

Appendix 1

THE REVIEW'S TERMS OF REFERENCE

Introduction

In accordance with commitments under the 1995 Competition Principles Agreement, a review has been commissioned by State, Territory and Commonwealth governments to examine State and Territory legislation relating to pharmacy ownership and registration of pharmacists, together with Commonwealth legislation relating to regulation of the location of the premises of pharmacists approved to supply pharmaceutical benefits.

BACKGROUND

On 13 May 1997 the Prime Minister, in his role as Chairman of the Council of Australian Governments (COAG), wrote to State Premiers and Territory Chief Ministers, seeking their agreement to a national competition review of pharmacy regulation. On 1 May 1998, the Prime Minister advised Premiers and Chief Ministers that all Governments had agreed to the review.

LEGISLATION TO BE REVIEWED

The specific items of legislation to be reviewed are listed at Attachment A.

In summary, they include:

- in relation to State and Territory responsibilities, legislation concerning pharmacy ownership and the registration of pharmacists; and
- in relation to Commonwealth responsibilities, section 99L of the National Health Act insofar as it relates to the regulation of the location of premises from which pharmacists may dispense pharmaceutical benefits.

OBJECTIVES AND SCOPE OF THE REVIEW

Clarify the objectives of the legislation listed at [Attachment A](#).

Identify the nature of any restrictions on competition arising from that legislation.

Analyse the likely effects of those restrictions on competition and on the economy generally.

Assess and balance the costs and benefits of the restrictions, and assess whether the objectives of the legislation can be achieved only by restricting competition.

Consider alternative means for achieving the objectives, including non-legislative approaches.

The review will have regard to the relevant sections of the Competition Principles Agreement, the COAG Guidelines and Principles for National Standard Setting and

In the case of Tasmania and Queensland, the review will not cover the registration of pharmacists as this legislation has already been reviewed.

Regulatory Action, the COAG Guidelines for Review of Professional Regulation and make use of material contained in guidelines published by Commonwealth and State governments on regulatory impact statements and on conducting National Competition Policy legislation reviews. If practicable, the review should also have regard to the outcome of related reviews such as the national competition review of drugs and poisons regulation.

The review should also assess the net public benefit of the legislation having regard to the public benefit criteria set out in clause 1(3) of the Competition Principles Agreement (see Attachment B).

REVIEW ADMINISTRATION

Chair and Steering Committee

The review will be conducted by an independent Chair who will be supported by a small secretariat. The Chair will be advised by a Steering Committee specifically established for that purpose.

The Chair should have familiarity with economic principles and the pharmacy industry. He/she will be selected from a short-list of nominees prepared by the Commonwealth Department of Health and Aged Care in consultation with State and Territory health departments.

Nominations for membership of the Steering Committee will be obtained through consultation involving Commonwealth, State and Territory Departments of Health and the Committee for Regulatory Reform of COAG. A key criterion for the Steering Committee is that it comprises one representative from each jurisdiction and that that person is able to represent the government agency whose legislation is subject to the review.

Resources

The Commonwealth will fund half the costs of the review, excluding Steering Committee participation costs, which are to be met separately by each participating government. The remaining costs of the review will be shared proportionately according to the population of each State and Territory. If considered appropriate, any participating government may offer to second an officer to the review Secretariat as part of its contribution.

Costs to be taken account of in developing a budget for this review include:

- staffing and office costs for secretariat;
- payment to an independent Chair;
- payment to any consultants contracted;
- costs of producing the report;
- costs associated with consultations, advertising for submissions etc; and
- associated travel costs.

The total cost of the review could be expected to be in the vicinity of \$500,000.

The Commonwealth Department of Health and Aged Care will provide the base for the Secretariat functions and significant staff support for the Review Secretariat itself. Final

details of staffing, including the appropriate level and mix of skills, can be resolved through the Steering Committee.

Conduct of the review

The Chair should seek submissions from the public through advertisements in the national press and other mechanisms considered appropriate. The Chair should also consult directly with key stakeholders on the issues covered by the review.

The review is to commence as soon as possible. The Chair should provide governments and key stakeholders with an interim report within 4 months of the commencement of the review to assist in their consideration of issues relating to pharmacy ownership, the registration of pharmacists and the location of pharmacies, and to provide an indication of the review's likely findings. The Chair should provide COAG with a final report on the review not more than 6 months after its commencement.

Legislation to be Reviewed**1. State and Territory legislation**

The relevant instruments relating to pharmacy ownership and registration of pharmacists for the States and Territories are as follows:

Western Australia, *Pharmacy Act 1964*

New South Wales, *Pharmacy Act 1964*

Victoria, *Pharmacists Act 1974*

South Australia, *Pharmacists Act 1991*

Queensland, *Pharmacy Act 1976*, Part 4

Tasmania, *Pharmacy Act 1908*, (not including those parts relating to the registration of pharmacists)

Northern Territory, *Pharmacy Act 1996*

Australian Capital Territory *Pharmacy Act 1931*

2. Commonwealth Legislation

There is one instrument involved:

Commonwealth Ministerial Determination under section 99L (1) of the *National Health Act 1953*: that part relating to “Approval to Supply Pharmaceutical Benefits”.

ATTACHMENT B**PUBLIC BENEFIT TEST**

Competition Principles Agreement, Clause 1(3) states:

“Without limiting the matters that may be taken into account, where this Agreement calls:

- (a) for the benefits of a particular policy or course of action to be balanced against the costs of the policy or course of action; or*
- (b) for the merits or appropriateness of a particular policy or course of action to be determined; or*
- (c) for an assessment of the most effective means of achieving a policy objective;*
- (d) the following matters shall, where relevant, be taken into account:*
- (e) government legislation and policies relating to ecologically sustainable development;*
- (f) social welfare and equity considerations, including community service obligations;*
- (g) government legislation and policies relating to matters such as occupational health and safety, industrial relations and access and equity;*
- (h) economic and regional development, including employment and investment growth;*
- (i) the interests of consumers generally or of a class of consumers;*
- (j) the competitiveness of Australian businesses; and*
- (k) the efficient allocation of resources”.*

Appendix 2

THE NATIONAL COMPETITION POLICY

INTRODUCTION

In 1995 the Council of Australian Governments (COAG) agreed to implement the National Competition Policy (NCP) based on the recommendation of the National Competition Policy Review Committee chaired by Professor Fred Hilmer AO.

NCP represents a commitment by all Australian governments to a consistent approach to fostering greater economic efficiency and improving the overall competitiveness of the Australian economy.

HOW NCP IS GIVEN EFFECT

NCP is being given effect through the implementation of three intergovernmental agreements signed by COAG in April 1995:

- The *Conduct Code Agreement*, which committed Governments to the application of uniform competition laws;
- The *Competition Principles Agreement*, which established consistent principles governing pro-competitive reform of government business enterprise and government regulation;
- The *Agreement to Implement National Competition Policy and Related Reforms*, which incorporated a timetable for reform and a commitment by the Commonwealth to make additional general purpose payments to the States conditional upon compliance with the agreed reform agenda and timetable.

COMPETITION PRINCIPLES AGREEMENT

As part of the *Competition Principles Agreement*, all governments agreed to adopt the following guiding legislative principle:

Legislation should not restrict competition unless it can be demonstrated that:

- The benefits of the restriction to the community as a whole outweigh the costs; and
- The objectives of the legislation can only be achieved by restricting competition.

To give effect to this principle, governments have agreed to:

- Review, and where appropriate, reform all existing legislative restrictions on competition against the guiding legislative principle; and
- Ensure that all new legislative proposals are assessed against this principle.

The *Competition Principles Agreement* provides that in assessing the costs and benefits of a restriction on competition, the following matters, where relevant, are taken into account:

- Government legislation and policies relating to ecologically sustainable development;
- Social welfare and equity considerations, including community service obligations;

- Government legislation and policies relating to matters such as occupational health and safety, industrial relations and access and equity;
- Economic and regional development, including employment and investment growth;
- The interests of consumers generally or of a class of consumers;
- The competitiveness of Australian businesses; and
- The efficient allocation of resources.

The *Competition Principles Agreement* also requires that a legislation review should consider the following:

- Clarify the objectives of the legislation;
- Identify the nature of the restriction on competition;
- Analyse the likely effect of the restriction on competition and on the economy generally;
- Assess and balance the costs and benefits of the restriction; and
- Consider alternative means for achieving the same result, including non-legislative approaches.

NCP PURPOSE AND PHILOSOPHY

The purpose of the guiding legislative principle is to critically assess whether restrictions on competition are necessary to achieve the objectives of the legislation in which they appear. As stated in the Victorian Government's *Guidelines for the Review of Legislative Restrictions on Competition*:

These [restrictions] typically evolved to serve wider public policy objectives, including protection of the consumer, the environment or the wider public from unscrupulous, unsafe or environmentally destructive practices, processes or products. The guiding legislative principle established under the Competition Principles Agreement does not imply that competition objectives should take precedence over these important policy objectives. However, the form which regulation takes often creates unwarranted barriers to entry to relevant markets, limiting consumer choice, stifling innovation and generating monopoly rents for existing producers which result in higher prices to consumers.

Application of the Policy's guiding legislative principle therefore is intended to establish whether particular restrictions on competition remain necessary to the achievement of specific public policy objectives through a rigorous assessment of the benefits to the public of each restriction compared with the costs involved, and assessment of non-regulatory alternatives.

The general proposition underlying these reviews is that open and unrestricted competition in markets is generally the most efficient method of allocating the community's resources, and that the benefits of a restriction on competition will generally only outweigh the costs in situations of 'market failure'. Therefore, intervention should generally be restricted to those situations.

This Appendix is an extract from the Victorian Department of Human Services' November 1998 discussion paper for the Review of Victorian Health Act 1958. It is adapted with permission.

Appendix 3

THE PHARMACEUTICAL BENEFITS SCHEME AND PHARMACIST REMUNERATION

The purpose of the Pharmaceutical Benefits Scheme (PBS) is to provide timely, reliable and affordable access for the Australian community to necessary and cost effective medicines.

The PBS has been in operation for more than 50 years. It has evolved into a scheme which from 1 February 1999 covers 559 drug substances (generic drugs), available in 1,354 forms and strengths (items) and marketed as 1,992 different drug products (brands). The list of benefits is comprehensive, providing suitable therapy for most medical conditions in which medicine is an accepted form of treatment and diagnosis by a medical practitioner is appropriate.

Eligibility is restricted to Australian residents and visitors from those countries with which Australia has a Reciprocal Health Care Agreement. Currently, those countries are the UK (including Northern Ireland), Ireland, New Zealand, Malta, Italy, Sweden, the Netherlands and Finland.

The PBS is complemented by the Repatriation Pharmaceutical Benefits Scheme (RPBS), which provides access to some additional pharmaceutical items to persons with entitlements under the *Veterans' Entitlements Act 1986*.

Decisions on what drugs are included, or "listed" under the PBS, are based upon the recommendations of an expert body of medical practitioners and pharmacists, the Pharmaceutical Benefits Advisory Committee. Over recent years, increasing emphasis has been placed on manufacturers having to demonstrate the cost effectiveness of the drugs they are seeking to have listed on the Schedule of Pharmaceutical Benefits.

PBS listed products must be:

- Prescribed by a registered medical practitioner or, for certain drugs, by a registered dental practitioner; and
- Dispensed by an approved pharmacist or, in limited cases where a pharmaceutical service is not available, by an approved medical practitioner.

The Commonwealth Government reduces the cost of pharmaceuticals to patients by:

- Negotiating an agreed price for the medicine with the supplier of the product;
- Controlling the mark-ups applied by wholesalers and dispensers;
- Remunerating dispensers an amount determined by the Pharmaceutical Benefits Remuneration Tribunal; and
- Subsidising the cost of the product to patients with the level of subsidy linked to the welfare needs of the patient.

In negotiating prices with manufacturers, which are used to establish prices paid to pharmacists, the Commonwealth Government has significant market power because only products listed on the PBS are subsidised and doctors tend to confine their prescribing to the

PBS list. As a result of this monopsony power, the pharmaceutical industry claims that Australian prices are significantly lower than most other comparable overseas countries.

Under the PBS, the current maximum cost to consumers for drugs listed under the PBS is \$20.30 for General Beneficiaries (who are members of the general public and do not have concession cards) and \$3.20 for Concessional beneficiaries (who are holders of Pensioner Concession, Commonwealth Seniors Health Cards and Health Care Cards), except where a special patient contribution, a brand premium, or a therapeutic group premium applies.

So, for example, if a person required treatment for multiple sclerosis with Interferon Beta-1b (*Betaferon*), the cost of a set of injections is \$1264.34, but a General Beneficiary would pay \$20.30 and a Concessional beneficiary \$3.20, with the Commonwealth meeting the balance of the cost.

COST OF THE PBS TO GOVERNMENT

In 1997/98, the PBS dealt with over 125 million benefit prescriptions. For that year, the cost to the Commonwealth of the PBS was \$2.541 billion and the patient contribution was \$571 million, making the total cost of the Scheme \$3.112 billion.

Of this total, the amount paid to pharmacists for dispensing the drugs was \$773 million, representing around 25 per cent of the total cost of the Scheme.

It took 40 years for the cost of the PBS to reach \$1 billion and only a further six years to double to nearly \$2 billion in 1994/95. Since then, the cost to the Government of pharmaceutical benefits has grown at an average annual rate of 9.7 per cent in real terms over the last 4 years. PBS costs are expected to grow at an average rate of 8.0 per cent real per annum over the next 5 years. The total cost to the Government of the PBS can be expected to double again in the next 11 to 12 years.

Government expenditure on the PBS represents 5.9 per cent of total health services expenditure; the PBS average annual expenditure growth rate of 9.7 per cent per annum compares with an average annual growth rate of around 4.8 per cent in total health services expenditure.

As in the case of other medical technologies, newer medicines tend to be more expensive than older ones and prescribers tend to favour the newer and more expensive medicines. So, for example, in 1997/98 there were over 6 million PBS prescriptions for cholesterol-lowering drugs, at an average price of \$50.78 and at a total cost to Government of some \$274 million. Antacids and drugs for treating peptic ulcers accounted for over 8 million PBS prescriptions, at an average price of \$46.58 and at a total cost to Government of over \$322 million.

The majority of expenditure on PBS prescriptions continues to be directed towards those least able to afford the cost of medicines, with Government expenditure on pharmaceuticals for Concessional beneficiaries representing around 80 per cent of total PBS expenditure in 1997/98. The remaining 20 per cent was spent on subsidising the price of drugs prescribed to General beneficiaries.

PHARMACIST REMUNERATION

The current Australian Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia provides for payments to approved pharmacists for the dispensing of PBS listed medicines. This agreement expires on 30 June 2000 and is currently being re-negotiated.

The amount paid to pharmacists consists of:

- A mark-up of 10 per cent on the Government agreed price to the pharmacist, up to \$180, or \$18.00 on the price to pharmacists above \$180 up to \$360, or 5 per cent on the price to pharmacists above \$360,
- **Plus** a Government composite fee of \$4.34 for ready prepared items or \$6.20 for extemporaneously prepared items,
- **Plus** a range of miscellaneous fees and allowances where applicable, such as:
 - the Isolated Pharmacy Allowance and Remote Pharmacy Allowance;
 - fees for accredited pharmacists undertaking medication reviews in nursing homes; and
 - additional charges for PBS medicines below the general patient copayment (of \$20.30)

Payments to suppliers (including manufacturers) are 90 per cent of the pharmacist price, whilst wholesalers receive 10 per cent of the pharmacist price.

This material was prepared by the Commonwealth Department of Health and Aged Care and is adapted with acknowledgment.

Appendix 4

POSSIBLE CORPORATE STRUCTURE MODEL

Please Note: This appendix is accessible on as a separate PDF document at www.health.gov.au/haf/pharmrev/final.htm

Appendix 5

ALTERNATIVES TO EXISTING REGULATION FOR NEW AND RELOCATED PHARMACIES

Further to Recommendations 9-13 in Chapter 3, the Review has considered how transitional arrangements may apply for regulations related to locating pharmacies to dispense Pharmaceutical Benefits Scheme (PBS) benefits. This Appendix assumes that relocated pharmacy restrictions would be phased out after the transition period, and that new pharmacy approval restrictions will in time be replaced with other measures.

NEW PHARMACY APPROVALS

For the transitional period, the existing rules for new pharmacy approvals would continue, and the ACPA's determining role would continue. The criteria applied would, however, be revised to make them more efficient, relevant and equitable, particularly to make them as "rural friendly" as possible.

Subject to negotiation and consultation, including with affected communities themselves, adjusted criteria could be more flexible, and take such factors into account as:

- Local population health characteristics (eg aged persons, persons with chronic illnesses, people with serious disabilities, numbers of children under 10) rather than disadvantaged social groups;
- The proximity of the nearest pharmacy and nearest hospital;
- The local community's ability to support the pharmacy business;
- A general practitioner being within a reasonable travelling time of the locality (of say 30 minutes) rather than present in a town full- or part-time; and
- Changing the population definition to reflect a locality's year-round profile, including temporary residents in peak periods (for example, in a holiday locality where a high transient population may be present for several months) rather than simply count the number of permanent residents.

RELOCATED PHARMACY APPROVALS

From the 1 July 2001 commencement date suggested in Chapter 3, the existing distance-based relocation rules would continue for a agreed time, with modifications to make their operation more effective and practical, and better to reflect contemporary and evolving trends in health care delivery in and beyond pharmacy.

"Long distance" relocations

Interim adjustments to the long distance relocation criteria could include:

- Shortening the new site relocation distance from 2 kilometres to 1.5 kilometres. This would continue the trend of the Second Agreement from the First in shortening the radius from 5 to 2 kilometres; and

- Changing the current route definition of the “shortest lawful distance door to door” to the “shortest reasonable access route”. This would not eliminate the potential for administrative or judicial review of distance-based decisions. It would, however, mean that they would be based on more practical considerations such as the degree of difficulty for an old, ill or infirm person, or a parent with young children, in reaching their nearest pharmacy.

Local relocations

For short distance relocations of an established pharmacy to a nearby site:

- The present 1 kilometre route measure for short distance relocations would be extended to 1.5 kilometres by the shortest reasonable access route;
- The period in one site before a short distance relocation could be sought would be reduced from 2 years to 1 year; and
- The need for Australian Community Pharmacy Authority (ACPA) approval of short relocations would be abolished, although the new premises would still need to satisfy any local State or Territory requirements.

Shopping centre relocations

For shopping centre relocations, existing distance-exempt provisions would continue, but:

- The present distinction between service and retail shops would be abolished, and the total number of shops in the complex would be the eligibility criterion;
- The ratio of pharmacies to shops in any one complex would not necessarily change (ie 1:30; 2:100; 3:200);
- The definition of an eligible shopping centre would be clarified along the lines of “*a discrete collection of shops, including a food store, supermarket or department store, within one exclusive pedestrian and car parking precinct*”; and
- The Secretary of the Department of Health and Aged Care (the Secretary) would have the discretion to approve a pharmacy in a community shopping precinct of less than 30 shops and less than 1.5 kilometres from the nearest pharmacy if:
 - (a) The existing pharmacy would be difficult for residents without private transport to reach easily (for example, due to topographical features or lack of access to existing public transport routes);
 - (b) A general practitioner is or will be co-located in the precinct.

SPECIFIC APPROVALS

Recognising that certain care facilities have special pharmacy needs, the Secretary could consider also new and relocated approvals for pharmacies in:

- Medical centres;
- Private hospitals with inpatient services (without a minimum bed requirement); and
- Aged care facilities (single or multi-complex) with sufficient residents and community-based clients to justify an in-house pharmacy service.

The distance criteria for relocations would not apply, although safeguard criteria and definitions of eligible facilities may be put in place to protect the public interest.

RURAL LOCALITIES

In limited circumstances, the Secretary may issue a PBS approval to a designated rural or isolated locality if that locality satisfies the revised definite community need criteria of the nature outlined above, and applies for the issue of a location specific PBS approval under these proposed arrangements.

In these circumstances:

- The PBS approval would be tied to that locality;
- The ACPA may not necessarily have a role in recommending locality-based applications;
- The approval could not be relocated with a pharmacy from the designated locality to another place;
- The local community may use the approval to attract a pharmacy business to that locality, and may be involved in selecting pharmacy proprietors applying for access to the approval; and
- The ongoing need for an approval specific to a given locality would be reviewed periodically by the Commonwealth Department of Health and Aged Care.

PERIOD OF OPERATION OF THE SUGGESTED MEASURES

These arrangements would commence on 1 July 2001, giving pharmacists and pharmacy proprietors reasonable notice of the changes coming into effect. Effectively, the starting date would be one year into the next Australian Community Pharmacy Agreement.

Once commenced, the measures outlined above would apply for a three to five year transitional period. At the end of that period:

- The pharmacy relocation restrictions would be abolished altogether; and
- The new approval restrictions would be abolished if different remunerative arrangements are put in place as discussed in Chapter 3.

Savings arrangements

PBS dispensing approval applications for new and relocated pharmacies commencing trading after 1 July 2001 would be considered under present rules in respect of pharmacies for which (a) deeds of sale or purchase have been executed, (b) leases have been signed, and (c) applications for PBS dispensing approvals have been lodged, before 30 June 2001.

THE AUSTRALIAN COMMUNITY PHARMACY AUTHORITY

For any transition period, there is a case for restructuring the composition and functions of the ACPA to ensure that it, and whatever rules it administers, are as responsive as possible to the needs of the community as a whole.

Under the transitional approach the ACPA would be retained but would:

- Be recognised by all parties as having its first duty to the Australian community rather than to the Commonwealth or to the community pharmacy industry and profession;

- Be composed of persons appointed by the Commonwealth Minister in consultation with the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, and consumer interests;
- Be chaired by a person with personal experience of community pharmacy but not a current proprietor, and include in its membership a legal practitioner and a lay member, neither of whom should also be a registered pharmacist; and
- Interpret the Determination rules fairly and consistently on the basis of clear guidelines and established precedent. The ACPA in doing so could exercise approved limited discretion on matters such as distance from the nearest pharmacy, and matters relating to community shopping precincts described above. The limits of such discretion, and procedures for dealing with any ACPA member's conflicts of interest in dealing with applications, should be set out in published guidelines approved by the Minister.

