend Standard Operating procedure 2.1.3.1 to read

The *pharmacy assistant* will

- interview the customer to ensure that a full assessment of risk factors has been made, and

*either*

- refer the customer to the pharmacist for attention where any doubt about the appropriateness of the request exist, and follow the pharmacist’s instructions

*or*

- if no risk factors are present, complete the sale, providing appropriate advice and offers of continuing care

**4.12 APPENDIX 4 – PROTOCOLS**

amend the first sentence to read

The following protocols are tools designed to assist pharmacy staff **[gather information that enables appropriate risk assessment to be made and]** deliver appropriate and consistent professional advice ...

## APPENDIX 5

### **Literature search strategies**

A database search was conducted using the search terms

- OTC or over-the-counter or non-prescription
- Scheduling or schedule shifts or switches or switching

The searches yielded the following useful articles:

- MEDLINE (57 items of which 14 were judged to have useful information)
- International Pharmaceutical Abstracts (8 items of which 5 were useful)
- Current Contents (10 items)
- AustHealth (1 item)

The addition of the search term 'health outcomes or outcomes' revealed two articles only.

A search was also carried out for literature on 'risk management' as it related to OTC medicines. No relevant literature was identified.

## APPENDIX 6

### **Membership requirements for the Canadian National Drug Advisory Schedule Committee (Source: [www.napra.ca](http://www.napra.ca) accessed 2 September 2003))**

The above website lists the knowledge, experience and qualities required for appointment to the Canadian NDASC.

‘NDSAC’s eight expert members are chosen for their knowledge and experience in such disciplines as pharmacotherapy, drug utilization, drug interactions and toxicology, pharmacy practise, academic research, the drug industry and pharmaceutical regulatory affairs at federal and provincial levels. This knowledge and experience must be relevant to the Canadian public and healthcare system.

In addition to the above, candidates for appointment to NDSAC must possess:

- an appreciation of the health, pharmaceutical and marketplace contexts in which the committee’s recommendations will have impact,
- objective analytical skills,
- no personal stake in the scheduling recommendations of the committee,
- a high degree of integrity and respect for the confidential nature of the proprietary information under study,
- effective interpersonal skills relevant to committee dynamics,
- an ability to serve in the best interests of the Canadian public, and
- Canadian residency

**NDSAC members** are mandated to serve in the public interest, aiming to promote optimal pharmacotherapy while recognizing the role and responsibility of the patient in health care. Appointments of expert members are not representational in nature and NDSAC expert members may not directly forward the views of any business, organization or association. Committee members must declare any real or perceived conflicts of interest and adhere to confidentiality codes.

In addition to the eight expert members, a representative of the Consumers’ Association of Canada serves on the Committee to ensure that the views of the Canadian public are directly represented in committee deliberations.

Committee appointments are made by NAPRA pursuant to consultation with a wide range of stakeholders including the Drug Scheduling External Liaison Group. Information on Committee vacancies, recruitment and nomination processes is posted on this site on an ongoing basis.

Appointments are for three-year terms, renewable once. Committee members select a Chairman and Vice-Chairman from among the members, both one-year term positions.’

## APPENDIX 7

### **Legal Status of selected drugs in the USA, UK, Canada, Australia, New Zealand and France (Source: [www.wsmi.org](http://www.wsmi.org) (last revised October 2002, accessed 30 July 2003))**

The above website provides the most comprehensive of the legal status of otc medicines available. The following notes pertain to the process of compiling the list of drugs for comparison.

1. The website was last revised in October 2002. There have been changes to scheduling in Australia (and no doubt in the other countries of comparison) since that date. However, to keep the comparison strictly accurate, we have taken the assignment of the October 2002 list strictly as the basis for comparisons.
2. The explanatory footnotes to the list are not always clear with relation to the scheduling of differential pack sizes, different strengths and doses, and different presentations (oral, topical etc). Where possible, information has been verified, but where information remained unclear, we have erred on the side of caution and not included drugs or preparations for comparison. The loss of data from this exclusion has been small.
3. In order to present the data in ways that can be readily understood without the requirement for extensive footnotes, categories of drugs have been reduced to simple forms – ‘large’ or ‘small’ packs; ‘high’ or ‘low’ doses/strengths; ‘external’ or ‘internal’ use. This has been done without loss of significant data. If readers require more detailed information, they are referred to the above website.
4. We have provided only three schedule categories: ‘general sale’, ‘over-the-counter’ – referring to pharmacy only schedules - and ‘prescription only’.
5. Entries in the world self-medication industry website were checked with respect to Canada and Australia. Although occasional errors were identified, these are of a minor nature and do not affect the overall results.

Ingredients	Australia	Canada	France	N.Zealand	UK	USA
<b>ANALGESICS, ANTI-INFLAMMATORY agents &amp; ANTIPYRETICS</b>						
Acetylsalicylic Acid - small packs	GS	GS	GS	GS	GS	GS
Codeine	Rx	Rx	Rx	Rx	Rx	Rx
Codeine in combination with paracetamol/ASA	OTC	OTC	OTC	OTC	OTC	Rx
Diclofenac large packs	Rx	OTC	Rx	Rx	Rx	Rx
Diclofenac small packs	OTC in 1997	OTC	OTC in 1996	OTC	OTC	Rx
Diflunisal	Rx	OTC	Rx	Rx	Rx	Rx
Dihydrocodeine	Rx	Rx	Rx	Rx	Rx	Rx
Ibuprofen -oral small packs	OTC in 1989	GS in 1989	OTC	OTC in 1985	OTC in 1983	GS in 1984
Ketoprofen -oral - smaller packs	OTC in 2000	Rx	OTC in 1997	OTC	OTC in 1993	GS in 1984
Ketoprofen - oral - higher packs	Rx	Rx	Rx	Rx	Rx	Rx
Mefenamic Acid	OTC	Rx	Rx	OTC	Rx	Rx
Naproxen - oral	OTC in 1990	Rx	Rx	OTC	Rx	GS in 1994
Paracetamol - small packs	GS	GS	OTC	GS	GS	GS in 1955
Piroxicam (topical)	OTC in 1998	Rx	Rx	OTC	OTC in 1994	Rx

Ingredients	Australia	Canada	France	N.Zealand	UK	USA
<b>ANTIBACTERIAL agents</b>						
Bacitracin (topical)	Rx	GS	OTC	Rx	Rx	GS
Chloramphenicol	Rx	Rx	Rx	Rx	Rx	Rx
Chlortetracycline	Rx	Rx	OTC	Rx	Rx	GS
Cilastatin	Rx	Rx	Rx	Rx	Rx	Rx
Clindamycin (oral)	Rx	Rx	Rx	Rx	Rx	Rx
Erythromycin	Rx	Rx	Rx	Rx	Rx	Rx
Mupirocin (topical)	Rx	Rx	Rx	Rx	Rx	Rx
Polymyxin B (topical)	Rx	OTC	OTC	Rx	Rx	GS
Silver sulfadiazine 1%	Rx	N.R.	OTC	OTC	Rx	Rx
Tetracycline	Rx	Rx	Rx	Rx	Rx	GS
<b>ANTIDIABETIC agents</b>						
Insulin	OTC	OTC	Rx	OTC	Rx	GS

Ingredients	Australia	Canada	France	N.Zealand	UK	USA
<b>ANTIFUNGAL agents</b>						
Amphotericin (topical)	Rx	Rx	Rx	OTC	Rx	Rx
Ciclopirox Olamine - oral	Rx	Rx	Rx	Rx	Rx	Rx
Clotrimazole (topical)	OTC	GS in 1994	OTC	GS	OTC	GS in 1989
Clotrimazole (vaginal)	OTC	OTC in 1994	OTC	OTC	OTC in 1992	GS in 1990
Econazole (oral)	Rx	Rx	Rx	Rx	Rx	Rx
Econazole (dermal/vaginal)	OTC in 1994	Rx	OTC	GS	OTC in 1992	Rx
Isoconazole (oral)	Rx	N.R.	Rx	Rx	Rx	Rx
Itraconazole	Rx	Rx	Rx	Rx	Rx	Rx
Miconazole (topical/vaginal)	OTC in 1994	OTC in 1994	OTC	OTC	OTC in 1992	OTC in 1982/1991
Nystatin (topical)	OTC	OTC	Rx	GS	Rx	Rx
Nystatin (oral)	Rx	Rx	Rx	Rx	Rx	Rx
Terbinafine (oral)	Rx	Rx	Rx	Rx	Rx	Rx
Terbinafine (topical)	OTC in 1996	Rx	Rx	GS	OTC in 2000	GS in 1999
Tioconazole (oral)	Rx	Rx	Rx	Rx	Rx	Rx
Tioconazole (topical)	OTC in 1987	GS in 1995	Rx	OTC	OTC in 1994	GS in 1997

Ingredients	Australia	Canada	France	N.Zealand	UK	USA
<b>ANTIHISTAMINES</b>						
Brompheniramine	OTC	OTC	OTC	OTC	OTC	GS in 1976
Cetirizine - adult use	OTC in 1997	OTC in 1995	OTC in 1998	OTC	OTC in 1993	GS
Cetirizine -child use	OTC	OTC	OTC	OTC	OTC	Rx
Chlorpheniramine	OTC	GS	OTC	OTC	OTC	GS in 1976
Cyproheptadine	OTC	OTC	OTC	OTC	OTC	Rx
Diphenhydramine	OTC	OTC	OTC	OTC	OTC	GS in 1981
Doxylamine succinate	OTC	OTC	OTC	OTC	OTC	GS
Fluticasone inhalers	Rx	N.R.	Rx	Rx	Rx	Rx
Fluticasone	OTC	N.R.	Rx	OTC	OTC in 2002	Rx
Loratadine	OTC	OTC in 1988	Rx	OTC	OTC in 1993	Rx
Promethazine	OTC	OTC	OTC	OTC	OTC	Rx
Trip(r)olidine	OTC	OTC	OTC	OTC	OTC	GS in 1982
<b>ANTIMIGRAINE agents</b>						
Sumatriptan	Rx	Rx	Rx	Rx	Rx	Rx
<b>ANTIMUSCARINIC agents</b>						
Hyoscine (Scopolamine) - lower doses	OTC	OTC	Rx	OTC	OTC in 1992	Rx
Hyoscine (Scopolamine) - higher doses	Rx	OTC	Rx	OTC	OTC in 1992	Rx
Propantheline	OTC	OTC	Rx	OTC	OTC	Rx



Ingredients	Australia	Canada	France	N.Zealand	UK	USA
<b>ANTIVIRAL agents</b>						
Aciclovir (topical)	OTC in 1996	Rx	OTC in 1997	OTC in 1992	OTC in 1993	Rx
Penciclovir (topical)	OTC in 1998	Rx	OTC	OTC	Rx	Rx
<b>, HYPNOTICS &amp; ANXIOLYTICS, SEDATIVES ANTI-PSYCHOTICS</b>						
Prochlorperazine - smaller packs	OTC in 2000	Rx	Rx	OTC	OTC in 2001	Rx
Prochlorperazine - larger packs	Rx	Rx	Rx	Rx	Rx	Rx
<b>CARDIOVASCULAR agents</b>						
Adenosine	Rx	Rx	OTC	Rx	Rx	Rx
Minoxidil (topical)	OTC in 1998	OTC in 2000	OTC in 1998	OTC	OTC in 1994	GS in 1996
Nitro-glycerine - other forms	OTC	OTC	OTC	Rx	OTC	Rx
Nitro-glycerine - injections	Rx	Rx	Rx	Rx	Rx	Rx
<b>CORTICOSTEROIDS</b>						
Beclometasone (nasal)	OTC in 1999	Rx	OTC in 2002	OTC	OTC in 1994	Rx
Budesonide (nasal)	OTC in 1999	Rx	Rx	OTC	OTC in 1995	Rx
Flunisolide (nasal)	OTC	Rx	Rx	OTC	OTC in 1994	Rx
Hydrocortisone (topical)	OTC	OTC in 1986	OTC in 1996	OTC	OTC in 1987	GS in 1979
Prednisolone	Rx	Rx	Rx	Rx	Rx	Rx
Triamcinolone (topical)	OTC in 1996	Rx	Rx	OTC	OTC	Rx

Ingredients	Australia	Canada	France	N.Zealand	UK	USA
<b>COUGH SUPPRESSANTS, EXPECTORANTS &amp; MUCOLYTICS</b>						
Acetylcysteine	Rx	OTC	OTC	OTC	Rx	Rx
Dextromethorphan - small packs	OTC	GS	OTC	GS	OTC in 1989	OTC
Dextromethorphan - larger packs	OTC	OTC	OTC	GS	OTC in 1989	Rx
<b>DERMATOLOGICAL agents (topical)</b>						
Benzoyl peroxide -topical (less than 10%)	OTC	OTC in 1981	Rx	GS	OTC	GS
Selenium sulfide	GS	OTC	OTC	OTC	OTC	GS
Tretinoin	Rx	Rx	Rx	Rx	Rx	Rx
<b>DISINFECTANTS &amp; PRESERVATIVES</b>						
Benzalkonium chloride	GS	OTC	OTC	OTC	OTC	GS
Povidone iodine	GS	OTC	OTC	OTC	OTC	GS
Triclosan	GS	OTC	OTC	GS	OTC	GS

Ingredients	Australia	Canada	France	N.Zealand	UK	USA
<b>GASTRO-INTESTINAL agents</b>						
Bisacodyl	GS	OTC	OTC	OTC	GS	GS
Cimetidine - (lower doses)	OTC in 1995	OTC	OTC in 1997	OTC in 1994	OTC in 1994	GS in 1995
Domperidone	Rx	Rx	Rx	Rx	OTC in 1998	Rx
Famotidine - small packs	OTC in 1995	GS in 1996	OTC in 1996	OTC	GS in 1994	GS in 1995
Famotidine - large packs	Rx	Rx	Rx	Rx	Rx	Rx
Lactulose	GS	OTC	OTC	OTC	OTC	Rx
Loperamide	OTC in 1987	OTC in 1986	OTC	OTC	OTC	GS in 1988
Metoclopramide	Rx	Rx	Rx	Rx	Rx	Rx
Nizatidine -(lower doses)	OTC in 1996	Rx	Rx	OTC	OTC	GS in 1996
Omeprazole	Rx	Rx	Rx	Rx	Rx	GS in 2002
Ranitidine -small packs	OTC in 1995	GS in 1997	OTC in 1997	OTC	GS in 1994	GS in 1997
Sucralfate	GS	Rx	OTC in 1994	OTC	Rx	Rx
<b>LIPID REGULATING agents</b>						
Cholestyramine	Rx	Rx	Rx	OTC	Rx	Rx
Pravastatin	Rx	Rx	Rx	Rx	Rx	Rx
Simvastatin	Rx	Rx	Rx	Rx	Rx	Rx
<b>LOCAL ANAESTHETICS</b>						
Lidocaine (topical)	OTC	GS	OTC	OTC	OTC	GS
Oxybuprocaine	Rx	OTC	Rx	Rx	Rx	Rx

Ingredients	Australia	Canada	France	N.Zealand	UK	USA
<b>NUTRITIONAL agents &amp; VITAMINS</b>						
Iron and folic acid preparations	OTC	OTC	OTC	OTC	GS	GS
Selenium - lower doses	OTC	OTC	OTC	OTC	OTC	GS
Vitamin A (Retinol)	GS	Rx	OTC	OTC	Rx	Rx
<b>PARAFFINS &amp; similar bases</b>						
Dimeticone	GS	OTC	OTC	OTC	OTC	GS
<b>PROPHYLACTIC ANTI-ALLERGY/ANTI-ASTHMA agents</b>						
Cromoglicate (sodium) - nasal/opthalmic	OTC in 1990	OTC in 1998	OTC in 1998	OTC	OTC	GS in 1997
<b>SEX HORMONES</b>						
Levonorgestrel	Rx	Rx	OTC in 1999	Rx	OTC in 2001	Rx
<b>SKELETAL MUSCLE RELAXANTS</b>						
Methocarbamol	Rx	OTC	OTC	Rx	Rx	Rx

Ingredients	Australia	Canada	France	N.Zealand	UK	USA
<b>SYMPATHOMIMETIC agents</b>						
Ephedrine - topical/eye/nasal	Rx	Rx	OTC	OTC	OTC	GS in 1980
Epinephrine (other than for asthma)	GS	Rx	Rx	OTC	Rx	GS in 1980
Epinephrine (asthma)	GS	N.R.	Rx	OTC	Rx	GS
Naphazoline	OTC	OTC	Rx	OTC	OTC	Rx
Orciprenaline	Rx	Rx	Rx	Rx	Rx	Rx
Oxymetazoline	OTC	OTC	Rx	OTC	OTC	GS in 1976
Phenylephrine (nasal)	OTC	OTC	Rx	OTC	OTC	GS in 1981
Pseudoephedrine -small packs	OTC	GS	OTC	OTC	OTC in 1994	GS in 1976
Salbutamol - aerosols	OTC	Rx	Rx	OTC	Rx	Rx
<b>XANTHINES</b>						
Theophylline - liquid oral preparations	OTC	Rx	OTC	OTC	OTC	Rx
<b>OTHERS &amp; non-identified</b>						
Aluminium (topical)	GS	OTC	OTC	GS	OTC in 1994	Rx
Fluoride - sodium for dental use	OTC	OTC	OTC	OTC	OTC	GS
Nicotine (gum)	OTC in 1998	GS in 1992	OTC in 1996	OTC	OTC in 1991	GS in 1996
Nicotine (patch)	OTC in 1997	GS in 1998	OTC in 1999	OTC	OTC	GS in 1996

## APPENDIX 8

### Study of Professional Interventions Census/Sample Study Pilot Study Form A

Non – Prescription Medicine Interventions														
<b>Date:</b> ____ / ____ / ____ <b>Time:</b> ____														
<b>PATIENT INFORMATION</b>														
<b>Age group:</b> <input type="checkbox"/> 0-2 years <input type="checkbox"/> 3-12 years <input type="checkbox"/> 13-64 years <input type="checkbox"/> 65+ years	<b>Sex:</b> <input type="checkbox"/> Male <input type="checkbox"/> Female													
<b>Relevant Medical history:</b> <i>(tick as many as applicable)</i> <div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%;"> <input type="checkbox"/> Hypertension  <input type="checkbox"/> Diabetes  <input type="checkbox"/> Skin disease  <input type="checkbox"/> Stomach/ulcer  <input type="checkbox"/> Recent Injury             </div> <div style="width: 50%;"> <input type="checkbox"/> Heart disease  <input type="checkbox"/> Cancer  <input type="checkbox"/> Arthritis  <input type="checkbox"/> Mental condition  <input type="checkbox"/> Other: .....             </div> </div>														
<b>INTERVENTION</b>														
<b>Origin of the intervention:</b> <i>(tick one only)</i> <input type="checkbox"/> Direct product request..... please fill in → <input type="checkbox"/> Symptom presentation <input type="checkbox"/> Other: .....	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #d3d3d3;"> <th colspan="3" style="text-align: left; padding: 5px;">Please Record Known Details of Any Product Requested</th> </tr> <tr> <th style="width: 33%; text-align: left; padding: 5px;">Brand</th> <th style="width: 33%; text-align: left; padding: 5px;">Formulation</th> <th style="width: 33%; text-align: left; padding: 5px;">Strength</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">.....</td> <td style="padding: 5px;">.....</td> <td style="padding: 5px;">.....</td> </tr> <tr> <td style="padding: 5px;">.....</td> <td style="padding: 5px;">.....</td> <td style="padding: 5px;">.....</td> </tr> </tbody> </table>		Please Record Known Details of Any Product Requested			Brand	Formulation	Strength	.....	.....	.....	.....	.....	.....
Please Record Known Details of Any Product Requested														
Brand	Formulation	Strength												
.....	.....	.....												
.....	.....	.....												
<b>Staff member(s) who performed intervention:</b> <i>(tick as many as applicable)</i> <input type="checkbox"/> Pharmacist <input type="checkbox"/> Graduate pharmacist <input type="checkbox"/> Pharmacy assistant <input type="checkbox"/> Other: .....	<b>Staff Initials</b> ..... ..... ..... .....	<b>Time</b> <i>(mins)</i> ..... ..... ..... .....												
<b>Freehand Description</b>														
<b>Describe the PROBLEM YOU HAVE IDENTIFIED:</b> <i>(include drug/condition/doses involved)</i> ..... ..... ..... ..... .....														
<b>Describe the INTERVENTION YOU UNDERTOOK FOR THIS PROBLEM:</b>														
..... ..... ..... ..... ..... .....														
<b>Classification of the Problem and Intervention</b>														
<b>THE PROBLEM YOU HAVE IDENTIFIED:</b> <i>(tick one box)</i>														
<input type="checkbox"/> Incorrect strength <input type="checkbox"/> Incorrect duration of therapy <input type="checkbox"/> Incorrect dose <input type="checkbox"/> Incorrect dosing schedule <input type="checkbox"/> Incorrect dosage form or route <input type="checkbox"/> Dosing problems eg spacing, food <input type="checkbox"/> Inappropriate drug choice <input type="checkbox"/> Therapeutic duplication <input type="checkbox"/> Untreated indications	<input type="checkbox"/> Drug used without indication <input type="checkbox"/> Treatment of drug-induced symptoms <input type="checkbox"/> Possible abuse or misuse <input type="checkbox"/> Adverse drug reaction <input type="checkbox"/> Drug-drug interaction <input type="checkbox"/> Drug allergy <input type="checkbox"/> Drug-disease contraindications <input type="checkbox"/> Use with caution/warnings <input type="checkbox"/> Other: .....													

<b>THE CAUSE OF THIS PROBLEM:</b> <i>(tick one only if applicable)</i>				
<input type="checkbox"/> Incorrect strength <input type="checkbox"/> Incorrect duration of therapy <input type="checkbox"/> Incorrect dose <input type="checkbox"/> Incorrect dosing schedule <input type="checkbox"/> Incorrect dosage form or route <input type="checkbox"/> Dosing problems eg spacing, food <input type="checkbox"/> Inappropriate drug choice <input type="checkbox"/> Therapeutic duplication <input type="checkbox"/> Untreated indications	<input type="checkbox"/> Drug used without indication <input type="checkbox"/> Treatment of drug-induced symptoms <input type="checkbox"/> Possible abuse or misuse <input type="checkbox"/> Adverse drug reaction <input type="checkbox"/> Drug-drug interaction <input type="checkbox"/> Drug allergy <input type="checkbox"/> Drug-disease contraindications <input type="checkbox"/> Use with caution/warnings <input type="checkbox"/> Other: .....			
<b>OTHER CONSIDERATIONS IN DEALING WITH THIS PROBLEM:</b> <i>(tick as many as applicable)</i>				
<input type="checkbox"/> Dosing problems eg spacing, food <input type="checkbox"/> Inappropriate drug choice <input type="checkbox"/> Therapeutic duplication <input type="checkbox"/> Untreated indications <input type="checkbox"/> Drug used without indication <input type="checkbox"/> Treatment of drug-induced symptoms <input type="checkbox"/> Possible abuse or misuse	<input type="checkbox"/> Adverse drug reaction <input type="checkbox"/> Drug-drug interaction <input type="checkbox"/> Drug allergy <input type="checkbox"/> Drug-disease contraindications <input type="checkbox"/> Use with caution/warnings <input type="checkbox"/> Other: .....			
<b>What ACTION(S) did you take in relation to this intervention?</b> <i>(tick as many as applicable)</i>				
<b>Actions Taken</b> <input type="checkbox"/> Advice only (no product) <input type="checkbox"/> Review of patient medication history <input type="checkbox"/> Contact with patient's GP <input type="checkbox"/> Contact with patient (if absent) or caregiver <input type="checkbox"/> Original product suggested: ..... <input type="checkbox"/> Alternative product suggested: ..... <input type="checkbox"/> Non-drug therapy suggested: .....	<b>Patient Referred</b> <input type="checkbox"/> to GP – next scheduled visit <input type="checkbox"/> to GP – conditional on response <input type="checkbox"/> to GP – immediately <input type="checkbox"/> to Accident and Emergency <input type="checkbox"/> to other health professional <input type="checkbox"/> <b>Other:</b> .....			
<b>PATIENT RESPONSE:</b>				
<input type="checkbox"/> Accepted Recommendation <input type="checkbox"/> Rejected Recommendation <input type="checkbox"/> Unknown	Any other information: ..... .....			
<b>PRODUCT(S) SOLD:</b>				
<b>Brand</b>	<b>Formulation</b> <i>(eg tablets/spray)</i>	<b>Strength</b>	<b>Pack Size</b>	<b>\$ Retail</b>
.....	.....	.....	.....	.....
.....	.....	.....	.....	.....
<b>OUTCOME OF INTERVENTION:</b> <i>(tick one of the following)</i>				
<input type="checkbox"/> Intervention had no impact on the patient <input type="checkbox"/> Intervention was harmful to the patient's well being <input type="checkbox"/> Intervention averted <i>minor</i> symptoms <input type="checkbox"/> Intervention averted <i>routine</i> medical attention <input type="checkbox"/> Intervention averted <i>emergency</i> medical attention <input type="checkbox"/> Intervention was potentially life-saving				
<b>ANY OTHER RELEVANT INFORMATION:</b>				
..... ..... .....				

## Study of Professional Interventions Census/Sample Study Pilot Study Form B

[illegible]



Describe the INTERVENTION YOU UNDERTOOK FOR THIS PROBLEM:
.....
.....
.....
.....
.....
.....
.....

What ACTION(S) did you take in relation to this intervention? (tick as many as applicable)	
<b>Actions Taken</b> <input type="checkbox"/> Advice only (no product) <input type="checkbox"/> Review of patient medication history <input type="checkbox"/> Contact with patient's GP <input type="checkbox"/> Contact with patient (if absent) or caregiver <input type="checkbox"/> Original product suggested: ..... <input type="checkbox"/> Alternative product suggested: ..... <input type="checkbox"/> Non-drug therapy suggested: .....	<b>Patient Referred</b> <input type="checkbox"/> to GP – next scheduled visit <input type="checkbox"/> to GP – conditional on response <input type="checkbox"/> to GP – immediately <input type="checkbox"/> to Accident and Emergency <input type="checkbox"/> to other health professional <input type="checkbox"/> <b>Other:</b> .....

PATIENT RESPONSE:	
<input type="checkbox"/> Accepted Recommendation <input type="checkbox"/> Rejected Recommendation <input type="checkbox"/> Unknown	Any other information: ..... .....

PRODUCT(S) SOLD:				
Brand	Formulation (eg tablets/spray)	Strength	Pack Size	\$ Retail
.....	.....	.....	.....	.....
.....	.....	.....	.....	.....

OUTCOME OF INTERVENTION: (tick one of the following)
<input type="checkbox"/> Intervention had no impact on the patient
<input type="checkbox"/> Intervention was harmful to the patient's well being
<input type="checkbox"/> Intervention averted <i>minor</i> symptoms
<input type="checkbox"/> Intervention averted <i>routine</i> medical attention
<input type="checkbox"/> Intervention averted <i>emergency</i> medical attention
<input type="checkbox"/> Intervention was potentially life-saving

ANY OTHER RELEVANT INFORMATION:
.....
.....
.....
.....
.....

## APPENDIX 10

### Census Recruitment Instruments: Introductory Letter



The University of Sydney

NSW 2006 AUSTRALIA



#### Cost Benefit Analysis of Non-Prescription Medicines

Faculty of Pharmacy A15  
Telephone +61 2 9036 9490  
Telephone +61 2 9036 5192  
Facsimile +61 2 9036 9197

Date

**Should S2 and S3 Medicines be available in supermarkets?**

**Should they remain for sale in pharmacies?**

Dear Colleague,

There is a current debate on whether Pharmacist Only (S3) and Pharmacy (S2) Medicines should stay exclusively in pharmacies or whether the system should change. The University of Sydney, in conjunction with The University of Queensland, The University of South Australia and Health Care Intelligence Pty Ltd is embarking on an important study to measure the added benefits and value that pharmacists and pharmacy assistants provide when dealing with non-prescription medicines. This study has the support of the Pharmacy Guild and the Pharmaceutical Society of Australia.

This is a unique study that aims to measure the significant input of pharmacists and pharmacy staff into **non-prescription** medication issues. We are currently undertaking a nationwide census of community pharmacies in Australia to build a picture of the clinical and economic impact provided when dealing with non-prescription medicines. This will tell us how much time and effort is going into solving non-prescription medicine problems. More importantly, the data will be analysed by expert clinical panels to predict the harm that was averted or other type of consequence thanks to the vigilance of the pharmacy staff. A health economist will analyse the data to estimate the costs and savings to the health care system. **This information will help to decide on the future of the non-prescription medicine schedules.**

**What is required?** Pharmacists and pharmacy staff are asked to record interventions made during the sale (or non-sale) of Pharmacist Only (S3) and Pharmacy (S2) Medicines, over a **two-week period starting 17<sup>th</sup> November 2003 and finishing 30<sup>th</sup> November 2003**. If you agree to participate on behalf of your pharmacy, please read the information sheet, sign the consent form (enclosed) and either fax or mail it back to us. We will then send you a kit containing all the recording forms and full instructions, and advise you of your two-week recording period.

We do hope that you will agree to become involved in this important census of pharmacy non-prescription medicine interventions and thank you in anticipation of your response.

Yours sincerely,

Prof S.I. (Charlie) Benrimoj  
Dean, Faculty of Pharmacy  
University of Sydney

## APPENDIX 11

### Census Recruitment Instruments: Information Sheet



The University of Sydney

NSW 2006 AUSTRALIA



#### Cost Benefit Analysis of Non-Prescription Medicines

Faculty of Pharmacy A15  
Telephone +61 2 9036 9490  
Telephone +61 2 9036 5192  
Facsimile +61 2 9036 9197

### NON-PRESCRIPTION MEDICINE INTERVENTIONS CENSUS -

#### INFORMATION SHEET

This is a study funded by the Commonwealth Department of Health and Ageing as part of the Third Community Pharmacy Agreement, and is part of the **Cost Benefit Analysis of Non-Prescription Medicines** — a broader project examining the costs and benefits of the Pharmacist Only (S3) and Pharmacy (S2) Medicines schedules. It is a collaborative project involving The University of Sydney, The University of Queensland, the University of SA and Health Care Intelligence Pty Ltd.

In this part of the study, we will be documenting information about the **interventions** that pharmacists and pharmacy staff undertake in relation to the sale of these products and related symptom requests, and in this way, we aim to gather information on the health benefits or otherwise that are provided to consumers as a result of these interventions. An intervention, for the purposes of this project, is defined as **the promotion of the quality use of medicines by the identification and resolution of an actual or potential drug- or disease-related problem resulting from an over-the-counter request.**

If you agree to participate, we will ask **all staff** in your pharmacy to collect information on certain interventions they perform for Pharmacist Only (S3) and Pharmacy (S2) Medicines during a two-week period. This would involve all staff in your pharmacy filling out a brief data collection form after each relevant intervention. At the end of each recording week, all of the forms are to be returned to the research centre by reply paid mail.

The information recorded on the interventions undertaken in your pharmacy will not include any identifying details of clients. We do ask for the initials of the staff member making the interventions, in case we need to contact your pharmacy to check details with that person. Furthermore, all aggregate analyses of data will only be carried out above the local government area level. Collated results will be written up in a report to the Commonwealth Government and may also be presented in a professional journal, but will not identify any individual pharmacy or staff member.

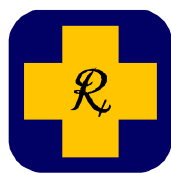
If you agree to participate on behalf of your pharmacy, please sign the consent form (enclosed) and either fax or mail it back to us. Participation in this study is entirely voluntary, and you are free to withdraw from the study at any stage. This information sheet is for you to keep.

If you would like any further information on any aspect of this study or the project in general, please contact:

Professor S.I. (Charlie) Benrimoj	Ph: (02) 9036 9490	Fax: (02) 9036 9197
Ms Catherine Raffaele	Ph: (02) 9036 9490	Email: catherine@pharm.usyd.edu.au
Dr Kylie Williams	Ph: (02) 9351 6063	Email: kylie@pharm.usyd.edu.au
Dr Lynne Emmerton	Ph: (07) 3365 8280	Email: lemmerton@pharmacy.uq.edu.au

*Any person with concerns or complaints about the conduct of a research study can contact the Manger for Ethics Administration, The University of Sydney on (02) 9351 4811.*

APPENDIX 12  
Census Recruitment Instruments: Endorsement Letter



## NON-PRESCRIPTION MEDICINE INTERVENTIONS CENSUS

### Important message to all community pharmacists and staff

You will most likely be seeing publicity soon for the **Cost-Benefit Analysis of Non-Prescription Medicines** project that is about to commence nationwide.

The project has been commissioned in response to the Galbally Report.<sup>1</sup> The Galbally Report requested evidence to support the future of the Pharmacist Only (S3) and Pharmacy (S2) Medicines schedules. Any changes to the current schedule system will have major implications for the pharmacy profession and pharmaceutical industry. Participation in this project is thus crucial to generate data that is needed to determine the future of the Pharmacist Only (S3) and Pharmacy (S2) Medicines schedules. **We strongly encourage you to take the time to be part of the project.**

The first part of this project is a **nationwide census of interventions that pharmacists and pharmacy staff perform for non-prescription medicines.**

The research is being undertaken by a team of experts from the Universities of Sydney, Queensland and South Australia, led by Professor Charlie Benrimoj. The Pharmacy Guild of Australia is managing this project through the Third Community Pharmacy Agreement Research and Development Grants Program.

The Pharmacy Guild of Australia and Pharmaceutical Society of Australia jointly endorse this research. It promises to provide important and exciting findings about current practice relating to Pharmacist Only and Pharmacy Medicines. We strongly urge you to participate fully in this research.

Yours sincerely

John Bronger,  
National President  
The Pharmacy Guild of Australia

Jay Hooper,  
National President  
Pharmaceutical Society of Australia

<sup>1</sup> Galbally R. *National competition review of drugs, poisons and controlled substances legislation*. Canberra: Commonwealth of Australia; 2000.

## Census Recruitment Instruments: Consent Form



**The University of Sydney**

NSW 2006 AUSTRALIA



**Cost Benefit Analysis of Non-Prescription Medicines**

Faculty of Pharmacy A15  
Telephone +61 2 9036 9490  
Telephone +61 2 9036 5192  
Facsimile +61 2 9036 9197

**NON-PRESCRIPTION MEDICINE INTERVENTIONS CENSUS**

**CONSENT FORM**

I hereby consent to \_\_\_\_\_ (pharmacy name)  
participating in the Non-Prescription Medicines Interventions Census, being conducted by the  
Faculty of Pharmacy, The University of Sydney, and I understand that I am free to withdraw  
this pharmacy from the study at any time by phoning the telephone numbers listed above.

The purpose and nature of the study have been explained to me to my full satisfaction, and I  
understand that I can contact the project members at any time regarding any queries I may have  
during the course of the project.

Name \_\_\_\_\_ Signature \_\_\_\_\_  
Please Print

Position (eg proprietor/manager) \_\_\_\_\_

Date \_\_\_\_/\_\_\_\_/\_\_\_\_  
d d m m y y

Pharmacy Name: \_\_\_\_\_

Pharmacy Address: \_\_\_\_\_

State: \_\_\_\_\_ Postcode \_\_\_\_\_

Phone: \_\_\_\_\_

Fax: \_\_\_\_\_

Email: \_\_\_\_\_

**PLEASE NOW FAX THIS FORM TO:**  
**NON-PRESCRIPTION MEDICINE INTERVENTIONS CENSUS**  
**FAX: (02) 9036 9197**

Alternatively, you can post this form to  
S2/S3 PROJECT  
FACULTY OF PHARMACY  
BUILDING A15  
THE UNIVERSITY OF SYDNEY NSW 2006

APPENDIX 14  
Census Pack: Introductory Letter



The University of Sydney

NSW 2006 AUSTRALIA



**Cost Benefit Analysis of Non-Prescription Medicines**

Faculty of Pharmacy A15  
Telephone +61 2 9036 9490  
Telephone +61 2 9036 5192  
Facsimile +61 2 9036 9197

Date

Thank you for agreeing to take part in the Non-Prescription Medicine Interventions Census.

This study is part of a larger project – the Cost Benefit Analysis of Non-Prescription Medicines – examining the health and economic impact of the current non-prescription medicines schedules in Australia: Pharmacist Only (S3) and Pharmacy (S2) Medicines. The project aims to find out the impact that pharmacy interventions have on people who purchase these medications in community pharmacies. This project was commissioned by The Pharmacy Guild of Australia as a response to the recommendations in the Galbally Report and funded by the Australian Government Department of Health and Ageing as part of the Third Community Pharmacy Agreement.

In this Census study, we are asking **all** community pharmacies to record **all significant interventions** their staff make relating to Pharmacist Only (S3) and Pharmacy (S2) Medicines. We will ask you to collect data over a two-week period:

Starting on: **Date**  
And finishing on: **Date**

*The survey is starting on a Tuesday instead of a Monday because the 14<sup>th</sup> June is a public holiday, but it will still go for two-weeks. If these dates are inconvenient to you, please call the project staff on (02) 90369490 or (02) 9036 9489.*

You will find the book of forms for recording your interventions in this package. A set of instructions has been provided for your reference. Please refer to these for specific instructions on how to fill out each part of the intervention collection form.

⇒ **Please ensure that ALL STAFF are given and read the Reference Instructions.**

It is important that all pharmacy staff members who deal with Pharmacist Only (S3) and Pharmacy (S2) Medicines are aware of the project and involved in the intervention collection.

⇒ Please **complete a form immediately after each intervention** to prevent loss of information due to recall problems.

⇒ Please **REMEMBER** to fill in the **Pharmacy Demographic Form**.

⇒ Please **RETURN** the **book of forms** and the **Pharmacy Demographic Form** at the end of the **two week** recording period using the **Reply Paid envelope** provided.

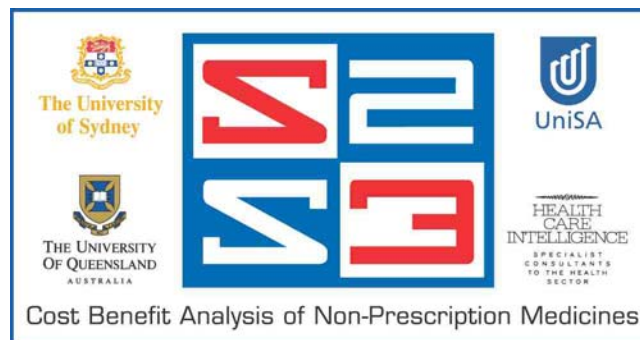
If you have any questions about the forms or any other aspect of the study, please contact the project staff:

**Ms Catherine Raffaele**, Project Manager  
☎ (02) 9036 9490  
Email: catherine@pharm.usyd.edu.au

**Mr Joel Werner**, Research Officer  
☎ (02) 9036 9490  
Email: joel@pharm.usyd.edu.au

# Non-Prescription Medicine Interventions Census

## REFERENCE INSTRUCTIONS



Please read these instructions carefully, as they explain how to correctly fill out the intervention collection forms.

Don't forget to record **ALL SIGNIFICANT INTERVENTIONS**  
that you make involving non-prescription medicines  
for this two-week period:

Starting on: **DATE**

and

Finishing on: **DATE**

**REMEMBER: If you don't know if you should record  
your intervention, RECORD IT ANYWAY**



## HOW TO RECORD INTERVENTIONS

### Who should record interventions

All staff working in your pharmacy and involved in the sale of non-prescription medicines should record their interventions. This includes full-time, part-time and casual staff, locums, pharmacists, pre-registration trainees and pharmacy assistants.

**Please ensure that ALL STAFF are aware of the importance of the study and the location of the book of intervention collection forms.**

### When to record interventions

Interventions should be recorded during all business hours, including day/night every day during your designated two-week time period. This will mean ensuring all your staff are aware of this study, including casual and relieving staff.

### What to do if you run out of Intervention Forms

There are 25 Intervention Forms in this pack for your pharmacy to record your **SIGNIFICANT** non-prescription interventions. If you run out, please contact the project staff (see below) so that we may either fax you a master copy from which you can make copies or send you a batch of forms. Alternatively, you may save a blank form from which you can make copies, if this is more convenient.

Or you can print copies of the form from our website:  
[www.pharm.usyd.edu.au/s2s3project](http://www.pharm.usyd.edu.au/s2s3project)

### What to do with your completed forms

☑ Please mail back the book of intervention collection forms and any other completed forms in the enclosed Reply Paid envelope at the **end of the two-week recording period**.

If you misplace or need another reply paid envelope, please contact the project staff (see below) so that we can send you another.

➔ **IMPORTANT:** Please send back the book of intervention collection forms even if it is blank at the end of the second recording week, so that we can account for all paperwork.

## CONTACTS

Please contact the project staff if you have any questions about the study or the intervention collection forms.

<b>Ms Catherine Raffaele</b> Project Manager ☎ (02) 9036 9490 Email: <a href="mailto:catherine@pharm.usyd.edu.au">catherine@pharm.usyd.edu.au</a>	<b>Mr Joel Werner</b> Research Officer ☎ (02) 9036 9489 Email: <a href="mailto:joel@pharm.usyd.edu.au">joel@pharm.usyd.edu.au</a>
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## WHAT IS AN INTERVENTION?

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

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

Please note that this does not include any standard counselling or warnings that take place during over-the-counter sales and enquiries, only situations in which pharmacy staff **detect and act upon a problem**. For example, if you sell a cough expectorant with the advice to consult a doctor if the condition worsens, your actions would **not** be classified as an intervention. If, however, you refer someone to the doctor because he/she appears to have pneumonia, your actions **would** be classified as an intervention.

## What is a SIGNIFICANT intervention?

In this Census study, we are interested in finding out about **all significant interventions** resulting from over-the-counter requests. We are not asking you to collect interventions that would only have had a minor impact.

- ★ Please record the intervention even if the customer rejects your advice.
- ★ Please record the intervention even if the chance of averting significant harm is small but possible.
- ★ If you are not sure PLEASE RECORD IT ANYWAY.

Significant interventions are:

### 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.

⇒ **For example:** a patient requests something for his mouth ulcers. Upon questioning, you determine that the cause of the mouth ulcers is an overdose of methotrexate that, undetected, could have led to the patient's death.

### INTERVENTIONS THAT POTENTIALLY AVERTED *EMERGENCY* MEDICAL ATTENTION OR SERIOUS HARM

- In your opinion, the intervention averted *emergency* medical attention, with or without hospitalisation.
- This includes:
  - 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.

⇒ **For example:** a man asks for a cold and flu product and a paracetamol product for his six-year-old son. He had intended to use them both together, unaware that it would have resulted in a doubling-up of the paracetamol dose. This could have led to hospitalisation of the child.

⇒ **For example:** a pregnant woman asks for a product that contains Vitamin A. This could have led to a birth defect in her unborn child.

### INTERVENTIONS THAT AVERTED *ROUTINE* MEDICAL ATTENTION

- The intervention resulted in an improvement in patient care and/or optimisation of therapy.
- This includes:
  - 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.

⇒ **For example:** a customer asks for an NSAID. On questioning, the pharmacist discovers that the customer is suffering from stomach troubles and recommends the use of paracetamol instead. This could have prevented an exacerbation of the customer's existing condition.

## EXCLUSIONS

We *do not* need information about interventions that relate to:

- Interventions that averted MINOR symptoms
- Interventions that would have had NO effect if accepted by the patient
- Standard patient counselling with S2/S3 sales
- Extra services, eg blood pressure monitoring
- Drug information that is not patient-specific, eg a GP asking your opinion about a new OTC product on the market
- Deliveries of medications to customers

## TERMS ON THE INTERVENTION COLLECTION FORM

To help you complete the intervention forms, we have outlined here the type of information that we are looking for. Each section below corresponds to a heading on the intervention collection form.

### DATE and TIME

The date and approximate time when you performed the intervention for this patient, which should be the same as the date and the time that you record the information on the form.

### PATIENT INFORMATION

#### **Age Group:**

Tick the age group category that best approximates the patient's age. While the age category of 13-64 years may seem unusual, it has been created to describe the broad 'adult' group who use similar doses of medicines. You do not have to ask the patient for his/her exact age, unless it is clinically relevant (such as the age/weight of a child).

#### **Sex:**

Tick 'Female' if the patient is female and 'Male' for male patients.

#### **Medical History:**

This is the medical history of the patient relevant to their current visit to your pharmacy, that is either known to you or has become apparent through talking to the patient. Tick as many of the listed categories as applicable.

Write under 'other' any other medical information not listed but relevant to the patient's current visit to your pharmacy.

### INTERVENTION

#### **Origin of the Intervention:**

##### Direct product request:

This is where an intervention was initiated as a result of the customer requesting a particular product by brand name or by drug name, eg "May I have some paracetamol please?" For direct product requests, please enter any details of the product as mentioned by the customer. For example, from the request of "May I have a small pack of [BRAND NAME] tablets please?" you can record the brand, the formulation and the strength, regardless of whether this product was eventually purchased.

##### Symptom presentation:

This is where an intervention was initiated as a result of the symptoms that the customer presented in your pharmacy, eg "Can you give me something for hay fever please?" or when the person asks for a broad group of medicines, eg "What do you have in the way of mouth ulcer gels?"

##### Other:

Where an intervention or an intervention resulted from any other event. Describe the nature of the event.

### ***Describe the PROBLEM YOU HAVE IDENTIFIED***

Describe the patient's presenting medical condition, any drugs that you know he/she is taking relevant to this presentation, the doses of such drugs, and the drug-related problem you have identified. You may need to check dispensing records to complete some details, if available. Please include as much detail as possible.

### ***Describe the INTERVENTION YOU UNDERTOOK FOR THIS PROBLEM***

Describe the intervention you undertook in relation to the presenting problem described above. Please include as much detail as possible using a separate form for each intervention.

✱ If you are busy serving customers, this is the best place to jot down notes on the intervention that took place, then fill in the details when you have time later.

### ***What ACTION(S) did you take in relation to this intervention?***

Tick all actions that took place during your attempt to resolve the problem. Please indicate the name of the original product if this was still considered appropriate treatment, the name of a new or different product if one was recommended, and/or any non-drug treatment recommended. Describe any actions not listed here under 'Other'.

### **PATIENT RESPONSE**

Please indicate if the patient accepted or rejected your recommended course(s) of action. Describe exactly what the patient did or did not do under 'Any other information'. Tick 'Unknown' if you don't know what the patient did after the intervention.

### **PRODUCT(S) SOLD**

<b><i>Brand Form Strength</i></b>	<b><i>Pack size</i></b>	<b><i>\$ Retail</i></b>	<b><i>Unsch/S2/S3</i></b>
-----------------------------------	-------------------------	-------------------------	---------------------------

Give details of all OTC products that the patient purchased following the intervention. These may be the original products requested if they were still considered suitable in light of the problem detected, or if the patient accepted a recommended product, only enter what he/she actually bought. This is important for our cost-benefit analysis and this information will only be used in unidentified, aggregate data. It is important to include **ALL DETAILS** of the product sold. Please fill these details in later if you do not have time when you are recording your intervention. **Form** refers to what the form the medicine is in, eg tablets/spray/drops. **Unsch/S2/S3** refers to Unscheduled, S2 (Pharmacy Medicines), S3 (Pharmacist Only Medicines).

For example:

<b>Brand</b>	<b>Formulation</b>	<b>Strength</b>	<b>Pack size</b>	<b>\$ Retail</b>	<b>Unsch/S2/S3</b>
Panadol®	tablets	500mg	100	\$X.XX	S2

#### ANY OTHER RELEVANT INFORMATION

##### ***STAFF MEMBER(S) INVOLVED IN THE INTERVENTION:***

Tick all staff members involved in the intervention.

##### **Time Spent:**

Write the estimated time (in minutes) that each staff member spent undertaking the intervention.


#### EXAMPLE OF HOW TO FILL OUT THE FORM

To help you complete the intervention forms, we have provided a common scenario that you might encounter and how you would then fill out the form

##### **Example Scenario: Overdosing of Paracetamol**

An adult male requested generic paracetamol 500mg and cold and flu tablets also containing paracetamol. The pharmacist identified the problem of therapeutic duplication, and advised the consumer not to use the two products together. The case took two minutes to resolve. This was rated by the researchers as an intervention that potentially averted emergency medical attention or serious harm, as unwitting use of the two products together over the normal duration of a cold may have resulted in hepatotoxicity.

NON-PRESCRIPTION MEDICINE INTERVENTION COLLECTION FORM																							
DATE: 24/11/03      TIME: 9:30am			What ACTION(S) did you take in relation to this intervention? (tick as many as applicable)																				
PATIENT INFORMATION			<b>Actions Taken</b> <input type="checkbox"/> Advice: ..... <input type="checkbox"/> Review of patient medication/computer records <input type="checkbox"/> Contact with patient's Doctor <input type="checkbox"/> Contact with patient (if absent) <input checked="" type="checkbox"/> Original product suggested: D/N Cold & Flu <input type="checkbox"/> New or different product suggested: ..... <input type="checkbox"/> Non-drug therapy suggested: .....  <b>Patient Referred</b> <input type="checkbox"/> to Doctor – next scheduled visit <input type="checkbox"/> to Doctor – conditional on response <input type="checkbox"/> to Doctor – immediately <input type="checkbox"/> to Accident and Emergency <input type="checkbox"/> to other health professional <input type="checkbox"/> Other: .....																				
<b>Age group:</b> <input type="checkbox"/> 0-2 years <b>Sex:</b> <input type="checkbox"/> Female (Estimate) <input type="checkbox"/> 3-12 years <input checked="" type="checkbox"/> Male <input checked="" type="checkbox"/> 13-64 years <input type="checkbox"/> 65+ years																							
<b>RELEVANT Medical history:</b> (tick as many as applicable) <input type="checkbox"/> Hypertension <input type="checkbox"/> Diabetes <input type="checkbox"/> Asthma <input type="checkbox"/> Heart disease <input type="checkbox"/> Arthritis <input type="checkbox"/> Pregnancy <input type="checkbox"/> Heartburn/ulcer <input type="checkbox"/> Skin disease <input type="checkbox"/> Other: .....																							
INTERVENTION																							
<b>Origin of the intervention:</b> (tick one only) <input checked="" type="checkbox"/> Direct product request..... please fill in → <input type="checkbox"/> Symptom presentation <input type="checkbox"/> Other: .....			<b>Please Record Known Details of Any Product Requested</b> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;">Brand</th> <th style="text-align: left; border-bottom: 1px solid black;">Formulation</th> <th style="text-align: left; border-bottom: 1px solid black;">Strength</th> </tr> </thead> <tbody> <tr> <td>Paracetamol</td> <td>Tablets</td> <td>500mg</td> </tr> <tr> <td>D/N Cold &amp; Flu</td> <td>Tablets</td> <td></td> </tr> </tbody> </table>			Brand	Formulation	Strength	Paracetamol	Tablets	500mg	D/N Cold & Flu	Tablets										
Brand	Formulation	Strength																					
Paracetamol	Tablets	500mg																					
D/N Cold & Flu	Tablets																						
Describe the PROBLEM YOU HAVE IDENTIFIED: (include drug/condition/doses involved)																							
<p>Consumer requested both D/N Cold &amp; Flu tablets and paracetamol tablets to treat symptoms of a cold - headache, runny nose, non-productive cough. Potential double dosing of paracetamol.</p>																							
Describe the INTERVENTION YOU UNDERTOOK FOR THIS PROBLEM:																							
<p>Explained to consumer that D/N Cold &amp; Flu tablets already contained paracetamol, therefore there was no need for him to take paracetamol tablets as well.</p>																							
PRODUCT(S) SOLD:																							
<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;">Brand</th> <th style="text-align: left; border-bottom: 1px solid black;">Form</th> <th style="text-align: left; border-bottom: 1px solid black;">Strength</th> <th style="text-align: left; border-bottom: 1px solid black;">Pack Size</th> <th style="text-align: left; border-bottom: 1px solid black;">\$Price</th> <th style="text-align: left; border-bottom: 1px solid black;">Unsch</th> </tr> </thead> <tbody> <tr> <td colspan="6" style="text-align: right; font-size: small;">(eg tats/spray) /S2/S3</td> </tr> <tr> <td>D/N Cold &amp; Flu</td> <td>Tablets</td> <td></td> <td>20</td> <td>\$X.XX</td> <td>S2</td> </tr> </tbody> </table>						Brand	Form	Strength	Pack Size	\$Price	Unsch	(eg tats/spray) /S2/S3						D/N Cold & Flu	Tablets		20	\$X.XX	S2
Brand	Form	Strength	Pack Size	\$Price	Unsch																		
(eg tats/spray) /S2/S3																							
D/N Cold & Flu	Tablets		20	\$X.XX	S2																		
Staff member(s) involved in the intervention      Time Spent (tick as many as applicable)      (Estimate of mins)																							
<input checked="" type="checkbox"/> Pharmacist      2 mins <input type="checkbox"/> Graduate pharmacist      ..... <input type="checkbox"/> Pharmacy assistant      ..... <input type="checkbox"/> Other: .....																							

Non-Prescription Medicine Interventions Intervention Collection Forms	
<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>Cost Benefit Analysis of Non-Prescription Medicines</p> </div> <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p><b>* Please read the Reference Instructions before filling out this form</b></p> </div> </div>	
INSTRUCTIONS FOR ALL STAFF	
<p><b>What should you do?</b> Every time you perform a SIGNIFICANT INTERVENTION involving a non-prescription medicine, regardless of whether a sale took place, we ask you to record this on one of the forms in this book.</p> <p><b>o Please fill in ALL parts of the form</b> including details of product sold and time of the staff members involved in the intervention.</p> <p><b>What is a SIGNIFICANT INTERVENTION?</b> An intervention is when you pick up and act on a problem. It is significant and should be recorded if you think that:</p> <ul style="list-style-type: none"> <li>• The intervention resulted in an improvement in patient care and/or optimisation of therapy. This includes: <ul style="list-style-type: none"> <li>o Prevention of a GP visit</li> <li>o Decrease in length of hospital stay</li> <li>o Decrease in risk of moderate adverse events or symptoms</li> <li>o Prevention of exacerbation of the condition;</li> </ul> </li> <li>• OR, the intervention averted <i>emergency</i> medical attention or serious harm, with or without hospitalisation. This includes: <ul style="list-style-type: none"> <li>o Prevention of disability, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life</li> <li>o Prevention of a birth defect</li> <li>o Prevention of serious drug toxicity or major adverse event;</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• OR, 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.</li> </ul> <p><b>Example:</b> Stopping a customer using two products containing paracetamol at the same time.</p> <ul style="list-style-type: none"> <li>o Even if there is only a small possibility that significant harm was avoided, RECORD IT ANYWAY.</li> <li>o Even if the customer rejects your advice, RECORD IT ANYWAY.</li> </ul> <p>→ At the end of the two-week collection period, please send us back the whole this book of forms (even if no interventions have been collected) in the Reply Paid Envelope provided.</p> <p>→ Remember to include a completed Pharmacy Demographics Form.</p> <p><b>Any questions?</b></p> <ol style="list-style-type: none"> <li>1. Refer to the reference instructions.</li> <li>2. Please phone the project staff at The University of Sydney: Catherine on (02) 9036 9490 or Celal on (02) 9036 5192.</li> <li>3. If you have any doubt, record your intervention anyway as fully as possible.</li> </ol> <p><b>Thank you for your assistance in this study.</b></p>
<p><b>REMEMBER: If you have any doubts about recording your intervention, RECORD IT ANYWAY.</b></p>	



## APPENDIX 17

### Census Pack: Data Collection Form

[illegible]

APPENDIX 18  
Pharmacy Demographics Form

PHARMACY DEMOGRAPHICS FORM							
<b>Name of Pharmacy</b>							
<b>Telephone</b>							
<b>State</b>							
<i>Please circle ONE choice or fill in details where applicable</i>							
1. Pharmacy location a. Metropolitan b. Country (Non-metropolitan)							
2. Description of premises a. Large shopping centre (Regional shopping centre) b. Small shopping centre (Non-regional shopping centre) c. Suburban strip shopping d. Medical centre e. Other (please specify: .....)							
3. Opening Hours (please fill in the normal hours your pharmacy is open on each day of the week)							
	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
4. Average daily staffing (please fill in number of full-time equivalents): Registered pharmacists: ..... Pre-registered graduate: ..... Pharmacy assistants: ..... Other: ..... .....							
5. QCPP accreditation status: a. Accredited b. Undergoing accreditation c. Never applied for accreditation / not a Guild member							
6. Turnover Range Per Year: a. Up to \$500,000 b. \$500,000 - \$700,000 c. \$700,000 - \$900,000 d. \$900,000 - \$1.2 m e. \$1.2 m - \$1.5 m f. \$1.5 m - \$2 m g. Over \$2m							
HOW TO RETURN THIS FORM							
Fax or mail back to:				FAX: (02) 9036 9197			
				MAIL: CATHERINE RAFFAELE S2/S3 COST BENEFIT PROJECT FACULTY OF PHARMACY BUILDING A15 THE UNIVERSITY OF SYDNEY NSW 2006			
						For office use only Code #: .....	

## APPENDIX 19

### Sample Study Recruitment Instruments: QCP Cover Letter

File: C526.LH/LH

Date

Dear QCPP member

As you would be aware, there is currently a debate on whether Pharmacist Only (S3) and Pharmacy (S2) medicines should stay exclusively in pharmacies or whether the system should change. It is being said that this is the second largest threat to Community Pharmacy after the 'pharmacy in supermarkets' campaign.

Under the Pharmacy Guild of Australia's Third Agreement R&D Grants Program, The University of Sydney, in conjunction with The University of Queensland, the University of South Australia and Health Care Intelligence Ltd has been funded to conduct a 'Cost Benefit Analysis of Non-Prescription Medicines' project.

The first part of the project was a census where only rare and clinically highly significant interventions were documented. Your pharmacy may have already participated in this first part. Recruitment has now begun for the second part, which is a smaller study involving samples of pharmacies. Pharmacies that participated in the census are also requested to participate in this second stage. However, your pharmacy need not have participated in the census to participate in the second part.

This second part of the project requires 160 pharmacies to participate over a two-week period, where they will need to record all interventions made during the sale of Pharmacist Only and Pharmacy Medicines, and recruit up to 25 customers (for whom an intervention was made) into a follow-up study whereby they will report to the researchers the real-life outcomes from your interventions.

The Guild, and in particular the QCP Division, views this as an extremely important project in helping to decide on the future of the non-prescription medicine schedules and encourages you, as a registered member of the QCPP, to participate.

Included with this letter are three documents from The University of Sydney;

- a letter inviting you to participate in the project,
- an information sheet explaining the study, and
- a consent form.

Please read these documents carefully, and if you agree to participate, fax the consent form back to The University of Sydney. Once you consent, the QCP Division will release information relating to your QCPP registration and accreditation status, and the result of any Standards Maintenance Assessment (SMA) visit to the researchers. This information will only be released on the grounds that it will be kept strictly confidential and will only be published in de-identified and aggregated form.

If you require any further information or clarification, please me or Catherine Raffaele, Research Officer, The University of Sydney on (02) 9036 9490.

Yours sincerely

**Lorraine Humphreys**  
**Director, QCP Division**

## APPENDIX 20

### Sample Study Recruitment Instruments: Letter to pharmacist-in-charge



The University of Sydney

NSW 2006 AUSTRALIA



#### Cost Benefit Analysis of Non-Prescription Medicines

Faculty of Pharmacy A15  
Telephone +61 2 9036 9490  
Telephone +61 2 9036 5192  
Facsimile +61 2 9036 9197

Date

#### Should S2 and S3 Medicines be available in supermarkets? Should they remain for sale in pharmacies?

Dear Colleague,

You may recall hearing about or even participating in the Non-Prescription Medicines Census several months ago. We are now selecting 160 pharmacies to participate in the Non-Prescription Medicines Sample Study. In the Census, we were collecting information on low-incidence high-significance interventions. In the forthcoming Sample Study, we are looking at **all** of the interventions that pharmacies make for non-prescription medicines, in order to study the full picture of the added benefits and value that pharmacists and pharmacy assistants provide when dealing with non-prescription medicines on a day-to-day basis.

This study will provide important evidence to the current debate on whether Pharmacist Only (S3) and Pharmacy (S2) Medicines should stay exclusively in pharmacies or whether the system should change. This will tell us how much time and effort is going into discovering and solving non-prescription medicine problems. More importantly, the data will be analysed by expert clinical panels to predict the harm that was averted or other type of consequence thanks to the vigilance of the pharmacy staff. A health economist will analyse the data to estimate the costs and savings to the health care system. **This information will help to decide on the future of the non-prescription medicine schedules.**

This project is being conducted The University of Sydney, in conjunction with The University of Queensland, The University of South Australia and Health Care Intelligence Pty Ltd by and has the support of the Pharmacy Guild and the Pharmaceutical Society of Australia.

**What is required?** Over a **two-week period**, pharmacists and pharmacy staff will be asked to:

1. Record all interventions made during the sale (or non-sale) of Pharmacist Only (S3) and Pharmacy (S2) Medicines, and
2. Recruit up to 25 of these consumers into the consumer follow-up study (you will be offered \$10 per recruitment to compensate for your time).

If you agree to participate on behalf of your pharmacy, please read the information sheet, sign the consent form (enclosed) and either fax or mail it back to us. We will then send you a kit containing the recording forms and full instructions, and advise you of your two-week recording period.

We do hope that you will agree to become involved in this important sample study of pharmacy non-prescription medicine interventions and thank you in anticipation of your response.

Yours sincerely,

Prof S.I. (Charlie) Benrimoj  
Dean, Faculty of Pharmacy  
University of Sydney

## APPENDIX 21

### Sample Study Recruitment Instruments: Information Sheet



The University of Sydney

NSW 2006 AUSTRALIA



#### Cost Benefit Analysis of Non-Prescription Medicines

Faculty of Pharmacy A15  
Telephone +61 2 9036 9490  
Telephone +61 2 9036 5192  
Facsimile +61 2 9036 9197

### NON-PRESCRIPTION MEDICINE INTERVENTIONS SAMPLE STUDY INFORMATION SHEET

This is a study funded by the Commonwealth Department of Health and Ageing as part of the Third Community Pharmacy Agreement, and is part of the **Cost Benefit Analysis of Non-Prescription Medicines** — a broader project examining the costs and benefits of the Pharmacist Only (S3) and Pharmacy (S2) Medicines schedules. It is a collaborative project involving The University of Sydney, The University of Queensland, the University of SA and Health Care Intelligence Pty Ltd.

In the Non-Prescription Medicine Interventions Census conducted previously, we were documenting only rare and clinically highly significant interventions made by pharmacies. In this part of the study, we will be documenting information about **all interventions** that pharmacists and pharmacy staff undertake in relation to the sale of these products and related symptom requests, and in this way, we aim to gather information on the health benefits or otherwise that are provided to consumers as a result of these interventions. Our analysis will also look at whether intervention rates differ between accredited pharmacies and non-accredited pharmacies. An intervention, for the purposes of this project, is defined as **the promotion of the quality use of medicines by the identification and resolution of an actual or potential drug- or disease-related problem resulting from an over-the-counter request.**

If you agree to participate, we will ask **all staff** in your pharmacy to collect information on **ALL** interventions they perform for Pharmacist Only (S3) and Pharmacy (S2) Medicines during a two-week period. This would involve all staff in your pharmacy filling out a brief data collection form after each intervention. We will also be asking you to recruit consumers (up to 25) who are over 16 yrs of age and fluent in English and who have had an intervention performed on them into our consumer follow-up study. A payment of \$10 + GST per consumer recruited (up to 25) will be made as reimbursement for your staff's time. At the end of each recording week, all of the forms are to be returned to the research centre by reply paid mail. Your pharmacy may be contacted to follow-up the completion, return and accuracy of the intervention and consent forms.

We will be requesting the release of any wholesale purchases that you make from IMS Pty Ltd and computerised point-of-sales data (if available) on specific non-prescription medicines. This will be used for validation purposes and to calculate intervention rates. All sales data will be kept strictly confidential and will be de-identified and aggregated for analysis.

The information recorded on the interventions undertaken in your pharmacy will not include any identifying details of clients, unless they have agreed to participate in the consumer follow-up study. All data will be de-identified on data-entry. Collated results will be written up in a report to the Commonwealth Government and may also be presented in a professional journal, but will not identify any individual pharmacy, staff member or consumer.

If you agree to participate on behalf of your pharmacy, please sign the consent form (enclosed) and either fax or mail it back to us. Participation in this study is entirely voluntary, and you are free to withdraw from the study at any stage. This information sheet is for you to keep. If you would like any further information on any aspect of this study or the project in general, please contact:

Professor S.I. (Charlie) Benrimoj    Ph: (02) 9036 9490    Fax: (02) 9036 9197  
Ms Catherine Raffaele    Ph: (02) 9036 9490    Email: catherine@pharm.usyd.edu.au

*Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, The University of Sydney on (02) 9351 4811.*

APPENDIX 22  
Sample Study Recruitment Instruments: Consent Form



**The University of Sydney**

NSW 2006 AUSTRALIA



**Cost Benefit Analysis of Non-Prescription Medicines**

Faculty of Pharmacy A15  
Telephone +61 2 9036 9490  
Telephone +61 2 9036 5192  
Facsimile +61 2 9036 9197

**NON-PRESCRIPTION MEDICINE INTERVENTIONS SAMPLE STUDY**

**CONSENT FORM**

I hereby consent to \_\_\_\_\_ (pharmacy name)  
participating in the Non-Prescription Medicines Interventions Sample Study, being conducted by the  
Faculty of Pharmacy, The University of Sydney, and I understand that I am free to withdraw this  
pharmacy from the study at any time by phoning the telephone numbers listed above. I understand that  
my pharmacy may be contacted to follow-up the completion, return and accuracy of the study's forms.

I understand that participation in this study will require access by the researchers to sales data for the  
pharmacy on selected non-prescription medicines. I understand that this information will be kept strictly  
confidential and will only be published in de-identified and aggregated form.

I consent to (please tick):

- ☐ Allowing the release to the research team of this pharmacy's PBS Approval number, matched QCPP  
accreditation details and SMA evaluation (if available) from the QCPP division.  
☐ Allowing the researchers to access this pharmacy's individual wholesale sales data through IMS Pty  
Ltd.  
☐ Allowing the researchers to access this pharmacy's point-of-sale data for non-prescription medicines.

The purpose and nature of the study have been explained to me to my full satisfaction, and I understand  
that I can contact the project members at any time regarding any queries I may have during the course of  
the project.

Name \_\_\_\_\_ Signature \_\_\_\_\_  
Please Print

Position (eg proprietor/manager) \_\_\_\_\_

Date \_\_\_\_/\_\_\_\_/\_\_\_\_  
d d m m y y

Pharmacy Name: \_\_\_\_\_ PBS Approval Number: \_\_\_\_\_

Pharmacy Address: \_\_\_\_\_

\_\_\_\_\_ State: \_\_\_\_\_ Postcode \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Email: \_\_\_\_\_

**PLEASE NOW FAX  
THIS FORM TO:  
NON-PRESCRIPTION MEDICINE  
INTERVENTIONS SAMPLE STUDY  
FAX: (02) 9036 9197**

**Alternatively, you can post this form to:  
S2/S3 PROJECT  
FACULTY OF PHARMACY  
BUILDING A15  
THE UNIVERSITY OF SYDNEY  
NSW 2006**  
If you do need to post your form, **please call** to let  
the researchers know: (02) 90369490.

## APPENDIX 23

### Sample Study Recruitment Instruments: Follow-up Fax

Date

Dear QCPP member

You may have received a fax and/or a phone call recently about the Non-Prescription Medicines Interventions Sample Study (as part of the Cost Benefit Analysis of Non-Prescription Medicines). If so, we apologise for contacting you again, however, we are having some difficulty reaching our target numbers of pharmacies required to make the study successful.

The Guild, and in particular the QCP Division, views the Cost Benefit Analysis of Non-Prescription Medicines' project as an extremely important project in helping to decide on the future of the non-prescription medicine schedules and strongly encourages you, as a registered member of the QCPP, to participate in the Sample Study.

As you would be aware, there is currently a debate on whether Pharmacist Only (S3) and Pharmacy (S2) medicines should stay exclusively in pharmacies or whether the system should change. It is being said that this is the second largest threat to Community Pharmacy after the 'pharmacy in supermarkets' campaign. The University of Sydney, in conjunction with The University of Queensland, the University of South Australia and Health Care Intelligence Ltd has been funded to conduct this project under the Pharmacy Guild of Australia's Third Agreement R&D Grants Program,

This current Sample Study is different to the Non-Prescription Medicines Interventions Census Study which you may or may not have been involved in. The census asked for pharmacy staff to collect only significant interventions, while this study is asking a sample of 160 pharmacies to record ALL their interventions on non-prescription medicines over a two-week period and recruit a maximum of 25 customers (for whom an intervention was made) into a follow-up study whereby they will report to the researchers the real-life outcomes from your interventions. Pharmacies that participated in the census are also requested to participate in this second stage. However, your pharmacy need not have participated in the census to participate in this study.

As an incentive, all pharmacies that participate in the study will receive 2 CQI points.

In order to participate, the researchers at The University of Sydney will first need to receive a completed consent form which has been faxed to you earlier. If you did not receive this form or have mislaid it, please contact the researchers on (02) 9036 9490 or (02) 9036 9489 to have another faxed to you. Once they receive your fax they will send you out the study pack which includes the intervention collection forms.

If you have any questions about the study or have already faxed in a consent form but have still received this fax, then please contact the researchers at The University of Sydney directly on (02) 9036 9490 or (02) 9036 9489.

Yours sincerely

**Lorraine Humphreys**  
**Director, QCP Division**



## APPENDIX 24

### Sample Study Pack: Introductory Letter



The University of Sydney

NSW 2006 AUSTRALIA



#### Cost Benefit Analysis of Non-Prescription Medicines

Faculty of Pharmacy A15  
Telephone +61 2 9036 9490  
Telephone +61 2 9036 5192  
Facsimile +61 2 9036 9197

Date

Thank you for agreeing to take part in the Non-Prescription Medicine Interventions Sample Study.

This study is part of a larger project – the Cost Benefit Analysis of Non-Prescription Medicines – examining the health and economic impact of the current non-prescription medicines schedules in Australia: Pharmacist Only (S3) and Pharmacy (S2) Medicines. The project aims to find out the impact that pharmacy interventions have on people who purchase these medications in community pharmacies. This project was commissioned by The Pharmacy Guild of Australia as a response to the recommendations in the Galbally Report and funded by the Australian Government Department of Health and Ageing as part of the Third Community Pharmacy Agreement.

In this Sample Study, we are asking selected community pharmacies to record **all interventions** their staff make relating to Pharmacist Only (S3) and Pharmacy (S2) Medicines. Once an intervention has been made on a consumer or a consumer's dependent, if the consumer is over 16 years of age, fluent in English, we ask that you try to recruit the customer (up to a total of 25) into a follow-up consumer study. As reimbursement for your staff's time, we will make a payment of \$10 + GST for each consumer recruited (up to 25). Full instructions can be found in the Reference Instructions.

We will ask you to collect data over a two-week period:

Starting on: **DATE** and finishing on: **Date**

*If these dates are inconvenient to you, please call the project staff on (02) 90369490 or (02) 9036 9489 to arrange an alternative.*

You will find the forms for recording your interventions in this package. A set of instructions has been provided for your reference. Please refer to these for specific instructions on how to fill out each part of the intervention collection form. Your pharmacy staff may be contacted by the project staff to follow-up the completion, return and accuracy of the study forms.

⇒ Please ensure that **ALL STAFF** are given and read the **Reference Instructions**.

It is important that all pharmacy staff members who deal with Pharmacist Only (S3) and Pharmacy (S2) Medicines are aware of the project and involved in the intervention collection.

⇒ Please **complete an intervention form immediately after each intervention** to prevent loss of information due to recall problems.

⇒ Please **RETURN** all complete **intervention and customer consent forms** and at the end of each week in the **two week** recording period using the **Reply Paid envelope** provided.

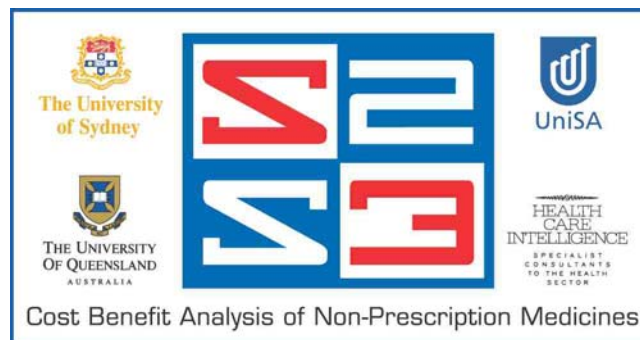
If you have any questions about the forms or any other aspect of the study, please contact the project staff:

<b>Ms Catherine Raffaele</b> , Project Manager ☎ (02) 9036 9490 Email: catherine@pharm.usyd.edu.au	<b>Mr Joel Werner</b> , Research Officer ☎ (02) 9036 9489 Email: joel@pharm.usyd.edu.au
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# Non-Prescription Medicine Interventions Sample Study

## REFERENCE INSTRUCTIONS



Please read these instructions carefully, as they explain how to correctly fill out the intervention collection forms.

Don't forget to record **ALL INTERVENTIONS**  
that you make involving non-prescription medicines  
for this two-week period:

**Starting on: Date**

and

**Finishing on: Date**

**REMEMBER: If you don't know if it is an intervention,  
RECORD IT ANYWAY**

## HOW TO RECORD INTERVENTIONS

### Who should record interventions

All staff working in your pharmacy and involved in the sale of non-prescription medicines should record their interventions. This includes full-time, part-time and casual staff, locums, pharmacists, pre-registration trainees and pharmacy assistants.

**Please ensure that ALL STAFF are aware of the importance of the study and the location of the book of intervention collection forms. Please ensure that ALL STAFF are aware of the recruitment procedures for the consumer follow-up study.**

### When to record interventions

Interventions should be recorded during all business hours, including day/night every day during your designated two-week time period. This will mean ensuring all your staff are aware of this study, including casual and relieving staff.

### What to do if you run out of Intervention Forms

There are 50 Intervention Forms in this pack for your pharmacy to record ALL of your non-prescription interventions. If you run out, please contact the project staff (see below) so that we may either fax you a master copy from which you can make copies or send you a batch of forms. Alternatively, you may save a blank form from which you can make copies, if this is more convenient.

Alternatively, you can print copies of the form from our website:  
<http://www.pharm.usyd.edu.au/s2s3project>

### What to do with your completed forms

✉ Please mail back all completed forms in the enclosed Reply Paid envelopes at the **end of EACH week of the two-week recording period**. Remember to include the consumer consent forms collected **each week**. This will allow us to make timely follow-ups with the consumers regarding their health behaviours and outcomes. If you have misplaced or need another reply paid envelope, please contact the project staff (see below) so that we can send you another.

➔ **IMPORTANT:** Please send back the book of intervention collection forms, even if it is blank at the end of the second recording week, so that we can account for all paperwork.

## CONTACTS

Please contact the project staff if you have any questions about the study or the intervention collection forms.

<b>Ms Catherine Raffaele</b> Project Manager ☎ (02) 9036 9490 Email: <a href="mailto:catherine@pharm.usyd.edu.au">catherine@pharm.usyd.edu.au</a>	<b>Mr Joel Werner</b> Research Officer ☎ (02) 9036 9489 Email: <a href="mailto:joel@pharm.usyd.edu.au">joel@pharm.usyd.edu.au</a>
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## Recruitment Procedure for Consumer Follow-Up Study

As part of this sample study, we plan to follow-up the consumers involved in the interventions recorded (either themselves or their dependent), to record their health behaviours and outcomes. We would like you to recruit up to 25 consumers for whom you have discovered and resolved a non-prescription problem. Once 25 consumers have been recruited, we no longer need you to recruit any more, but please continue to record interventions.

➔ **IMPORTANT:** Please only attempt to recruit consumers who are over 16 years of age and who are fluent in English. The patient can be under 16 years of age if the consumer was the parent or guardian and 16 years or older.

**We will reimburse the pharmacy \$10 + GST for each consumer** (up to 25) recruited into the Post Marketing Surveillance study.

After an intervention has been performed, please ask the consumer if they would be willing to participate in the consumer follow-up study.

### **An example script which you can use:**

“Our pharmacy is currently participating in nationwide University study looking at the availability of medicines like the one(s) we have just talked about. As part of this study, the researchers would like to follow up customers like you, who have had some kind of problem discovered and talked about by pharmacy staff. This is very simple – all you’d have to do is fill out a questionnaire in 7 days’ time and sending it back to The University of Sydney. All of your details will remain confidential. Would you be interested in participating?”

### **If they agree to participate:**

1. Give the consumer a Consumer Follow-up Study Information Sheet.
2. Ask them to fill out the consent form. It is important that **all details are clearly filled in** and that the consumer signs this form. **Remember to keep this form and return it to the researchers** at the end of each week with that week’s completed interventions forms.
3. Give the consumer the attached Questionnaire Pack. Make sure that it has the same number as the consumer consent form.
4. Record the questionnaire number on the related intervention form on which you are asked to record the details of this intervention (as usual). You will find this number on the consumer consent form and the questionnaire pack. This is very important as we will need to match them up later.

### **What does the consumer have to do?**

The questionnaire pack contains 1 questionnaire and a reply paid envelope. They will be required to fill in the questionnaire **ONE WEEK** after they were given it and then return it directly to the researchers (not the pharmacy) in the reply paid envelope.

### **REMEMBER:**

- ★ **Please record the questionnaire number on the original intervention form**
- ★ **Please return the consumer consent forms at the end of each week**

## WHAT IS AN INTERVENTION?

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

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

Please note that this does not include any standard counselling or warnings that take place during over-the-counter sales and enquiries, only situations in which pharmacy staff **detect and act upon a problem**. For example, if you sell a cough expectorant with the advice to consult a doctor if the condition worsens, your actions would **not** be classified as an intervention. If, however, you refer someone to the doctor because he/she appears to have pneumonia, your actions **would** be classified as an intervention.

- ✱ Please record the intervention even if the consumer rejects your advice.
- ✱ If you are not sure PLEASE RECORD IT ANYWAY.

We are looking to collect all interventions performed in the pharmacy from the potentially life-saving to those that had minor/no impact or were harmful to the patient.

### 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.

⇒ **For example:** a patient requests something for his mouth ulcers. Upon questioning, you determine that the cause of the mouth ulcers is an overdose of methotrexate that, undetected, could have led to the patient's death.

### INTERVENTIONS THAT POTENTIALLY AVERTED *EMERGENCY* MEDICAL ATTENTION OR SERIOUS HARM

- In your opinion, the intervention averted *emergency* medical attention, with or without hospitalisation.
- This includes:
  - 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.

⇒ **For example:** a man asks for a cold and flu product and a paracetamol product for his six-year-old son. He had intended to use them both together, unaware that it would have resulted in a doubling-up of the paracetamol dose. This could have led to hospitalisation of the child.

⇒ **For example:** a pregnant woman asks for a product that contains Vitamin A. This could have led to a birth defect in her unborn child.

#### **INTERVENTIONS THAT AVERTED *ROUTINE* MEDICAL ATTENTION**

- The intervention resulted in an improvement in patient care and/or optimisation of therapy.
- This includes:
  - 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.

⇒ **For example:** a customer asks for an NSAID. On questioning, the pharmacist discovers that the customer is suffering from stomach troubles and recommends the use of paracetamol instead. This could have prevented an exacerbation of the customer's existing condition.

#### **INTERVENTIONS THAT AVERTED *MINOR* SYMPTOMS**

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

⇒ **For example:** a woman with period pain reports that the product she was recommended doesn't work very effectively. Upon questioning, she reveals that she takes the minimum dose and only when the pain is severe. The pharmacist suggests an increase in dose (to the recommended range) and regular dosing every four to six hours while the pain persists.

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

- We would also like you to record any interventions that, in your opinion, had no real impact on the patient or the patient's wellbeing.

⇒ **For example:** an elderly patient complains that her paracetamol tablets are too large to be swallowed. The pharmacy assistant suggests soluble paracetamol as an alternative.

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

- We would also like you to record any interventions you made that have had, or may have had, a harmful or negative impact on the patient or the patient's wellbeing.

⇒ **For example:** a man who has been overusing a nasal decongestant spray is suspected to have rebound congestion. The pharmacist recommends pseudoephedrine tablets instead, but omits to ask about the patient's other medication. It turns out that the patient has uncontrolled high blood pressure. Although one problem is solved (the rebound congestion), another is potentially created (hypertensive crisis).

## EXCLUSIONS

We ***do not*** need information about interventions that relate to:

- Standard patient counselling with S2/S3 sales
- Extra services, eg blood pressure monitoring
- Drug information that is not patient-specific, eg a GP asking your opinion about a new OTC product on the market
- Deliveries of medications to consumers

## TERMS ON THE INTERVENTION COLLECTION FORM

To help you complete the intervention forms, we have outlined here the type of information that we are looking for. Each section below corresponds to a heading on the intervention collection form.

### CONSUMER RECRUITMENT INFORMATION

**Did you try to recruit the consumer?** yes ☐ no ☐ → **reason(s):**

Please indicate whether you tried to recruit the consumer into the Consumer Follow-up Study or not. If not, please indicate the reasons why not.

**If yes, did the consumer:** accept ☐ decline ☐:

If you tried to recruit the consumer into the Consumer Follow-up Study, please indicate whether they accepted or declined

**If the consumer declined, what reason was given?**

Please note down any reason given for declining. If no reason was given, you do not need to press the consumer for a reason

**If the consumer accepted, what is the questionnaire number?**

It is VERY IMPORTANT that this questionnaire number is recorded on the intervention form so that we can match the follow-up questionnaire with the correct intervention later.

The questionnaire number is prominently displayed on both the consumer consent form and the questionnaire pack.

**DATE and TIME**

The date and approximate time when you performed the intervention for this patient, which should be the same as the date and the time that you record the information on the form.

**PATIENT INFORMATION****Age Group:**

Tick the age group category that best approximates the patient's age. While the age category of 13-64 years may seem unusual, it has been created to describe the broad 'adult' group who use similar doses of medicines. You do not have to ask the patient for his/her exact age, unless it is clinically relevant (such as the age/weight of a child).

**Sex:**

Tick 'Female' if the patient is female and 'Male' for male patients.

**Medical History:**

This is the medical history of the patient relevant to their current visit to your pharmacy, that is either known to you or has become apparent through talking to the patient. Tick as many of the listed categories as applicable.

Write under 'other' any other medical information not listed but relevant to the patient's current visit to your pharmacy.

**INTERVENTION****Origin of the Intervention:**Direct product request:

This is where an intervention was initiated as a result of the customer requesting a particular product by brand name or by drug name, eg "May I have some paracetamol please?" For direct product requests, please enter any details of the product as mentioned by the customer. For example, from the request of "May I have a small pack of [BRAND NAME] tablets please?" you can record the brand, the formulation and the strength, regardless of whether this product was eventually purchased.

Symptom presentation:

This is where an intervention was initiated as a result of the symptoms that the customer presented in your pharmacy, eg "Can you give me something for hay fever please?" or when the person asks for a broad group of medicines, eg "What do you have in the way of mouth ulcer gels?"

Other:

Where an intervention or an intervention resulted from any other event. Describe the nature of the event.

***Describe the PROBLEM YOU HAVE IDENTIFIED***

Describe the patient's presenting medical condition, any drugs that you know he/she is taking relevant to this presentation, the doses of such drugs, and the drug-related problem you have identified. You may need to check dispensing records to complete some details, if available. Please include as much detail as possible.

***Describe the INTERVENTION YOU UNDERTOOK FOR THIS PROBLEM***

Describe the intervention you undertook in relation to the presenting problem described above. Please include as much detail as possible using a separate form for each intervention.

★ If you are busy serving customers, this is the best place to jot down notes on the intervention that took place, then fill in the details when you have time later.

***What ACTION(S) did you take in relation to this intervention?***

Tick all actions that took place during your attempt to resolve the problem. Please indicate the name of the original product if this was still considered appropriate treatment, the name of a new or different product if one was recommended, and/or any non-drug treatment recommended. Describe any actions not listed here under 'Other'.

**PATIENT RESPONSE**

Please indicate if the patient accepted or rejected your recommended course(s) of action. Describe exactly what the patient did or did not do under 'Any other information'. Tick 'Unknown' if you don't know what the patient did after the intervention.

**PRODUCT(S) SOLD**

<i>Brand</i>	<i>Form</i>	<i>Strength</i>	<i>Pack size</i>	<i>\$ Retail</i>	<i>Unsch/S2/S3</i>
--------------	-------------	-----------------	------------------	------------------	--------------------

Give details of all OTC products that the patient purchased following the intervention. These may be the original products requested if they were still considered suitable in light of the problem detected, or if the patient accepted a recommended product, only enter what he/she actually bought. This is important for our cost-benefit analysis and this information will only be used in unidentified, aggregate data.

It is important to include **ALL DETAILS** of the product sold. Please fill these details in later if you do not have time when you are recording your intervention.

**Form** refers to what the form the medicine is in, eg tablets/spray/drops.

**Unsch/S2/S3** refers to Unscheduled, S2 (Pharmacy Medicines), S3 (Pharmacist Only Medicines).

For example:

<b>Brand</b>	<b>Formulation</b>	<b>Strength</b>	<b>Pack size</b>	<b>\$ Retail</b>	<b>Unsch/S2/S3</b>
Panadol®	tablets	500mg	100	\$X.XX	S2



#### ANY OTHER RELEVANT INFORMATION

##### ***STAFF MEMBER(S) INVOLVED IN THE INTERVENTION:***

Tick all staff members involved in the intervention.

##### **Time Spent:**

Write the estimated time (in minutes) that each staff member spent undertaking the intervention.


#### EXAMPLE OF HOW TO FILL OUT THE FORM

To help you complete the intervention forms, we have provided a common scenario that you might encounter and how you would then fill out the form.

##### **Example Scenario: Overdosing of Paracetamol**

An adult male requested generic paracetamol 500mg and cold and flu tablets also containing paracetamol. The pharmacist identified the problem of therapeutic duplication, and advised the consumer not to use the two products together. The case took two minutes to resolve. This was rated by the researchers as an intervention that potentially averted emergency medical attention or serious harm, as unwitting use of the two products together over the normal duration of a cold may have resulted in hepatotoxicity.

<b>NON-PRESCRIPTION MEDICINE INTERVENTION COLLECTION FORM</b>		Did you try to recruit the consumer into the consumer follow-up study? yes <input checked="" type="checkbox"/> no <input type="checkbox"/> → reason(s): ..... If yes, did the consumer: accept <input checked="" type="checkbox"/> decline <input type="checkbox"/> → reason(s): ..... <b>If the consumer accepted, what is the questionnaire number? <u>1</u> <u>3</u> <u>5</u> <u>9</u></b>																			
<b>DATE:</b> <b>TIME:</b>		<b>What ACTION(S) did you take in relation to this intervention? (tick as many as applicable)</b>																			
<b>PATIENT INFORMATION</b>		<b>Actions Taken</b> <input type="checkbox"/> Advice: ..... <input type="checkbox"/> Review of patient medication/computer records <input type="checkbox"/> Contact with patient's Doctor <input type="checkbox"/> Contact with patient (if absent) <input checked="" type="checkbox"/> Original product suggested: <i>D/N Cold &amp; Flu</i> <input type="checkbox"/> New or different product suggested: ..... <input type="checkbox"/> Non-drug therapy suggested: .....  <b>Patient Referred</b> <input type="checkbox"/> to Doctor – next scheduled visit <input type="checkbox"/> to Doctor – conditional on response <input type="checkbox"/> to Doctor – immediately <input type="checkbox"/> to Accident and Emergency <input type="checkbox"/> to other health professional <input type="checkbox"/> <b>Other:</b> .....																			
<b>Age group:</b> <input type="checkbox"/> 0-2 years <b>Sex:</b> <input checked="" type="checkbox"/> Female (Estimate) <input type="checkbox"/> 3-12 years <input type="checkbox"/> Male <input checked="" type="checkbox"/> 13-64 years <input type="checkbox"/> 65+ years  <b>RELEVANT Medical history:</b> (tick as many as applicable) <input type="checkbox"/> Hypertension <input type="checkbox"/> Diabetes <input type="checkbox"/> Asthma <input type="checkbox"/> Heart disease <input type="checkbox"/> Arthritis <input type="checkbox"/> Pregnancy <input type="checkbox"/> Heartburn/ulcer <input type="checkbox"/> Skin disease <input type="checkbox"/> Other: .....																					
<b>INTERVENTION</b>																					
<b>Origin of the intervention: (tick one only)</b> <input checked="" type="checkbox"/> Direct product request..... please fill in → <input type="checkbox"/> Symptom presentation <input type="checkbox"/> Other: .....		<b>Please Record Known Details of Any Product Requested</b>																			
		<table style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left;">Brand</th> <th style="text-align: left;">Formulation</th> <th style="text-align: left;">Strength</th> </tr> <tr> <td><i>Paracetamol</i></td> <td><i>Tablets</i></td> <td><i>500mg</i></td> </tr> <tr> <td><i>D/N Cold &amp; Flu</i></td> <td><i>Tablets</i></td> <td></td> </tr> </table>		Brand	Formulation	Strength	<i>Paracetamol</i>	<i>Tablets</i>	<i>500mg</i>	<i>D/N Cold &amp; Flu</i>	<i>Tablets</i>										
Brand	Formulation	Strength																			
<i>Paracetamol</i>	<i>Tablets</i>	<i>500mg</i>																			
<i>D/N Cold &amp; Flu</i>	<i>Tablets</i>																				
<b>Describe the PROBLEM YOU HAVE IDENTIFIED: (include drug/condition/doses involved)</b>																					
<p>.....</p> <p><i>Consumer requested both D/N Cold &amp; Flu tablets and paracetamol tablets to treat symptoms of a cold - headache, runny nose, non-productive cough. Potential double dosing of paracetamol.</i></p> <p><i>Consumer requested both D/N Cold &amp; Flu tablets and paracetamol tablets to treat symptoms of a cold - headache, runny nose, non-productive cough.</i></p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>																					
<b>Describe the INTERVENTION YOU UNDERTOOK FOR THIS PROBLEM:</b>																					
<p>.....</p> <p><i>Explained to consumer that D/N Cold &amp; Flu tablets already contained paracetamol, therefore there was no need for him to take paracetamol..... tablets as well.....</i></p> <p>.....</p> <p>.....</p> <p>.....</p>																					
<b>PRODUCT(S) SOLD:</b>																					
<table style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left;">Brand</th> <th style="text-align: left;">Form</th> <th style="text-align: left;">Strength</th> <th style="text-align: left;">Pack Size</th> <th style="text-align: left;">\$Price</th> <th style="text-align: left;">Unsch/ S2/S3</th> </tr> <tr> <td colspan="6" style="text-align: center;">(eg tabs/spray)</td> </tr> <tr> <td><i>D/N Cold &amp; Flu Tablets</i></td> <td></td> <td></td> <td><i>20</i></td> <td><i>\$X.XX</i></td> <td><i>S2</i></td> </tr> </table>				Brand	Form	Strength	Pack Size	\$Price	Unsch/ S2/S3	(eg tabs/spray)						<i>D/N Cold &amp; Flu Tablets</i>			<i>20</i>	<i>\$X.XX</i>	<i>S2</i>
Brand	Form	Strength	Pack Size	\$Price	Unsch/ S2/S3																
(eg tabs/spray)																					
<i>D/N Cold &amp; Flu Tablets</i>			<i>20</i>	<i>\$X.XX</i>	<i>S2</i>																
<b>Staff member(s) involved in the intervention      Time Spent</b> (tick as many as applicable)                      (Estimate of mins)																					
<input checked="" type="checkbox"/> Pharmacist                      ...2mins... <input type="checkbox"/> Pre-Registration Graduate                      ..... <input type="checkbox"/> Pharmacy assistant                      ..... <input type="checkbox"/> Other: .....                      .....																					

<h2 style="margin: 0;">Non-Prescription Medicine Interventions - Sample Study -</h2>	
<h2 style="margin: 0;">Intervention Collection Forms INSTRUCTIONS FOR ALL STAFF</h2>	

### What should you do?

Every time you perform ANY INTERVENTION involving a **non-prescription medicine**, regardless of whether a sale took place, record this on one of the forms in this book and ask the consumer if they would be willing to participate in the follow-up consumer study.

**o Please fill in ALL parts of the form** including details of product sold and time of the staff members involved in the intervention.

### What is an INTERVENTION?

An intervention is when you **find and act on a problem that a patient has with a non-prescription medicine**, regardless of whether a sale took place.

For example, if you deal with a drug interaction or a side effect, or change a patient's dose or switch them to a more appropriate product, these should be recorded. We do not need you to record any standard advice that you give, only when you **do something in response to a problem** you find relating to a **non-prescription medicine**.

**o** Even if the consumer rejects your advice, **RECORD IT ANYWAY**.

**o** Even if you are not sure, **RECORD IT ANYWAY**.

### Any questions?

1. Refer to the reference instructions.
2. Please phone the project staff at The University of Sydney: Catherine on (02) 9036 9490 or Joel on (02) 9036 9489.
3. If you have any doubt, record your intervention anyway as fully as possible.

➔ At the end of each week, please send us back all completed forms and all consumer consent forms in the Reply Paid envelope provided.

### Recruitment of consumers

After each intervention, if the intervention involved the consumer or their dependent, please ask consumers who are over 16 years of age and who are fluent in English to participate in the follow-up consumer study (up to 25 consumers).

**Example Script:** "Our pharmacy is currently participating in nationwide University study looking at the availability of medicines like the one(s) we have just talked about. As part of this study, the researchers would like to follow up customers like you, who have had some kind of problem discovered and talked about by pharmacy staff. This is very simple – all you'd have to do is fill out a questionnaire in 7 days' time and sending it back to The University of Sydney. All of your details will remain confidential. Would you be interested in participating?"

If they agree to participate:

1. Give the consumer a Consumer Follow-up Information Sheet.
2. Ask them to fill out the consumer consent form. **It is important that all details are clearly filled in and the consumer signs it.**
3. Give the consumer the attached Questionnaire Pack. Make sure that it has the same number as the consumer consent form.
4. Record the questionnaire number on the related intervention form. You will find this number on the consumer consent form and the questionnaire pack. We will need to match them up later.

➔ **IMPORTANT: Remember to keep all consumer consent forms and return them to the researchers with the completed intervention forms at the end of each week in the Reply Paid envelope provided.**

**Thank you for your assistance in this study.**

**REMEMBER: If you don't know if you should record your intervention, RECORD IT ANYWAY.**

APPENDIX 27  
Sample Study Pack: Data Collection Form

NON-PRESCRIPTION MEDICINE INTERVENTION COLLECTION FORM		Did you try to recruit the consumer into the consumer follow-up study? yes <input type="checkbox"/> no <input type="checkbox"/> → reason(s): ..... If yes, did the consumer: accept <input type="checkbox"/> decline <input type="checkbox"/> → reason(s): .....	
If the consumer accepted, what is the questionnaire number?			
DATE: .....	TIME: .....	What ACTION(S) did you take in relation to this intervention? (tick as many as applicable)	
<b>PATIENT INFORMATION</b> <b>Age group:</b> <input type="checkbox"/> 0-2 years <input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> 3-12 years <input type="checkbox"/> 13-64 years <input type="checkbox"/> 65+ years <b>RELEVANT Medical history:</b> (tick as many as applicable) <input type="checkbox"/> Hypertension <input type="checkbox"/> Diabetes <input type="checkbox"/> Asthma <input type="checkbox"/> Heart disease <input type="checkbox"/> Arthritis <input type="checkbox"/> Pregnancy <input type="checkbox"/> Heartburn/ulcer <input type="checkbox"/> Skin disease <input type="checkbox"/> Other: .....		<b>Actions Taken</b> <input type="checkbox"/> Advice: ..... <input type="checkbox"/> Review of patient medication/computer records <input type="checkbox"/> Contact with patient's Doctor <input type="checkbox"/> Contact with patient (if absent) <input type="checkbox"/> Original product suggested: ..... <input type="checkbox"/> New or different product suggested: ..... <input type="checkbox"/> Non-drug therapy suggested: .....	
<b>INTERVENTION</b>		<b>Patient Referred</b>	
<b>Origin of the intervention:</b> (tick one only) <input type="checkbox"/> Direct product request..... please fill in → <input type="checkbox"/> Symptom presentation <input type="checkbox"/> Other: .....		<input type="checkbox"/> to Doctor – next scheduled visit <input type="checkbox"/> to Doctor – conditional on response <input type="checkbox"/> to Doctor – immediately <input type="checkbox"/> to Accident and Emergency <input type="checkbox"/> to other health professional <input type="checkbox"/> Other: .....	
<b>Describe the PROBLEM YOU HAVE IDENTIFIED:</b> (include drug/condition/doses involved)		<b>PATIENT RESPONSE:</b>	
.....		<input type="checkbox"/> Accepted Recommendation	
.....		<input type="checkbox"/> Rejected Recommendation	
.....		<input type="checkbox"/> Unknown	
.....		Any other information: .....	
.....		<b>PRODUCT(S) SOLD:</b>	
.....		<b>Brand</b>	<b>Form</b>
.....		<b>Strength</b>	<b>Pack Size</b>
.....		<b>Price</b>	<b>Unsch/S2/S3</b>
.....		.....	
<b>Describe the INTERVENTION YOU UNDERTOOK FOR THIS PROBLEM:</b>		<b>Staff member(s) involved in the intervention</b>	
.....		(tick as many as applicable)	
.....		<input type="checkbox"/> Pharmacist	
.....		<input type="checkbox"/> Pre-Registration Graduate	
.....		<input type="checkbox"/> Pharmacy assistant	
.....		<input type="checkbox"/> Other: .....	
.....		<b>Time Spent</b>	
.....		(Estimate of mins)	

## APPENDIX 28

### PMS Study Recruitment Instruments: Consumer Information Sheet



**The University of Sydney**

NSW 2006 AUSTRALIA



#### **Cost Benefit Analysis of Non-Prescription Medicines**

Faculty of Pharmacy A15  
Telephone +61 2 9036 9490  
Telephone +61 2 9036 5192  
Facsimile +61 2 9036 9197

### **NON-PRESCRIPTION MEDICINE INTERVENTIONS CONSUMER FOLLOW-UP STUDY INFORMATION SHEET**

This study is part of the **Cost Benefit Analysis of Non-Prescription Medicines** — a broader project examining the costs and benefits of the current non-prescription medicine schedules. This is a collaborative project involving The University of Sydney, The University of Queensland, the University of SA and Health Care Intelligence Pty Ltd. The project is funded by the Commonwealth Department of Health and Ageing and managed by the Pharmacy Guild as part of the Third Community Pharmacy Agreement

As part of the Non-Prescription Medicine Interventions Sample Study, a number of pharmacies are being asked to document the conversations that they have with consumers in which they discover a potential problem relating to a non-prescription medicine. We are then asking a number of these consumers to participate in the Consumer Follow-up Study to follow up on the actual outcome of the pharmacy staff's advice. This study will provide important information about whether it is worthwhile making certain types of medicines only available in pharmacies.

If you agree to participate in this survey, your pharmacist/pharmacy assistant will issue you with a questionnaire pack asking you about the outcome of the pharmacy staff's advice. This contains a questionnaire, instructions and a reply paid envelope. The questionnaire is to be completed in a week's time (seven days from when you were recruited in the pharmacy) and returned to the researchers in the reply paid envelope.

Your contact details will only be used if we need to remind you about completing or returning the questionnaire or to ask for more detail about specific answers. The questionnaires will be entered into the research database without any information that could directly identify you. Group results will be written up in a report to the Commonwealth Government and may also be published in a professional journal, but will not identify any individual pharmacy, staff member or consumer.

If you agree to participate, please sign the attached consent form and give it to your pharmacist/pharmacy assistant who will send it back to us. They will then issue you with a questionnaire pack.

Participation in this study is entirely voluntary, and you are free to withdraw from the study at any stage. This information sheet is for you to keep. If you would like any further information on any aspect of this study or the project in general, please contact:

Professor S.I. (Charlie) Benrimoj	Ph: (02) 9036 9490	Fax: (02) 9036 9197
Ms Catherine Raffaele	Ph: (02) 9036 9490	Email: <a href="mailto:catherine@pharm.usyd.edu.au">catherine@pharm.usyd.edu.au</a>

*Any person with concerns or complaints about the conduct of a research study can contact the Manager for Ethics Administration, The University of Sydney on (02) 9351 4811.*

## APPENDIX 29

### PMS Study Recruitment Instruments: Consumer Consent Form



The University of Sydney

NSW 2006 AUSTRALIA



#### Cost Benefit Analysis of Non-Prescription Medicines

Faculty of Pharmacy A15  
Telephone +61 2 9036 9490  
Telephone +61 2 9036 5192  
Facsimile +61 2 9036 9197

### NON-PRESCRIPTION MEDICINE INTERVENTIONS CONSUMER FOLLOW-UP STUDY CONSENT FORM

QUESTIONNAIRE NUMBER: XXXX (To be Allocated)

I \_\_\_\_\_ (**your name**) hereby consent to participating in the Non-Prescription Medicines Interventions Consumer Follow-up Study, being conducted by the Faculty of Pharmacy, The University of Sydney, and I understand that I am free to withdraw this pharmacy from the study at any time by phoning the telephone numbers listed above.

The purpose and nature of the study have been explained to me to my full satisfaction, and I understand that I can contact the project members at any time regarding any queries I may have during the course of the project.

I understand that my contact details will only be used if the project need to follow-up the completion or return of the questionnaire or to ask for more detail about specific answers.

Name \_\_\_\_\_ Signature \_\_\_\_\_  
Please Print

Date \_\_\_\_/\_\_\_\_/\_\_\_\_  
d d m m y y

Phone: \_\_\_\_\_

➔ Please give this to your pharmacist/pharmacy assistant to return.

#### **For Pharmacy Staff ONLY:**

Please Return this form with your intervention forms in the reply paid envelopes provided.

If these envelopes are missing please contact the project staff:  
Catherine Raffaele (02) 9036 9490 or Joel Werner (02) 9036 9489.

APPENDIX 30  
PMS Study Pack: Consumer Cover Letter



The University of Sydney

NSW 2006 AUSTRALIA

**Cost Benefit Analysis of Non-Prescription Medicines**



Faculty of Pharmacy A15  
Telephone +61 2 9036 9490  
Telephone +61 2 9036 9489  
Facsimile +61 2 9036 9197

Date

Thank you for agreeing to take part in the Non-Prescription Medicine Interventions Consumer Follow-up Study. You will have been recruited into this study because a pharmacy staff member alerted you to a potential problem regarding a medicine you may have requested or taken or a condition that needs further attention. In this study, we are asking the pharmacy staff member to document the problem he/she found, and we are asking you to report back to us what has happened one week after your visit to the pharmacy.

In your questionnaire pack you will find a questionnaire and a reply paid envelope. Please fill out the questionnaire **ONE WEEK AFTER** the date of being recruited into this study and return it as soon as it is completed in the reply paid envelope.

Your contact details will only be used so that a member of the project staff can remind you about completing or returning the questionnaire or ask for more detail about specific answers. Your responses will be entered into the database without any identifying information, so your data will be completely anonymous.

⇒ Please **complete the questionnaire SEVEN DAYS** after this visit to the pharmacy. As a reminder, please write today's date and the date in seven days on the front of the questionnaire.

⇒ Please **RETURN** your questionnaire to the research centre (not the pharmacy) as soon as you have completed it, using the **Reply Paid envelope** provided.

**If you have any questions about the questionnaire** or any other aspect of the study, please contact the project staff:

<b>Ms Catherine Raffaele</b> Project Manager ☎ (02) 9036 9490 Email: catherine@pharm.usyd.edu.au	<b>Mr Joel Werner</b> Research Officer ☎ (02) 9036 9489 Email: joel@pharm.usyd.edu.au
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# Non-Prescription Medicine Interventions Consumer Follow-up Study QUESTIONNAIRE

Number: \_\_\_\_\_



- ➔ Please complete this questionnaire ONE WEEK (i.e. seven days) after your visit to your pharmacy when you were allocated this questionnaire.

Date of pharmacy visit: \_\_\_\_\_ day, \_\_\_\_\_ / \_\_\_\_\_ / 04

Date to complete questionnaire: \_\_\_\_\_ day, \_\_\_\_\_ / \_\_\_\_\_ / 04

- ➔ Once you have completed this questionnaire, please return it to the project team in the reply paid envelope.
- ➔ If you have any questions or misplace the reply paid envelope, please contact one of the researchers:

**Ms Catherine Raffaele**, Project Manager

☎ (02) 9036 9490 Email: catherine@pharm.usyd.edu.au

**Mr Joel Werner**, Research Officer

☎ (02) 9036 9489 Email: joelw@mail.med.usyd.edu.au

**Address:** Catherine Raffaele  
S2/S3 Cost Benefit Project  
Faculty of Pharmacy A15  
The University of Sydney NSW 2006



### Your Pharmacy Visit

These questions relate to your talk with a pharmacy staff member **this time last week**, when he/she found a potential problem with a non-prescription medicine, or a condition about which you asked for advice.

**THESE QUESTIONS SHOULD BE ANSWERED FROM THE POINT OF VIEW OF THE PERSON WHOSE PROBLEM RESULTED IN THE PHARMACY VISIT.**

1. The pharmacy staff member asked some questions and found a potential problem with the situation you described. Who did this problem relate to?
  - ☐ Myself
  - ☐ A child (15 years or younger)
  - ☐ Dependent relative
2. What is the age (or approximate age) of this person? \_\_\_\_\_ years
3. What is the sex of this person?
  - ☐ Male
  - ☐ Female
4. What did the pharmacy staff member recommend as a result of your conversation?

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### The Medicine(s) Recommended

5. Did the pharmacy staff recommend you buy a product?
  - ☐ No → Go to Q10
  - ☐ Yes → What product(s)? \_\_\_\_\_
6. If the pharmacy staff recommended you buy a product(s), did you buy them?
  - ☐ Yes
  - ☐ No → Why not?

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---

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7. Have you (or your relative) taken any of the product(s) yet?

☐ Yes

☐ No → Why not?

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---

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8. On how many days was this product(s) used?

Product 1: \_\_\_\_\_ Days: \_\_\_\_\_

Product 2: \_\_\_\_\_ Days: \_\_\_\_\_

9. How effective did you find these medication(s)?

---

---

10. We are interested in how the product(s) you purchased were administered over the past week. Please mark the time of day that you took each dose and how many tablets/capsules/mLs you took at each time (as shown in the example).

**EXAMPLE**

On DAY 1, Ms X took 2 Naprogesic tablets before she left for work (8am), 1 tablet after lunch (2pm) and 1 tablet with dinner (8pm). She would fill the table as follows:

Time	Name/Number of Tablets or Capsules Taken	Time	Name/Number of Tablets or Capsules Taken	Time	Number of Tablets or Capsules Taken
5 am		1 pm		9 pm	
6 am		2 pm	<i>Naprogesic - 1 tablet</i>	10 pm	
7 am		3 pm		11 pm	
8 am	<i>Naprogesic - 2 tablets</i>	4 pm		12 midnight	
9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm	<i>Naprogesic - 1 tablet</i>	4 am	

Please fill in one table for each day you took the medication (up to 7 days).

Time	Name/Number of Tablets or Capsules Taken	Time	Name/Number of Tablets or Capsules Taken	Time	Number of Tablets or Capsules Taken
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

Time	Name/Number of Tablets or Capsules Taken	Time	Name/Number of Tablets or Capsules Taken	Time	Number of Tablets or Capsules Taken
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

Time	Name/Number of Tablets or Capsules Taken	Time	Name/Number of Tablets or Capsules Taken	Time	Number of Tablets or Capsules Taken
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

Time	Name/Number of Tablets or Capsules Taken	Time	Name/Number of Tablets or Capsules Taken	Time	Number of Tablets or Capsules Taken
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

Time	Name/Number of Tablets or Capsules Taken	Time	Name/Number of Tablets or Capsules Taken	Time	Number of Tablets or Capsules Taken
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

Time	Name/Number of Tablets or Capsules Taken	Time	Name/Number of Tablets or Capsules Taken	Time	Number of Tablets or Capsules Taken
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

Time	Name/Number of Tablets or Capsules Taken	Time	Name/Number of Tablets or Capsules Taken	Time	Number of Tablets or Capsules Taken
5 am		1 pm		9 pm	
6 am		2 pm		10 pm	
7 am		3 pm		11 pm	
8 am		4 pm		12 midnight	
9 am		5 pm		1 am	
10 am		6 pm		2 am	
11 am		7 pm		3 am	
12 noon		8 pm		4 am	

### Self Care Advice

11. Did the pharmacy staff recommend anything else to assist with your problem that did not involve medication? (e.g., steam inhalation for a blocked nose)

- ☐ No → Go to Q12  
☐ Yes → What? \_\_\_\_\_

12. If so, did you follow this advice?

- ☐ Yes  
☐ No → Why not? \_\_\_\_\_

### Referral

13. Did the pharmacy staff recommend that you see anyone else?

- ☐ No → Go to Q21  
☐ Yes

14. If so, who?

- ☐ GP (family doctor)  
☐ Specialist  
☐ Hospital Emergency Department  
☐ Other Health Care Professional: \_\_\_\_\_  
☐ Other: \_\_\_\_\_

15. Did they recommend you go

- ☐ Immediately  
☐ At your next scheduled visit  
☐ If the condition doesn't improve  
☐ Other: \_\_\_\_\_

16. Did you follow this advice?

☐ No → Why not?

---

*Go to Q21.*

☐ Yes → What did you do?

---

17. Were there any costs associated with this for you? (e.g., visited GP – consultation fee \$30)

☐ Yes → how much? \$\_\_\_\_\_

→ what for? \_\_\_\_\_

☐ No

18. As a result of this visit, were you (*Tick all that are appropriate*) :

☐ Recommended a non-prescription medication

☐ Given a prescription

☐ Referred for further tests

☐ Sent to the hospital

☐ Referred to a specialist

☐ Told to take time off work/school

☐ Other: \_\_\_\_\_

19. Did you follow this advice?

☐ No → Why not?

---

---

☐ Yes → What did you do?

---

20. Were there any costs associated with this for you? (e.g., filled prescription – \$21)

☐ Yes → how much? \$\_\_\_\_\_

→ what for? \_\_\_\_\_

☐ No

### Your Personal Views

21. To what extent do you think the problem for which you went to the pharmacy has been resolved?

- ☐ Totally resolved
- ☐ Partly resolved
- ☐ Not at all resolved
- ☐ Don't know

Please explain your rating:

---

---

22. Generally, how satisfied are you with what you were told in the pharmacy?

- ☐ Very satisfied
- ☐ Satisfied
- ☐ Not at all satisfied

Please explain your rating:

---

---

### Contact Details

In case we need to ask for more detail about any of your answers, please write your contact details below. In accordance with University research requirements, this information will be kept secure and not be used for any other purpose, and it will not be entered into the research database.

Name: \_\_\_\_\_


Phone: \_\_\_\_\_

**➔ Now please place this questionnaire in the reply paid envelope and mail it to the research team at your earliest convenience.**

*Many thanks for your cooperation – your answers are greatly appreciated!*

**➔** If you have any questions or misplace the reply paid envelope, please contact one of the researchers:

**Ms Catherine Raffaele**, Project Manager

 (02) 9036 9490 Email: catherine@pharm.usyd.edu.au

**Mr Joel Werner**, Research Officer

 (02) 9036 9489 Email: joelw@mail.med.usyd.edu.au

**Address:** S2/S3 Project, Faculty of Pharmacy A15  
The University of Sydney NSW 2006

<b>CLINICAL EVALUATION OF INTERVENTION</b>
--

INTERVENTION No ..... EVALUATOR INITIALS .....

Date of completing this form ...../...../.....

1. What was the result of the intervention that occurred? *(tick one and follow the steps)*

☐

No effect  
*(form is now completed)*

☐

ONLY a POSITIVE outcome  
*(complete ONLY the Adverse Health Consequence Avoided (POSITIVE OUTCOME) form)*

☐

ONLY a NEGATIVE outcome  
*(complete ONLY the Adverse Health Consequence Created (NEGATIVE OUTCOME) form)*

☐

BOTH a POSITIVE and a NEGATIVE outcome  
*(complete BOTH the Adverse Health Consequence Avoided (POSITIVE OUTCOME) form AND the Adverse Health Consequence Created (NEGATIVE OUTCOME) form)*



Please record the ADVERSE HEALTH CONSEQUENCES AVOIDED as a result of the intervention.

- .....

0    0.000001    0.00001    0.0001    0.001    0.01    0.1    0.2    0.3    0.4    0.5    0.6    0.7    0.8    0.9    1

(1 in 1 000 000)    (1 in 100 000)    (1 in 10 000)    (1 in 1000)    (1 in 100)    (1 in 10)

3. What level of health care would be needed to treat the adverse health consequence specified above, assuming that it did occur? (rank one or two items by placing a (1) in the box for the most likely outcome, and (2) for the next likely outcome)

- ☐ Intensive care in hospital
- ☐ Standard ward in hospital
- ☐ Accident and Emergency (Casualty) at hospital
- ☐ Urgent GP visit
- ☐ Next regular GP visit
- ☐ Nursing home admission
- ☐ Self-care (*specify: .....*)
- ☐ Other (*e.g. long-term rehabilitation:.....*)

4. What would be the likely duration of the adverse health consequence had the pharmacist/pharmacist assistant not intervened?

Duration of harm: ..... Days ..... Months ..... Years or ☐ permanent

5. Please rate the clinical significance of the intervention. This should provide an idea of its impact on patient care. (*circle one response*)

- ☐ Averted minor symptoms (Minor)
- ☐ Averted routine medical attention (Significant)
- ☐ Averted emergency medical attention (Very Significant)
- ☐ Potentially life-saving

6. What adverse health consequence(s) do you consider most serious to have resulted **had the pharmacist not intervened**? *Please describe in medical terminology.*

7. What is the **probability** that this problem would have resulted in the adverse health consequence specified above? (circle one point or write the probability in the space provided below)



- ☐ Intensive care in hospital
- ☐ Standard ward in hospital
- ☐ Accident and Emergency (Casualty) at hospital
- ☐ Urgent GP visit
- ☐ Next regular GP visit
- ☐ Nursing home admission
- ☐ Self-care (*specify: .....*)
- ☐ Other (*e.g. long-term rehabilitation:.....*)

- Duration of harm: ..... Days ..... Months ..... Years or ☐ permanent

- ☐ Averted minor symptoms (Minor)
- ☐ Averted routine medical attention (Significant)
- ☐ Averted emergency medical attention (Very Significant)
- ☐ Potentially life-saving

Please record the ADVERSE HEALTH CONSEQUENCES RESULTING from the intervention.

- .....

OFFICE USE ONLY: Diagnosis Code

- 

- ☐ Intensive care in hospital
- ☐ Standard ward in hospital
- ☐ Accident and Emergency (Casualty) at hospital
- ☐ Urgent GP visit
- ☐ Next regular GP visit
- ☐ Nursing home admission
- ☐ Self-care (*specify: ... ..*)
- ☐ Other (*e.g. long-term rehabilitation:.....*)

- Duration of harm: ..... Days .... Months ..... Years or ☐ permanent

- ☐ Caused minor symptoms (Minor)
  - ☐ Required routine medical attention (Significant)
  - ☐ Required emergency medical attention (Very Significant)
  - ☐ Potentially fatal

11. What adverse health consequence(s) do you consider most serious to have resulted **had the pharmacist not intervened**? *Please describe in medical terminology.*

12. What is the **probability** that this problem would have resulted in the adverse health consequence specified above? (circle one point or write the probability in the space provided below)

0    0.000001    0.00001    0.0001    0.001    0.01    0.1    0.2    0.3    0.4    0.5    0.6    0.7    0.8    0.9    1

(1 in 1 000 000)    (1 in 100 000)    (1 in 10 000)    (1 in 1000)    (1 in 100)    (1 in 10)

13. What level of health care would be needed to treat the adverse health consequence specified above, assuming that it did occur? (rank one or two items by placing a (1) in the box for the most likely outcome, and (2) for the next likely outcome)

14. What would be the likely duration of the adverse health consequence had the pharmacist/pharmacist assistant not intervened?

15. Please rate the clinical significance of the intervention. This should provide an idea of its impact on patient care. (*circle one response*)

- 250

## APPENDIX 33

### Kappa Analysis

Kappa statistics were calculated in STATA for the Census and Sample Study panels. Outcomes were analysed across the 20 intervention forms common to all Census panels and the 18 intervention forms common to all Sample Study panels. For the 3 panels for the Census, an overall Kappa statistic of 0.0252 was obtained and for the 2 panels for the Sample Study, an overall Kappa statistic of 0.1787 was obtained.

These results indicate poor agreement across panels on the panels' raw data. However, if the outcomes are recoded so that differences that vary by a value of 1 (severity) are coded to be the same, the Kappa statistic improves substantially. This suggests that although exact agreement between panels was poor, there was good to excellent agreement on similar outcomes.

**Table X: Kappa Analysis on Census Panels**

	Actual Data			Recoded Data §		
	Expected % Agreement*	Actual % agreement	Kappa Statistic†	Expected % Agreement*	Actual % agreement	Kappa Statistic†
Panel 1 vs Panel 2	34	35	0.0152	46	85	0.7248
Panel 1 vs Panel 3	28	30	0.0311	43	90	0.8246
Panel 2 vs Panel 3	28	35	0.0972	30	80	0.7163

\* Expected agreement if left to chance.

† Kappa >0.75 Excellent agreement, Kappa 0.4-0.75 Fair to good agreement, Kappa <0.4 Poor agreement

§ Recoded so that differences in values that differ by 1 (severity) are coded to be the same

**Table X: Kappa Analysis on Sample Panels**

	Actual Data			Recoded Data §		
	Expected % Agreement*	Actual % agreement	Kappa Statistic†	Expected % Agreement*	Actual % agreement	Kappa Statistic†
Panel 1 vs Panel 2	19	33	0.1787	24	67	0.561

\* Expected agreement if left to chance.

† Kappa >0.75 Excellent agreement, Kappa 0.4-0.75 Fair to good agreement, Kappa <0.4 Poor agreement

§ Recoded so that differences in values that differ by 1 (severity) are coded to be the same

## APPENDIX 34

Evaluation of the Hawthorne Effect in the Cost Benefit Analysis of Non-Prescription Medicines Project: Research Submission to the Pharmacy Guild of Australia

# **Evaluation of the Hawthorne Effect in the Cost Benefit Analysis of Non-Prescription Medicines Project**

**Research Submission to the Pharmacy Guild of Australia**

## **Lead Investigator**

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## PROPOSAL SUMMARY

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The Cost Benefit Analysis of Non-Prescription Medicines Project includes two studies: a 'census' and a 'sample' study. Both measure non-prescription medicine interventions, i.e. situations in which pharmacy staff detect and act upon problems associated with S2 or S3 medicine requests.

It is possible that the vigilance of pharmacy staff in detecting such problems is influenced by the fact that they are participating in a study, effectively creating a bias in the detection rate for medicine-related problems. This change in behaviour while under study is known as the Hawthorne Effect.

The purpose of the project is to determine whether or not the Hawthorne Effect is apparent in the sample study. Specifically, we aim to determine whether there is any difference in pharmacy staff diligence in detecting and acting upon medicine-related problems between study and non-study periods.

Trained pseudo-patrons will visit a number of pharmacies during the two-week data collection period, and then again two to four weeks later during a non-collection (non-study) period. Scenarios and patient demographics will be matched, and intervention rates compared between the study and non-study periods. Significantly higher intervention rates during the data collection period would indicate the presence of a Hawthorne Effect.

If the Hawthorne Effect is evident in our research, the implications are three-fold:

1. Good research practice would require us to declare and adjust for this bias when presenting study results relating to incidence rates of detected problems.
2. Future studies involving pharmacy staff vigilance would benefit from this application of pseudo-patron methodology.
3. Future training and/or assistance for pharmacy staff may be necessary to ensure all potential medicine-related problems are detected and resolved.



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## SIGNIFICANCE OF PROPOSED RESEARCH

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### **The Hawthorne Effect**

The Hawthorne Effect involves individual behaviour being altered because those being studied are aware that they are being studied. Mayo (1933) observed that the workers who were being closely attended significantly improved their productivity irrespective of changing conditions. This has since become known as the Hawthorne Effect. Whereas some business (Parsons, 1992) and medical (Bates, 1988) research has employed the Hawthorne Effect as a tool to improve productivity, in research settings it can represent a bias that artificially alters results.

### **The Hawthorne Effect in the Cost Benefit Analysis of Non-Prescription Medicines Project**

The National Co-ordinating Committee Of Therapeutic Goods (NCCTG) has indicated to the Expert Advisory Group (EAG) that they are concerned about the level of non-prescription medicine interventions recorded and the potential for over-reporting in the study due to the Hawthorne Effect.

The Hawthorne Effect poses a potentially significant bias for the Cost Benefit Analysis of Non-Prescription Medicines Project. If the Hawthorne Effect is asserting an influence on the research programme, it may result in an overestimation of pharmacy staff interventions that could in turn overestimate their contribution in the cost-benefit analysis.

The aim of this project is to employ pseudo-patients to present scenarios in pharmacies both during the data collection period and two to four weeks later in a non-data collection period, and compare the intervention rates between the two. Should evidence of a Hawthorne Effect be found, intervention rates can be adjusted accordingly for the subsequent economic analysis.

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## DETAILS OF PROJECT METHODOLOGY

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**Aim:** To test for the presence of the Hawthorne Effect in the Cost Benefit Analysis of Non-Prescription Medicine sample study.

**H<sub>0</sub>:** There is no difference in pharmacy staff intervention rates between the observation and non-observation periods.

**Method:** Sample size has been calculated based on Quality Care Pharmacy Practice (QCPP) intervention rate data which records an average intervention rate of 39%. To detect a difference of between 40% and 55% in the observation and non-observation periods, n=111 pseudo-patients would be required in the study period, and n=222 in the non-study period (as our case:control ratio is 1:2). This is with alpha=0.05 and 80% power.

Pharmacies (n=111) will be selected randomly from those participating in the sample study from the five most populous states: NSW, Vic, Qld, WA, and SA, proportional to the spread of pharmacies in the sample study. A researcher will visit each of the five states to provide training to the pseudo-patients. The current sample study consent forms will be amended to include the pharmacy's consent to pseudo-patient testing. So as to avoid biasing the results of the sample study, the time and date of pseudo-patient visits will be recorded and will be matched to interventions documented in the observation period which will then be removed from the sample study results. While the pharmacies will have given their consent to pseudo-patient visits, they will not be told the dates that testing will occur. Pharmacies will not be informed of the time or the results of their pseudo-patient testing until after the second round of pseudo-patient visits.

Pseudo-patients are to be matched by demographic and scenario information. QCPP-validated scenarios will be used in this study. The pseudo-patient visits will follow QCPP methodology, and scoring of visits will adhere to QCPP guidelines. Pseudo-patients will be provided with a basic outline of the scenario for use as a guideline. Research staff will discuss the basic facts of the scenario with pseudo-patients and then assess their interpretation of the scenario. Role-plays are used to put the scenario into the context of potential questions and appropriate responses. The pseudo-patient will enter the pharmacy and approach pharmacy staff to enact the scenario. Each visit will be audio-taped using a concealed recorder. Following each visit, research staff listen to the taped encounter, discuss the visit with the pseudo-patient and document the visit.

A follow-up letter will inform them of the pseudo-patient visits. This differs from the QCPP methodology where pharmacies are presented with their results soon after the pseudo-patient visit. As QCPP testing has an educative role this is appropriate, however in this study, knowledge at the time of the visits could possibly bias the results of the sample study.

## ETHICAL CLEARANCE

The Human Ethics Committee at The University of Sydney will be required to give ethical clearance before the study research can commence.

## PROPOSED TIMELINES AND BUDGET

Duration of Project	May – August (4 months)
Proposed Total Budget (exclusive of GST)	\$128 868.60
GST component	\$12 886.86
Total Budget including GST	\$141 755.46

Indication of Budget (excluding GST)	Year 1	Year 2
Staff/Personnel		
Research Officer Level 6 Step 3 (4 months)	\$16 644	
12 Pseudo patients (in 5 States)	\$28 800	
University Loading (30%)	\$13 633.20	
Equipment		
Digital Recorders (Samsung YP-55 digital voice recorders): 12 x \$289	\$3 468	
University Loading (5%)	\$173.40	
Administration		
Postage/Telephone/Stationery	\$5 000	
University Loading (5%)	\$250	
Travel		
Pseudo-patient training		
Researcher travel to 5 states	\$5 500	
Pseudo-patient visits travel intrastate (variable) (165 rural visits x \$300/visit)	\$49 500	
University Loading (5%)	\$2 750	
Printing (data forms, final report etc)	\$1 500	
University Loading (5%)	\$75	
Audit	\$1 500	
University Loading (5%)	\$75	
<b>TOTALS</b>	<b>\$128 868.60</b>	

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## JUSTIFICATION OF BUDGET

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### **Staff/Personnel**

#### *Level 6 Step 3 Research Officer*

A Level 6 Step 3 Research Officer has been budgeted for 4 months. The appointed researcher's main duties will be organising recruitment, training and managing pseudo-patients, managing pseudo-patient visit schedules, scoring the results and associated administrative tasks. The level has been chosen to reflect the fact that we will be looking to employ someone with pharmacy experience/qualifications.

#### *Pseudo-patients*

Pseudo-patients have been budgeted at a rate of \$20/hour. This amount has been calculated on the time needed to complete 165 rural pharmacy visits (144 days) and 168 metropolitan pharmacy visits (36 days).

### **Equipment**

A digital recorder has been budgeted for each pseudo-patient to record the interviews for verification purposes. Digital (mp3) technology is preferred as it gives clearer and more reliable voice reproduction and files can be stored and transferred digitally.

### **Administration (Postage/Telephone/Stationery)**

This amount has been set aside for telephone contact with pseudo-patients, and insured and registered postage for return of testing materials.

### **Travel**

#### *Pseudo-patient training*

The Level 6 researcher is to travel to each of the five states to train pseudo-patients. The budget covers air travel to the five states (\$4500) and accommodation/meals (\$200/visit).

#### *Pseudo-patient travel*

165 rural visits have been budgeted at \$300/visit to cover travel and necessary accommodation.

### **Printing**

This amount has been set aside for printing of materials and the final report.

### **Audit**

Fees for auditing. Projects are required by contract to have an external audit at the completion of project

### **University Loading**

30% on-costs have been added to all salary items and 5% added to all other items above in accordance with University regulations.

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## CHIEF INVESTIGATOR

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## RESEARCH TEAM

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APPENDIX 35  
Study of Professional Interventions Data Tables

**Table A1:** Description of MIMS Categories used to code Products requested and Sold

Code	Description
1(a)	Hyperacidity, reflux and ulcers - Alimentary System
1(b)	Antispasmodics and motility agents - Alimentary System
1(c)	Laxatives - Alimentary System
1(d)	Antidiarrhoeals - Alimentary System
1(e)	Digestive supplements and cholelitholytics - Alimentary System
1(f)	Topical anorectal medication - Alimentary System
10(c)	Immunomodifiers - Immunology
11(a)	Expectorants, antitussives, mucolytics, decongestants - Respiratory System
11(b)	Bronchospasm relaxants - Respiratory System
11(c)	Bronchodilator aerosols and inhalations - Respiratory System
12(a)	Antihistamines - Allergic Disorders
13(a)	Topical otic medication - Ear, Nose and Oropharynx
13(b)	Topical nasopharyngeal medication - Ear, Nose and Oropharynx
13(c)	Topical oropharyngeal medication - Ear, Nose and Oropharynx
14(a)	Topical ocular anti-infective preparations - Eye
14(e)	Ocular astringents, decongestants, local anaesthetics - Eye
14(e)	Ocular astringents, decongestants, local anaesthetics - Eye
14(f)	Ocular lubricants - Eye
15(a)	Emollients, antipruritics and protective preparations - Skin
15(b)	Psoriasis, seborrhoea and ichthyosis - Skin
15(c)	Acne, keratolytics and cleansers - Skin
15(d)	Wart and corn removers - Skin
15(e)	Topical corticosteroids - Skin
15(g)	Topical antifungals - Skin
15(h)	Topical antiparasitics - Skin
15(i)	Topical antiseptics, anti-infectives - Skin
15(j)	Leg ulcer preparations - Skin
15(k)	Other dermatological preparations - Skin
16(a)	Anaesthetics - local and general - Surgical Preparations
16(e)	Surgical antiseptics and applications - Surgical Preparations
17(c)	Ovulation, pregnancy detection agents - Diagnostic Agents
18(b)	Progestogen only contraceptive agents - Contraceptive Agents
19(a)	Infant formulas - Nutrition
19(b)	Supplemental and enteral nutrition - Nutrition
19(d)	Oral and parenteral electrolytes - Nutrition
19(e)	Anorectics and weight reducing agents - Nutrition
2(a)	Antihypertensive agents - Cardiovascular System
2(c)	Diuretics - Cardiovascular System
2(d)	Antiarrhythmic agents - Cardiovascular System
2(e)	Antiangina agents - Cardiovascular System
2(j)	Antimigraine preparations - Cardiovascular System
2(k)	Anticoagulants, antithrombotics - Cardiovascular System
2(n)	Other cardiovascular agents - Cardiovascular System
20(b)	Agents used in drug dependence - Poisoning, Toxicity and Drug Dependence
21(a)	Vitamins (single agents) - Vitamins and Minerals



- 
- 21(b) Minerals - Vitamins and Minerals
  - 21(c) Fatty acid supplements - Vitamins and Minerals
  - 21(d) Fat soluble vitamins - Vitamins and Minerals
  - 21(f) Multivitamins and minerals - Vitamins and Minerals
  - 21(g) Tonics - Vitamins and Minerals
  - 21(h) Children's vitamins - Vitamins and Minerals
  - 21(i) Iron - Vitamins and Minerals
  - 22(b) Herbal circulatory system preparations - Herbal and other complementary medicines
  - 22(c) Herbal nervous system preparations - Herbal and other complementary medicines
  - 22(c) Herbal nervous system preparations - Herbal and other complementary medicines
  - 22(d) Herbal analgesics and anti-inflammatories - Herbal and other complementary medicines
  - 22(e) Women's supplements - Herbal and other complementary medicines
  - 22(f) Men's supplements - Herbal and other complementary medicines
  - 22(g) Herbal respiratory preparations - Herbal and other complementary medicines
  - 22(h) Herbal skin preparations - Herbal and other complementary medicines
  - 22(i) Herbal urinary tract preparations - Herbal and other complementary medicines
  - 22(j) General well-being, multiple use preparations, others - Herbal and other complementary medicines
  - 3(a) Sedatives, hypnotics - Central Nervous System
  - 3(b) Antianxiety agents - Central Nervous System
  - 3(h) Antiemetics, antinauseants - Central Nervous System
  - 4(a) Narcotic analgesics - Analgesia
  - 4(b) Simple analgesics and antipyretics - Analgesia
  - 4(c) Combination simple analgesics - Analgesia
  - 5(a) Nonsteroidal anti-inflammatory agents - Musculoskeletal System
  - 5(d) Rubefacients, topical analgesics/NSAIDs - Musculoskeletal System
  - 5(e) Agents used in gout and hyperuricaemia - Musculoskeletal System
  - 6(d) Insulin preparations - Endocrine and Metabolic Disorders
  - 6(e) Hypoglycaemic agents - Endocrine and Metabolic Disorders
  - 7(a) Urinary antiseptics, alkalinisers and acidifiers - Genitourinary System
  - 7(d) Topical vaginal medication - Genitourinary System
  - 8(b) Cephalosporins - Infections and Infestations
  - 8(c) Tetracyclines - Infections and Infestations
  - 8(h) Antifungal agents - Infections and Infestations
  - 8(l) Anthelmintics - Infections and Infestations
- 

#### MIMS – Description

**Table A2:** Census Frequency of Products Requested in Interventions coded by MIMS Categories

MIMS Category	Recorded Census frequency	Estimated freq of annual Australian interventions*
11(a)	1284	118359
5(a)	763	153083
4(a)	269	10364
4(c)	246	49666
4(b)	224	37075
12(a)	190	26065
11(c)	133	22141
1(a)	106	13508

13(b)	92	4384
5(d)	84	1533
7(d)	71	2765
13(c)	61	1825
15(i)	59	59
15(g)	55	55
15(e)	52	2478
14(e)	50	4041
1(d)	48	11603
22(c)	45	45
20(b)	43	43
1(c)	42	42
14(a)	29	2661
15(a)	24	24
11(b)	22	3242
7(a)	22	22
8(l)	20	3942
22(d)	19	19
18(b)	18	18
15(d)	17	17
16(e)	14	14
13(a)	13	13
3(a)	13	1154
3(h)	12	12
1(f)	11	1306
2(k)	10	1528
19(d)	9	9
21(i)	9	9
1(b)	8	4782
15(h)	6	6
15(k)	6	6
19(e)	6	6
21(a)	6	6
21(f)	5	5
22(g)	4	4
8(h)	4	4
15(b)	3	3
16(a)	3	3
19(b)	3	3
21(g)	3	3
22(b)	3	3
22(e)	3	3
22(j)	3	3
1(e)	2	2
14(f)	2	2
17(c)	2	2
21(b)	2	2
22(h)	2	2
15(c)	1	1
15(j)	1	1

19(a)	1	1
2(a)	1	1
2(c)	1	1
2(d)	1	1
2(e)	1	1
2(j)	1	1
2(n)	1	1
21(c)	1	1
21(d)	1	1
22(f)	1	1
22(i)	1	1
3(b)	1	1
5(e)	1	1
6(d)	1	1
6(e)	1	1
8(b)	1	1
8(c)	1	1

**Table A3:** Sample Study Frequency of Products Requested in Interventions coded by MIMS Categories

MIMS Category	Frequency	Weighted Frequency
11(a)	242	1441634
5(a)	73	463184
4(c )	38	116251
4(a)	38	181339
12(a)	31	142129
4(b)	21	25993
15(g)	21	102470
15(I)	13	13
13(b)	13	106880
1(d)	11	27708
1(a)	11	24876
14(e)	9	69113
7(d)	8	48361
14(a)	8	4791
13(c)	7	11321
11(b)	7	44731
13(a)	6	46612
15(d)	5	5
15(a)	5	5
8(h)	4	49413
7(a)	4	4
3(a)	4	8704
11(c)	4	28367
1(c)	4	4750
8(l)	3	3
5(d)	3	25493
15(e)	3	2162
1(f)	3	1977
3(h)	2	2

22(g)	2	2
22(d)	2	2
22(c )	2	2
21(i)	2	2
20(b)	2	25311
19(e)	2	2
18(b)	2	2
6(a)	1	1
22(h)	1	1
21(h)	1	1
21(g)	1	1
21(a)	1	1
2(k)	1	7156
19(b)	1	1
19(a)	1	1
17(c )	1	1
16(e)	1	1
16(a)	1	25491
15(k)	1	1
15(h)	1	1
14(f)	1	1
10(c )	1	1
1(e)	1	1
1(b)	1	1

APPENDIX 36  
Calculation Of Benefit In The Cost-Benefit Model

The tables below are taken from the cost-benefit spreadsheet model, in reference to the main report.

**Table A4: Disease category data**

Disease category	Disability weight	Duration of disease (days)	Survival years*	Case cost, \$
A2d Other sexually transmitted diseases	0.455	4.43		\$5,827
A4 Diarrhoeal diseases	0.093	10.86		\$35
A5b Whooping cough	0.178	10.00		\$1,118
A6 Meningitis	0.913	0.00	0	\$19,362
B1 lower respiratory tract infection	0.047	13.63		\$238
B2 Upper respiratory tract infections	0.014	7.06		\$11
B3 Otitis media	0.110	4.00		\$213
C3 Hypertension in pregnancy	0.117	0.00	0	\$2,456
C6 Other maternal conditions	0.349	16.00	2	\$2,471
D4 Neonatal Causes	0.494	0.00	0	\$9,285
F25 Other malignant neoplasms	0.930	0.00	2	\$261,925
I4 Other endocrine and metabolic	0.250	13.11		\$26,116
J1c Sedative dependence/abuse	0.184	218.47		\$343
J3a Depression	0.140	365.00		\$2,463
K8a Glaucoma	0.020	16.62		\$696
K9 Other nervous system sense organ	0.480	2.46	2	\$1,589
L5 Hypertensive heart disease	0.352	3.29		\$13,499
L9 Other cardiovascular disease	0.352	4.90	2	\$71,200
M2 Asthma	0.170	58.54	0	\$542
M3 Other chronic respiratory diseases	0.164	3.49	2	\$17,763
N1 Peptic ulcer disease	0.066	6.95	2	\$1,067
N4 Intestinal obstruction	0.211	6.42		\$4,526
O1 Nephritis and nephrosis	0.290	0.84		\$48,766
O3 Urinary incontinence	0.025	3.79		\$135
O4 Other urinogenital diseases	0.180	4.99		\$9,871
P1 Eczema	0.056	5.00		\$2,167
P2 Other skin diseases	0.056	2.99		\$5,047
R10 Other congenital anomalies	0.575	14.55	0	\$55,427

R3 Congenital heart disease	0.110	6.57		\$73,107
S1/S2 Dental disease	0.003	1.00		\$3
T1 Road traffic accidents	0.149	0.00	0	\$4,569
T11a/b Surgical/drug medical misadventure	0.417	0.76		\$32,359
T3 Poisoning	0.593	1.14		\$1,771

\* For disease categories in which deaths were recorded.

**Table A5:** Cases of temporary disability avoided

Disease category	S2			S3			Total		
	Central	Lower CI	Upper CI	Central	Lower CI	Upper CI	Central	Lower CI	Upper CI
A2d Other sexually transmitted diseases	696	17	3,878	1,721	43	9,589	2,417	60	13,468
A4 Diarrhoeal diseases	11,057	3,589	25,803				11,057	3,589	25,803
A5b Whooping cough	10	0	56				10	0	56
A6 Meningitis	1	0	3				1	0	3
B1 lower respiratory tract infection	21,953	5,982	56,211	98	2	546	22,051	5,985	56,757
B2 Upper respiratory tract infections	501	13	2,792				501	13	2,792
B3 Otitis media									
C3 Hypertension in pregnancy									
C6 Other maternal conditions	206	5	1,148				206	5	1,148
D4 Neonatal Causes									
F25 Other malignant neoplasms	215	5	1,198				215	5	1,198
I4 Other endocrine and metabolic	211	105	378	204	5	1,137	415	110	1,514
J1c Sedative dependence/abuse	1,063	27	5,923	1,234	31	6,876	2,297	57	12,799
J3a Depression				-814	-20	-4,536	-814	-20	-4,536
K8a Glaucoma	19,182	5,227	49,116	1,090	27	6,073	20,272	5,254	55,189
K9 Other nervous system sense organ	1	0	4	86	10	311	87	11	314
L5 Hypertensive heart disease	13,402	7,943	21,181	2,754	1,011	5,994	16,156	8,954	27,175
L9 Other cardiovascular disease	2,796	1,026	6,085	766	19	4,268	3,562	1,045	10,354
M2 Asthma	3,344	1,728	5,841	3,945	1,586	8,128	7,289	3,314	13,970
M3 Other chronic respiratory diseases	160	4	892	911	188	2,662	1,071	192	3,554

N1 Peptic ulcer disease	15,101	9,675	22,469	323	88	827	15,424	9,763	23,296
N4 Intestinal obstruction	1,058	128	3,822	169	4	942	1,227	132	4,764
O1 Nephritis and nephrosis	54	1	301	29	1	162	83	2	462
O3 Urinary incontinence	2,549	64	14,203	15,537	388	86,572	18,086	452	100,775
O4 Other urinogenital diseases				600	73	2,168	600	73	2,168
P1 Eczema	3,076	77	17,139				3,076	77	17,139
P2 Other skin diseases	1,313	159	4,743	7,156	179	39,873	8,469	338	44,616
R10 Other congenital anomalies	12	5	24				12	5	24
R3 Congenital heart disease	25	5	73				25	5	73
S1/S2 Dental disease	1,508	311	4,407				1,508	311	4,407
T1 Road traffic accidents									
T11a/b Surgical/drug medical misadventure	13,414	7,950	21,200	2,108	1,269	3,292	15,522	9,219	24,492
T3 Poisoning	1,771	1,082	2,735	3,017	1,689	4,976	4,788	2,770	7,711
Total for all disease categories	114,679	45,130	271,623	40,934	6,593	179,861	155,613	51,723	451,484

CI = 95% confidence interval

**Table A6: Deaths avoided**

Disease category	S2			S3			Total		
	Central	Lower CI	Upper CI	Central	Lower CI	Upper CI	Central	Lower CI	Upper CI
A2d Other sexually transmitted diseases									
A4 Diarrhoeal diseases									
A5b Whooping cough									
A6 Meningitis	125	15	452				125	15	452
B1 lower respiratory tract infection									
B2 Upper respiratory tract infections									
B3 Otitis media									
C3 Hypertension in pregnancy	21	1	117				21	1	117
C6 Other maternal conditions									
D4 Neonatal Causes	26	1	145				26	1	145
F25 Other malignant neoplasms	215	5	1,198				215	5	1,198



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I4 Other endocrine and metabolic									
J1c Sedative dependence/abuse									
J3a Depression									
K8a Glaucoma									
K9 Other nervous system sense organ				39	1	217	39	1	217
L5 Hypertensive heart disease									
L9 Other cardiovascular disease	456	55	1,647	766	19	4,268	1,222	74	5,915
M2 Asthma				143	4	797	143	4	797
M3 Other chronic respiratory diseases	29	1	162				29	1	162
N1 Peptic ulcer disease	176	4	981				176	4	981
N4 Intestinal obstruction									
O1 Nephritis and nephrosis									
O3 Urinary incontinence									
O4 Other urinogenital diseases									
P1 Eczema									
P2 Other skin diseases									
R10 Other congenital anomalies									
R3 Congenital heart disease									
S1/S2 Dental disease									
T1 Road traffic accidents				3	0	11	3	0	11
T11a/b Surgical/drug medical misadventure	175	4	975				175	4	975
T3 Poisoning	42	1	234				42	1	234
Total for all disease categories	1,265	87	5,910	951	24	5,293	2,216	111	11,203

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CI = 95% confidence interval