

A PERSPECTIVE ON AUSTRALIA'S NATIONAL MEDICINES POLICY

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ABSTRACT

There is international interest in Australia's health care system for prescription medicines. The issue is particularly topical in Canada with the debate following publication of the Romanow Report into the future of health care in Canada. This Report recommended a new National Drug Agency. Australia has a National Medicines Policy with four arms – quality, safety and efficacy of medicines; equity of access; a viable and responsible pharmaceutical industry; quality use of medicines. The four arms of the Policy are interlinked and interdependent for optimal functioning. In this paper, an overview of how the prescription drug system in Australia works is presented. The manuscript focuses upon specific aspects of the Policy, describing how it functions and some of the processes integral to success, from the viewpoint of the author. The discussion includes some of the advantages of Australia's system for pharmaceuticals as well as some of the problems, as these present opportunities for development and change.

Keywords: Medicines Policy, Prescription Drug Policy, Quality Use of Medicines

There is current interest in Canada in a national approach to prescription medicine access and rational use. The Romanow Report about the future of health care in Canada recommended the formation of a National Drug Agency with a wide ranging remit. The Report also recommended a new Centre for Innovation on Pharmaceutical Policy. It is useful in this context to have information about other health care systems with a national approach to prescription medicines subsidy and use. Australia has this approach.

There are geographical and political similarities between Australia and Canada also. Australia has a federated system of 6 states (similar to provinces) and 2 territories. There is an elected Federal (Commonwealth) Government and elected State Governments. The population of Australia is currently about 19 million. It is a large country (about 7.7 million square kilometres) with an average population density of only about 2.5 people per square kilometre. Most of the population, however, is congregated in the south east corner of the country in a few major cities, leaving most of the land with a very dispersed population. As a simple overview, medical services in Australia are insured by a publicly

funded system (Medicare) and health care provider reimbursement occurs from the Commonwealth Government. Public hospitals, however, are run by State Governments, with a formula distribution of taxation revenue from the Commonwealth Government to support these. There is also parallel private health insurance, mainly for hospitals and associated procedures.

Pharmaceuticals are insured separately to other health services, by a publicly funded national scheme, the Pharmaceutical Benefits Scheme (PBS). The Commonwealth Government reimburses pharmacists for prescriptions dispensed. The National Health Act (1953) in Australia established the PBS for public subsidy of community use of necessary and life-saving medication.¹ Australia's endorsed National Medicines Policy is available at www.health.gov.au/haf/nmp/objectives/policy.htm (all websites accessed 2nd June 2003). The Policy was developed collaboratively, with all groups having an interest in medicines in Australia involved as partners in this development including consumers, health professionals, pharmaceutical industry (including the complementary medicines industry), medical media, and state and

commonwealth governments. There are four central objectives of Australia's National Medicines Policy:

1. quality, safety and efficacy of medicines;
2. timely access to medicines, at an affordable cost;
3. responsible and viable medicines industry;
4. quality use of medicines.

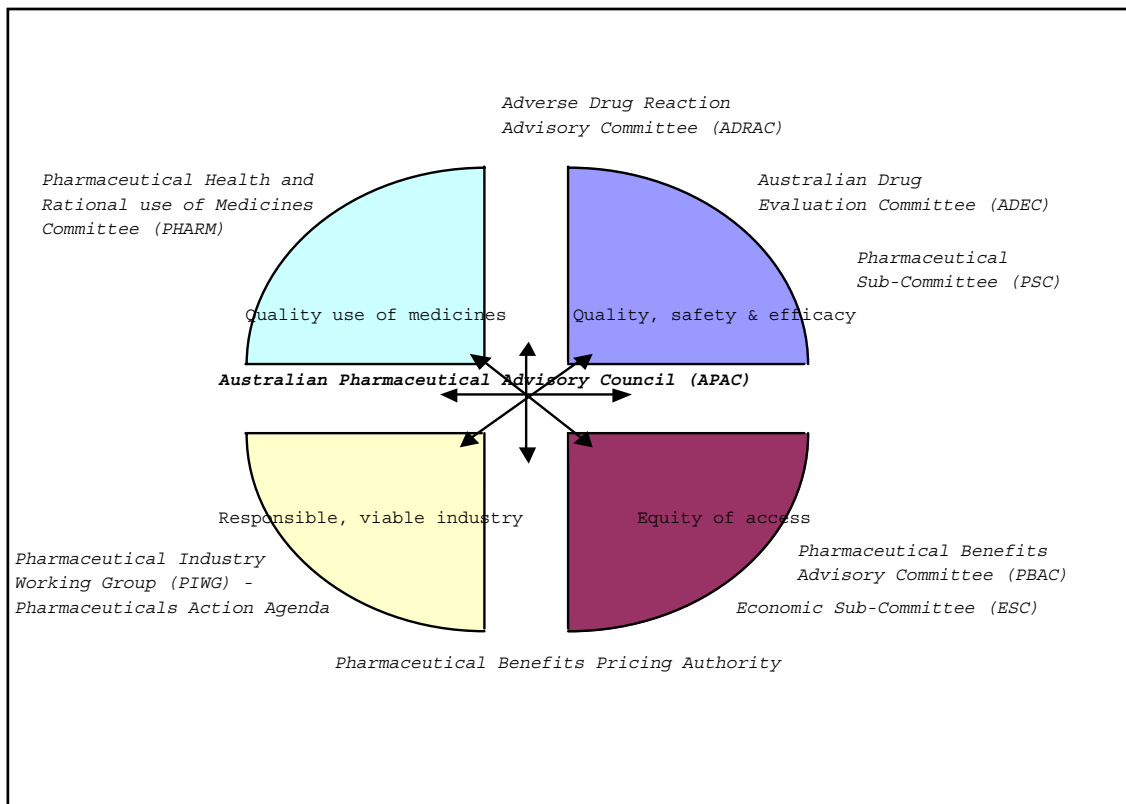
This paper provides an overview of how the Australian health care system works for pharmaceuticals, particularly for prescription medicines. The manuscript illustrates the importance and inter-relationships of all four arms of Australia's National Medicines Policy. This could be useful to inform Canada's current discussions on the formation of a National Drug Agency.

Four Arms of Australia's National Medicines Policy

All four arms of Australia's National Medicines Policy are vital and inter-related (Figure 1). For example, if a consumer has access at a reasonable cost to a safe, new, effective medicine, produced by a profitable pharmaceutical company in accordance with the highest quality standards, but then has trouble remembering to take the medicine, or gets confused about which medicine to take (i.e., the quality use of medicines aspect is not fulfilled), then the whole purpose of having the Policy is lost. The same could be said if one of the other arms, not quality use of medicines, were missing. An overview of each arm of the Policy is given below. The Committees referred to are shown in Figure 1.

FIGURE 1.

Schematic showing the four arms of Australia's National Medicines Policy and demonstrating their inter-relationships. Some of the main committees influencing the different parts of the National Medicines Policy are shown in italics, with APAC shown as the primary forum for engagement of all stakeholders with interests overall in the whole Policy.



Quality, safety and efficacy

The quality, safety and efficacy arm of the Policy in Australia is mainly the jurisdiction of the Therapeutic Goods Administration (TGA) (www.health.gov.au/tga). There is an internationally recognised process for registration of medicines for the Australian market, with guidelines and procedures to be followed accessible on the website. The stated objective of the Therapeutic Goods Act (1989) is to provide a national framework for the regulation of therapeutic goods to ensure their quality, safety, efficacy and timely availability. In many respects, the evaluation process for new drugs, or new formulations, is similar to processes in other countries.²

Initially, for prescription medicines, pharmaceutical manufacturers compile an application for registration (on the Australian Register of Therapeutic Goods (ARTG)) for evaluation by the TGA. The submission encompasses chemistry and quality aspects, toxicology, pharmacokinetics, bioavailability and clinical information. These parts are comprehensively and critically evaluated both within the TGA as well as by contracted external evaluators from around Australia. With harmonisation of registration requirements, evaluations from other countries (eg. the EU, Canada, New Zealand), may be accepted and facilitate the process for Australian evaluation. When evaluations for chemistry and quality aspects, and bioavailability are essentially complete, these are sent to the Pharmaceutical Sub-Committee (PSC) of the Australian Drug Evaluation Committee (ADEC) for advice (www.health.gov.au/tga/docs/html/dec/dec.htm). PSC meets every two months and discusses all new chemical entities and relevant policy changes. PSC recommendations, together with the full clinical and toxicological evaluations then go to ADEC. ADEC also meets every two months and discusses all new chemical entities. The evaluations provided to PSC and ADEC and the information on which these rest are deemed to be 'commercial in confidence' and no information is publicly available, unlike the U.S. Food and Drug Administration, for example, which publishes

evaluations on a website, and the EU, which is following similar lines in transparency.

Product Information and Consumer Medicine Information are also negotiated throughout this process and are commented on by PSC and ADEC. At the end of this registration process, a recommendation goes to the Minister for Health and Ageing and, if favourable, the product becomes registered and obtains an AUSTR number. Once a product is registered it can be marketed as a private prescription, with the consumer paying the full cost as determined by the company. The product can also be marketed in the public hospital system (again with the full cost determined by the pharmaceutical company).

There is also an Adverse Drug Reaction Advisory Committee (ADRAC) which feeds in to the ADEC process, collating data on voluntary adverse drug reaction reports, producing newsletters and information for health care professionals and providing advice to ADEC on adverse reactions requiring changes to market status or labelling. There are separate processes for over the counter medicines and complementary medicines and separate advisory committees to oversee these activities. Importantly, all the advisory committees are expert committees. Expertise is selected from all around Australia.

Timely access, at affordable cost

Australia has a Pharmaceutical Benefits Scheme (PBS). This is a publicly funded, national scheme ensuring all Australian residents access to necessary and life-saving medication at an affordable price (www.health.gov.au/pbs). Affordable cost (to the community as well as to the individual), is dealt with under the provisions of the National Health Act (1953), by the PBS process of listing and pricing.¹⁻³ After drug registration the pharmaceutical company submits an application to the Commonwealth Department of Health & Ageing for listing on the PBS. For inclusion on the PBS, the manufacturer must demonstrate both clinical efficacy and cost-effectiveness.^{1,4}

The dossier submitted by the company consists of four main sections:

1. what the drug is used for and what it is being compared to;
2. scientific evidence of efficacy and effectiveness (usually the largest part);
3. economic evaluation versus comparator (societal perspective);
4. expected budget impact analysis.³

The guidelines for preparation of submissions have evolved over time. See www.health.gov.au/pbs/pubs/pharmpac/gusubpac.htm.⁵ The detail of requirements for clinical and economic evaluations are described elsewhere.^{1,3,4}

The dossier is comprehensively and critically evaluated, sometimes internally by staff of the Commonwealth Department of Health & Ageing, but more often externally at one of the centres established in Australia. These centres have expertise to re-evaluate the clinical aspects of the application as well as to check and critique the economic models. New data may be modelled, depending upon the findings of the evaluators' literature reviews. The evaluations are completed within a six week time frame and the material collated and sent to the Economics Sub-Committee (ESC) of the Pharmaceutical Benefits Advisory Committee (PBAC).

The Pharmaceutical Benefits Advisory Committee (PBAC) was established in 1954 under the National Health Act (1953) www.health.gov.au/pbs/listing/committee.htm#pbac (amended in 1987) in order to:

1. make recommendations to the Minister as to drugs to be made available as pharmaceutical benefits; and to
2. consider effectiveness and cost, compared with alternatives (including non-drug) therapies.

The PBAC established an Economics Sub-Committee (ESC) in 1993 to assist with the latter role, when cost-effectiveness

requirements became mandatory.¹ The PBAC meets 4 times per year.¹

If a product is recommended for inclusion for subsidy, preliminary estimates of costs are made and recommendations are made about the amount of medicine to be available per prescription and the number of repeats (usually a one month supply, with five repeats, for a medicine for chronic use). These are then referred to the Pharmaceutical Benefits Pricing Authority which negotiates directly with the company for the price (based upon the PBAC evaluations of cost-effectiveness) that the Commonwealth Government will reimburse pharmacists for provision of that item (www.health.gov.au/pbs/pricing.htm).

This process has been described in more detail¹ and case examples given.⁴ The Commonwealth Minister for Health & Ageing can then directly approve the inclusion of a product with a budget estimate of less than \$10 million per year. Decisions for drugs of higher budget impact must go to the full Cabinet. If favourable, the prescription drug then receives an 'item number' and is included on the Pharmaceutical Benefits Schedule (www.health.gov.au/pbs/index.htm).

An example of an item number, and how it is listed, is shown in Table 1. All products are grouped according to WHO Anatomic Therapeutic Chemical classification. For major submissions for public subsidy on the PBS, if companies submit their applications 11 weeks prior to a meeting, the commitment is that the application will be reviewed and evaluated in time for that PBAC meeting. The companies receive written advice of the PBAC recommendation within three weeks of the meeting. Ministerial or Cabinet approval (for large anticipated expenditures) may take a further three months, so it may be five months between PBAC recommendation and actual listing as a benefit.

TABLE 1 EXAMPLE OF A LISTED PHARMACEUTICAL BENEFIT

NAME, RESTRICTION, MANNER OF ADMINISTRATION AND FORM
<ul style="list-style-type: none"> • SERUM LIPID REDUCING AGENTS • Cholesterol and triglyceride reducers • HMG CoA reductase inhibitors • SIMVASTATIN • Restricted Benefit • For use in patients that meet the criteria set out in the General Statement for Lipid Lowering Drugs

GENERAL: Cardiovascular System							
CODE	DOSE	MAX QTY.	NO. OF REPEATS	BRAND PRICE PREMIUM \$	DISPENSED PRICE FOR MAX. QTY. \$	MAX. RECORDABLE VALUE FOR SAFETY NET \$	NAME AND MANUFACTURER
2013y	Tablet 5 mg	30	5	...	31.02	23.10	Lipex 5 AD Zocor MK
2011 W	Tablet 10 mg	30	5	...	42.34	23.10	Lipex 10 AD Zocor MK
2012X	Tablet 20 mg	30	5	...	58.40	23.10	Lipex 20 AD Zocor MK
8173E	Tablet 40 mg	30	5	...	81.58	23.10	Lipex 40 AD Zocor MK
8313 M	Tablet 80 mg	30	5	...	114.75	23.10	Lipex 80 AD Zocor MK

Adapted from Schedule of Pharmaceutical Benefits, May 2003 (ISSN 1037-3667)

The economic reviews and their subsequent evaluations are extremely thorough.³ It is in the company's interests to produce a comprehensive, accurate pharmacoeconomic evaluation in the first place, as, if it does not withstand scrutiny, or perhaps just contains budgetary impact analyses, the delay before recompilation of the data and resubmission (the company responsibility) may be extensive. The rationale for the PBAC evaluations is based on 'allocative efficiency', obtaining value for each unit of money spent by comparing health outcomes between alternative therapies.³

The main problems with the pharmacoeconomic data presented for review and evaluation have been described.⁶ The PBAC has started making public the positive recommendations arising from each meeting (www.health.gov.au/pbs/listing/pbacrec/index.htm) Other decisions are deemed 'commercial in confidence' and are currently not available. The types of PBAC recommendations, subsequent to the value for money analyses, may range from positive recommendation for listing at the requested or a lower price, recommendations for restrictions on prescribing or recommendations for rejection on clinical and/or cost considerations.¹

Case studies of specific products have been discussed, but this is very difficult and in many cases product names and actual issues can not be disclosed because of commercial concerns.⁴ This makes transparency in the process impossible. As for other expert committees within Australia, the PBAC membership is appointed by the Minister for Health and Ageing. At the end of 2000 the composition of both the PBAC and the ESC was changed. There was a lot of debate about this political interference and concerns about pharmaceutical company influence and potential impact for future drug costs and PBS listings.^{3, 7, 8}

There is always a risk, calculated or otherwise, in having such committees appointed by elected politicians. In April 2002 there were 593 drugs available as general benefits on the PBS, available in 1,461 forms and strengths (784 restricted, with 288 by authority only), as a total of

2,502 products/ brands. Section 100, expensive and/or special use drugs, encompassed 63 drugs as 197 products/ brands. In addition, Repatriation benefits covered 161 more drugs, as 419 products/ brands. The Health Insurance Commission (HIC) processes claims from pharmacists and manages statistical data about pharmaceuticals (www.hic.gov.au/statistics).

Australia's PBS has a system of copayments and 'extras', transferring some of the medicines costs to the consumer. The maximum copayment per item (generally one month supply of a chronic medication) for general beneficiaries was AUD\$23.10 as at June 2003, and for concessional beneficiaries (pensioners and concession card holders eg. full time students) was \$3.70. There is a safety net. Above \$708.40 total copayment expenditure in one calendar year for general and \$192.40 for concession beneficiaries, maximum copayments drop to \$3.70 and zero, respectively, for the rest of that year.

Australia has brand price premiums to encourage generic substitution. For these specified drugs, the maximum price the government pays for bioequivalent products is the price of the lowest generic brand.⁹ The consumer may still elect to purchase another brand, or the doctor may request 'not for substitution', but the price difference must be met by the consumer, in addition to the copayment. Therapeutic group premiums (reference based pricing) encourage prescribing of the most cost-effective agent in a therapeutic class. The price the government will pay is the lowest for any product in a specific therapeutic group, with the consumer paying any difference to obtain a different product in that group.

Patient co-payments continue to be a debated issue as a mechanism for containing costs. There are data to demonstrate that they have the most impact on those least likely to be able to afford them – the working poor and those with chronic disease.¹⁰ The cost to the Australian Government of the PBS in the financial year 2000-01 (from 1 July 2000 to 30 June 2001) was AUD\$4,160 million, a 19% increase over the previous year (\$3,490 million in 1999-00). In addition, patient

copayments amounted to \$744 million in 2000-01 and \$652 million in 1999-00. Of the government payment, it is estimated that manufacturers end up receiving 70%, pharmacists 22% and wholesalers 8%.

Responsible, viable medicines industry

Viability for the pharmaceutical industry is partly assured by the remuneration negotiated for products being listed on the PBS and partly by a series of incentives and taxation relief packages for research and development. Industry incentives are administered by the Commonwealth Department of Industry, Tourism and Resources.

There is a Pharmaceutical Industry Working Group to advise the Department. The Pharmaceuticals Partnerships Program has been developed recently from the Pharmaceuticals Action Agenda (www.industry.gov.au/pharmaceuticals).

The medicines industry is also a full partner in the quality use of medicines aspects of the National Medicines Policy, as part of their responsibility. Initiatives, such as Consumer Medicines Information (CMI), guidelines for development and readability of these and assessment of CMI as they are produced has largely been led by the industry, with other partners involved collaboratively.

The main manufacturer's organization, Medicines Australia, also has a Code of Conduct, specifying responsibility in areas of concern to the National Medicines Policy.

Quality use of medicines

Quality use of medicines involves consideration and selection of the best management options for a specific individual, including the option of no medicine, appropriate choice of a medicine when one is needed, and safe and effective use of that medicine (including monitoring of outcomes, minimising misuse, solving medication related problems).

More information about Australia's National Strategy for Quality Use of Medicines is available (www.health.gov.au/haf/nmp/quality.htm). In

1991, two major advisory committees about medicines were formed. The Australian Pharmaceutical Advisory Committee (APAC) is a representative council, with representatives from all partners interested in the National Medicines Policy (www.health.gov.au/haf/nmp/advisory/apac.htm).

Currently there are about 30 members, from a diverse range of organizations. This is a very influential body, meeting twice a year and resolving difficult issues around medicines in a collaborative way. Decisions around medicines policy taken in this forum are taken back to the parent organizations and groups for adoption and implementation. The APAC has provided an excellent voice at the representational level. The other advisory committee formed at this time was the Pharmaceutical Health and Rational use of Medicines (PHARM) Committee (www.health.gov.au/haf/nmp/advisory/pharm.htm).

This is a committee of 12 experts chosen for their expertise in the area of quality use of medicines from around Australia. This committee is free to be a true expert body as APAC contains all the representational issues. PHARM gives advice principally on the Quality Use of Medicines aspects of the National Medicines Policy, whereas APAC gives advice on the whole Policy.

All appointments to APAC and PHARM are by the Commonwealth Minister for Health and Ageing and both Committees directly report to the Minister. There is a national strategy on the Quality Use of Medicines and information about activities and initiatives can be accessed (www.health.gov.au/haf/nmp/quality.htm).

A website has also been specifically developed to interactively collate all the quality use of medicines projects around Australia (www.qummap.health.gov.au). Some of the achievements of APAC and PHARM over their first decade of operation in the Quality Use of Medicines arena have been described. See for example, (www.health.gov.au/haf/nmp/publications/pharm.htm). One such example is the successful development and implementation of medication management reviews in nursing homes as well as in home situations for people

at risk of medication misadventure. These services are now running successfully with pharmacists and general practitioners able to access resources and reimbursement.

Other successful initiatives to improve the use of medicines include the National Prescribing Service (www.nps.org.au). The National Prescribing Service commenced in 1998, with a budget of AUD\$3 million for establishment, with AUD\$6 million per annum for the first three years. Savings from the PBS were required to be demonstrated in order to achieve subsequent funds. The Service has been evaluated (search 'evaluation' on www.nps.org.au), and the budget was renewed based on these findings, to a level of AUD\$41.6 million over the next four years.

The National Prescribing Service offers an extensive programme to influence prescribing, including clinical self-reflection audit topics, academic detailing, prescribing practice review, newsletters, written information and education, satellite broadcasts and many other activities. The National Prescribing Service provides funds for Quality Use of Medicines facilitators all around Australia to run the programs at a disseminated level for prescribers.

What is to be learned and how can the system be improved?

Of course, the Australian system for medicines is not perfect. There are several negative as well as positive aspects which can be drawn out and which can be used to inform any process of change. Some advantages and problems are shown in Table 2. There are administrative efficiencies gained by a national system.¹¹ Everyone in Australia is covered by the one publicly funded reimbursement scheme for pharmaceuticals, the PBS, and payments to pharmacies are made

by one body, the Health Insurance Commission. This body can then also readily collate statistics about the prescription drugs dispensed in Australia. These in turn can be used to improve prescribing and to develop initiatives to improve the use of medicines in Australia (interlinking with the Quality Use of Medicines arm of Australia's National Medicines Policy).

Monitoring policy changes and effects of external influences (eg. pivotal clinical trials) can also then be evaluated at a population level.^{9, 12} For effective cost controls, it has been argued that the payer should also be the price negotiator.¹³ This is the case for pharmaceuticals in Australia. Australia also uses the expertise available in the country well. For example, there are only 19 million people, and therefore not too many pharmacoeconomists or experienced evaluators.

The national system focuses these individuals and draws them together to enable the expertise to be used optimally for the small country. It is a physically disseminated system and is not just 'controlled' from the capital city, Canberra. As the PBS is a national scheme, potential savings due to, for example, improved prescribing of very expensive drugs may be very large. These savings can be used to fund the intervention, for example academic detailing, which leads to such large savings.

The National Prescribing Service in Australia, which has been fully evaluated for such cost savings, is run in just such a manner. Savings can also be put towards reimbursement for professional services, for example for pharmacists (paying for professional activities designed to optimise medication use, rather than paying just for a drug product) or for general practitioners (to move away from the fee for service model).

TABLE 2 ADVANTAGES OF AND OPPORTUNITIES FOR THE AUSTRALIAN SYSTEM FOR PRESCRIPTION MEDICINES

FEATURE	COMMENTARY
ADVANTAGES National, publicly funded re- imbursement scheme	Everyone covered – equity and transparency in coverage. No need for separate schemes to cover different consumer groups, or for schemes such as ‘catastrophic’ drug coverages.
Price control and responsibility for payment reside in the same body	The Commonwealth Government is directly responsible for the costs of the drugs that are purchased as well as being the organization which negotiates the price (single purchasing body).
National expert committees	These are used well for all aspects of National Medicines Policy – from drug registration, to PBS listing, to ensuring optimal quality use of medicines. They make the most of the expertise around the country.
Formulary listing	Able to use and combine national expertise in order to make the best decisions for the public good.
Performing pharmacoeconomic analyses	Major responsibility for this is with the pharmaceutical companies – they have the incentive (national PBS listing).
Evaluation of pharmacoeconomic studies	May be done centrally or at a number of expert centres (non-industry) around Australia. The emphasis is on critical evaluation of submitted information rather than conducting the analyses from the start.
Implementation of cost containment strategies	Occur at a national level, consistent across the country (eg. generic substitution).
Use of ‘savings’	Any demonstration of ‘savings’ to the PBS budget can be used for other initiatives – eg. remuneration for pharmacist professional services (move reimbursement away from product); funding for the National Prescribing Service.
Economies of scale	Because the whole Australian public is covered, prescription drug purchasing is essentially occurring for 19 million people. Evaluations (clinical, economic) are occurring once, rather than being repeated for each province.
Administrative efficiencies	Pharmacies submit a claim to one reimbursement agency. No need for replication of multiple administration systems.
National drug use statistics	The system enables collation of dispensing data for products covered by the PBS. Should be possible to relatively easily transfer to electronic medication records.
PROBLEMS Lack of information to public about real costs of medicines	The Australian public and prescribers, in general do not have a concept of the real price of medicines they use. This could be made explicit to both consumers and prescribers.

A perspective on Australia's National Medicines Policy

Some of the 'extra' payments difficult for public to understand	Brand price premiums (generic pricing) and therapeutic group premiums (reference based pricing) can be difficult to explain. Consumer education efforts need to be
Some of the 'extra' payments difficult for public to understand	Brand price premiums (generic pricing) and therapeutic group premiums (reference based pricing) can be difficult to explain. Consumer education efforts need to be increased.
'Silo' savings	To fund new or extended services, savings must be demonstrated from the PBS budget, not from hospitals or other aspects of health care. Transparency of dollar savings across health care areas should be possible and health care savings from any sector re-distributed appropriately.
Lack of transparency	'Commercial in confidence' concerns mean that many decisions and discussions can not be made public. Barriers need to be identified and addressed.
Adverse impacts of changes	Any adverse impacts, for example from generic substitution or increasing copayments, will be across the whole population before being detected. Very close evaluation programmes, perhaps through pilot schemes, need to be established as a routine part of implementation of any changes, specifically to detect any adverse or beneficial effects of any planned changes.
Possibilities of political interference	Does the system have the ability to reject drugs based on poorly performed economic studies? Can politicians, who make the final decisions based on expert advice, be lobbied to influence additions or modifications to the PBS? These issues require further public discussion.

The disadvantages apparent in Australia's current system include that the consumer has no real idea about how much they are being subsidised. Internationally, prescribers have very little idea of costs of medicines and the same is true in Australia.¹⁴ This could be remedied by making the subsidised amount clear and transparent on every item, for example on prescribing software. As well as true costs being made transparent, the Australian system could make more information about decisions to list or not list a product on the PBS transparent.

Reasons for listing or not listing would help health professionals and consumers understand more of the issues. Information about prescription drug registration should also be transparent and much more freely available, especially the evaluations of the submitted clinical trials. The provision of information will also assist Australia's population in their participation in open and informed debate about which medicines

should be subsidised, what is a reasonable, affordable level of subsidy and difficult questions around the lack of subsidy for certain medicines which need to be faced.

There are also difficulties with a national system because of the extent of any adverse effects on essential medication use that may be caused by, for example, increases in copayments. They will affect many people before they can be identified!

There is also a current difficulty for funding new services, that savings to the PBS must be demonstrated, whereas many medication related interventions often cause savings to other parts of health care.

CONCLUSIONS

Australia has an integrated National Medicines Policy, developed collaboratively by all partners with an interest in how medicines are produced, made available to the public and actually used. The four arms of the

Policy all need to be functioning effectively in order to fulfil the goals of improving health outcomes for consumers. Medicines need to be of high quality, demonstrated efficacy and high safety (with appropriate feedback and resolution of safety issues arising after marketing).

These medicines need to be produced by a viable pharmaceutical industry, which has a responsibility for ensuring those medicines are marketed and used in the best ways possible. There needs to be quick access to new drugs offering significant benefits in terms of reduced mortality or morbidity as they are developed and these need to be made available in an equitable manner to the Australian public at a cost both they, and the community in general, can afford.

These three preceding factors will not be of any use if the medicine available is not used in the best way possible. Quality use of medicines initiatives in Australia are plentiful. There are many examples of policy implementation and program development and evaluation that point the way towards better use of medicines in the community and at the individual consumer level.

An integrated National Medicines Policy is important for all the partners in medicines. Many barriers are erected by a process which focuses merely on one aspect, for example a public system for reimbursement for prescription drugs. An integrated Policy has many 'wins' to negate these barriers, for example viability of the medicines industry does not totally rely on reimbursement for publicly subsidised medicine provision.

The big picture is important for Medicines Policy and, as in the case of Australia, can assist with structuring and the efficient functioning of the many components making up a national, coherent approach to medicines. There are always challenges and opportunities which need to be taken to improve any system and, in particular, explicit public discussion of issues and priorities is an essential component.

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