



Australian Government  
Department of Health and Ageing

# *National Medicines Policy*

2000

*National  
Medicines  
Policy*

2000

© Commonwealth of Australia 1999

ISBN 0 642 41568 4

This work is copyright. It may be reproduced in whole or part subject to the inclusion of an acknowledgment of the source and no commercial usage or sale. Reproduction for purposes other than those indicated above, require the written permission of the Commonwealth available through AusInfo. Requests and inquiries should be addressed to the Manager, Legislative Services, AusInfo, GPO Box 1920, Canberra ACT 2601.

For further information and other publications produced by the department, visit our website at [www.health.gov.au](http://www.health.gov.au), or call 1800 020 103.

Publication approval number: 2654

For additional copies of this document please fax your request to (02) 6289 7746 or visit the website at [www.nmp.health.gov.au/pdf/nmp2000.pdf](http://www.nmp.health.gov.au/pdf/nmp2000.pdf)

# NATIONAL MEDICINES POLICY

## A partnership for better health outcomes

Governments - Commonwealth, States and Territories - health educators, health practitioners, and other healthcare providers and suppliers, the medicines industry, healthcare consumers, and the media recognise the benefits of a National Medicines Policy and resolve to work together as partners to promote the objectives of the policy.

Each partner accepts that all must be engaged in a cooperative endeavour to bring about better health outcomes for all Australians, focusing especially on people's access to, and wise use of, medicines. The term "medicine" includes prescription and non-prescription medicines, including complementary healthcare products.

Each partner accepts the responsibility to contribute to the achievement of the objectives of the policy, drawing on their unique perspectives and abilities. These contributions will require co-ordination and integration with each other to ensure optimal outcomes.

## Objectives of the policy

In June 1996, the Council of Australian Governments agreed that systems for health and community services delivery should:

- provide quality care responsive to people's needs;
- provide incentives for preventive health and cost effective care;
- give better value for taxpayers' dollars;
- more clearly define roles and responsibilities; and
- retain the benefit of universal access to basic health services through Medicare.

In line with this agreement, the overall aim of the National Medicines Policy is to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved.

Based on the shift of emphasis from healthcare program inputs to quality health outcomes, the National Medicines Policy likewise focuses first on people's needs and brings individual partners' skills, experience and knowledge to bear on these central objectives:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

Each partner shares responsibility to various degrees for achieving each of these objectives, and all partners need to consider these central objectives in any relevant initiatives.

This Policy recognises the fundamental role consumers have in reaching these objectives, and there needs to be a commitment from all partners to ensuring consultation with consumer representatives when new arrangements are contemplated.

## **Access to medicines**

There are a number of aspects to providing access to medicines. There may be potential risks as well as benefits associated with the use of medicines, and before taking or prescribing a medicine the relative benefits and risks need to be considered. These risks, as well as the potential public health implications, are addressed through scheduling or other controls. These controls may require intervention by suitably qualified health practitioners to ensure appropriate use.

Cost should not constitute a substantial barrier to people's access to medicines they need. Therefore normal market mechanisms may be tempered in access arrangements, to increase the affordability of important medicines. For example, the Pharmaceutical Benefits Scheme (PBS) facilitates access to certain prescribed medicines by subsidising costs, and subsidies also occur when hospitals supply medicines to patients. Such subsidies are not costless, and the community as a whole must bear them.

However, access to medicines should support the rational use of those medicines. Users should be encouraged to understand the costs, benefits and risks of medicines, and wherever possible the public benefit of provision of medicines should be achieved through the regulated marketplace in which medicines are placed.

In the context of the ongoing development and release of new medicines which are often relatively expensive, it can be difficult to meet the community's expectations regarding subsidised access to all available treatments. Both the effectiveness and cost-effectiveness of the treatments need to be considered in making decisions about subsidisation.

In attempting to balance health needs and responsible fiscal discipline, the partners will need to address the following issues; that:

- financing and supply arrangements for medicines optimise health outcomes and represent value for money;
- all partners take adequate responsibility for achieving value for money;
- access to necessary medicines occurs at a cost the community as a whole can afford, particularly in the context of pressures such as the development of new high cost medicines and Australia's ageing population;
- access processes are made as simple and streamlined as possible, so that subsidisation of medicines is timely, mechanisms are understood, and unnecessary administrative barriers and expenses are avoided;
- financing arrangements for medicines avoid incentives for cost-shifting between levels of government or other funders, or other perverse incentives;
- efficient and effective distribution and supply networks (distributors, hospital, and retail) exist; and
- a fair distribution of costs and savings between the partners is achieved.

These commitments mainly require action by Governments (especially to avoid or minimise cost-shifting and to implement appropriate subsidy or reimbursement arrangements), but also involve partnership with other sectors.

## **Quality, safety, and efficacy of medicines**

All partners consider that the quality, safety and efficacy of medicines available in Australia should be equal to that of comparable countries. To this end:

- nationally standardised regulation of medicines should be managed through rational and transparent criteria and processes;
- regulation should ensure that appropriate practices are followed in the development, production, supply and disposal of medicines, and that any problems are met with a quick, effective and appropriate response;
- the level of regulation should be consistent with the potential benefits and risks for the community and based on appropriate risk-assessment processes;

- the pre-marketing assessment of medicines should aim towards both assurance of quality, safety, and efficacy, and timely availability;
- there should be an effective post-market monitoring system (for example, for adverse drug reactions), to ensure ongoing assessment of safety;
- regional and international harmonisation of regulatory requirements should be pursued vigorously to reduce duplication and unnecessary restrictions and to facilitate early availability of therapeutic advances; and
- a positive and co-operative relationship should be maintained between the regulators and the medicines industry, with effective models for co-regulation being used wherever appropriate.

Regulatory arrangements are primarily the responsibility of the Therapeutic Goods Administration, in co-operation with State and Territory Governments and with industry. These particular partners, together with health practitioners and consumers, need to undertake cooperative action to maintain an efficient, contemporary registration and scheduling process consistent with community interest and the principles of best practice.

## Quality use of medicines

The partners recognise that Australia has an established and well accepted national policy on the quality use of medicines.

The partners consider that all medicines should be used:

- judiciously - medicines, whether prescribed, recommended, and/or self-selected should be used only when appropriate, with non-medicinal alternatives considered as needed;
- appropriately - choosing the most appropriate medicine, taking into account factors such as the clinical condition being treated, the potential risks and benefits of treatment, dosage, length of treatment, and cost;
- safely - misuse, including overuse and underuse, should be minimised; and
- efficaciously - the medicines must achieve the goals of therapy by delivering beneficial changes in actual health outcomes.

To achieve quality use of medicines, people must be provided with the most appropriate treatment, and have the knowledge and skills to use medicines to their best effect. Health practitioners have a particularly important role to play in promoting the quality use of medicines, through good treatment choices, good communication with consumers, collaboration with other health practitioners, including across professional boundaries, the development and implementation of models of best practice, and maximising professional roles to provide optimal contribution from the various health practitioners.

To achieve optimum use of medicines:

- consumers and health practitioners should have timely access to accurate information and education about medicines and their use;
- public health and health education programs, and other programs relating to quality use of medicines (eg development and implementation of guidelines, implementation of schemes for the disposal of unwanted medicines) should be coordinated between the Commonwealth Government and State/Territory Governments as well as others in this partnership;
- industry and health practitioners should contribute through appropriate information, education and promotion activities; and
- issues relating to use of medicines should be reported accurately and responsibly by the media.

Quality use of medicines depends on committed teamwork between all members of the partnership on behalf of the Australian community. It follows that all members must be committed to ensuring exchange of relevant information between involved groups and members of the community to ensure they are able to make informed decisions.

## **A responsible and viable medicines industry in Australia**

It is clear that the first three objectives of the National Medicines Policy require the continued existence of a responsible and viable medicines industry in Australia. It is essential that industry policy and health policy be coordinated, providing a consistent and supportive environment for the industry, and appropriate returns for the research and development, manufacture, and supply of medicines.

International competitiveness will only be achieved if Australian industry can operate in a global environment. Thus regulatory partners should be committed to early achievement of harmonisation of standards and/or mutual recognition, and to the promotion of a strong export culture consistent with standards and ethics endorsed by the World Health Organization. Industry is likewise committed to these objectives, and recognises the need to be forward-looking and proactive. Intellectual property protection should be in line with international standards, and medical research and innovation supported.

To the extent possible, partners must recognise the primary position of the consumer. Industry must therefore be able to communicate directly and clearly with health practitioners and provide information to potential consumers about the nature and benefits of their products. They should be able to do so by means of educational materials, Consumer Medicine Information, and responsible advertising, where to do so will enhance the health outcomes of the Australian people.

## **Making the partnership work**

All partners need to enact their part of progressing the National Medicines Policy in a manner which is both cognisant and respectful of the interrelationships and expertise of other partners.

Different partners, or groups of partners, bear responsibility for the various outcomes, and to various degrees. In broad terms, however, it is recognised that the following have prime carriage of work to advance each of the four main agendas:

### ***Access to medicines -***

- Commonwealth Government, in relation to the Pharmaceutical Benefits Scheme, Repatriation Pharmaceutical Benefits Scheme, social welfare, product scheduling, etc;
- State Governments, in relation to subsidised hospital-based medicines access and that regulations controlling the retail supply of medicines;
- Private health insurance bodies;
- Health practitioners and retailers, in relation to recommending, prescribing, or providing particular medicines;
- Industry, in providing medicines in a timely fashion at reasonable cost;
- Partners in collaborative agreements to address specific barriers to access for identified groups, including Aboriginal and Torres Strait Islander peoples.

### ***Quality, safety and efficacy -***

- Governments, working collaboratively and consistently with a view to achieving a best practice regulatory system;
- Health practitioners, in relation to prescribing, supplying or administering medicines, and participating in clinical trials and post-marketing surveillance;
- Industry, by adhering to high research and development, manufacturing and regulatory standards;
- Consumers, in considering both the benefits and the risks of medicines.

### ***Quality use of medicines -***

- Consumer organisations and health practitioners, by providing patients/consumers with information and counselling to promote quality use of medicines;
- Health educators, by promoting these ideas in public education programs;
- Health practitioners, in the education of their peers and adoption of appropriate standards and models of practice;
- Regulatory agencies, by encouraging use of modern communication principles in provision of Consumer Medicine Information, label information, etc.;
- Industry, by ensuring truthful, balanced and understandable information is provided to health practitioners and consumers about medicines;
- Media, in relation to the responsible reporting of medicines issues;
- Consumers, by taking responsibility for good health outcomes;
- Government, by coordinating and funding efforts to promote quality use of medicines, including public information campaigns.

### ***A responsible and viable medicines industry -***

- Industry, by ensuring best and most efficient practices are followed, and by identifying further opportunities;
- Governments, by
  - promoting a sensible regulatory and reimbursement regime for medicines;
  - pursuing international harmonisation; and
  - ensuring a stable and conducive business environment for the industry;
- Consumers, through a recognition of the benefits of accessing quality medicines and information;
- Health practitioners, by working with industry in research and development and educational initiatives.

It is important that each of the parties identified above actively takes responsibility for achieving the objectives of the National Medicines Policy, in collaboration with the other partners, and that mechanisms are developed to assess progress against the objectives of the policy, and to hold parties accountable for progress in areas where they have an identified responsibility.

## **Challenges in integrating the objectives of the policy**

Each arm of the National Medicines Policy must coordinate with the other arms in pursuing its goals, and the partners should work to ensure that the policy integrates into other components of national health strategy.



This will help to ensure that medicines policy is developed and implemented in a rational and integrated way.

There can be challenges in integrating the objectives of the policy, and these need to be identified and addressed. Some links and tensions between the objectives are discussed below. These challenges can best be addressed through a partnership approach.

### ***Quality assurance and access -***

While quality assurance of medicines is necessary and desirable, the time and expense involved in evaluating medicines in order to be marketed can be a barrier to access. A medicine is not freely available until it has marketing approval, so any delays in the process can mean delays in access. The process is costly, and these costs are reflected in the eventual price of the medicine to the community. In addition, companies may not submit a product for evaluation if the likely market for the medicine in Australia is not large or profitable enough to recoup costs, which can present a barrier to access to medicines needed for unusual conditions, including conditions generally found only in particular sections of the population (eg Aboriginal and Torres Strait Islander communities).

Medicines evaluation in itself can put pressures on the funding system for access, as once a medicine has been approved for marketing in Australia, there is an expectation that people should have assistance in paying for the medicine, whether or not cost and effectiveness compared with other available treatments have been demonstrated.

### ***Quality assurance and quality use of medicines -***

Part of the quality assurance process involves assessing the evidence for the efficacy and effectiveness of a medicine for specified conditions or indications, and how a medicine should be used (dosage, length of treatment, etc). This helps to ensure that the necessary information is available on which to attain quality use of medicines. The next step is to ensure that health practitioners and consumers have access to and use this information.

### ***Quality assurance and the maintenance of a viable medicines industry -***

The policy recognises the importance of the medicines industry and the significant contribution it makes to both health outcomes and economic development in Australia.

The quality assurance process means that the medicines industry is faced with financial and time costs in bringing a product onto the market in Australia. On the other hand, the process helps to create confidence in and acceptance of Australian medicines on overseas markets, helping to maintain a viable medicines industry and earn export income for Australia. International harmonisation of some aspects of the regulatory process assists the medicines industry by rationalising the demands placed on it for evidence in other markets.

The existence of a local industry can assist the quality assurance process through improved opportunities for liaison between regulators, healthcare providers and industry, and involvement of the medicines industry in the research and development of new and improved medicines.

### ***Access and quality use of medicines -***

Effective mechanisms for access to medicines can assist quality use of medicines, by reducing cost barriers to use of the most appropriate treatment, but easy access can also work against quality use of medicines. For example, people may stock up on unnecessary medicines simply because they are available free or at low cost, which increases the risk of problems such as people using out of date medicines, or young children finding and taking stored medicines. In the absence of information about price, a doctor may prescribe unnecessarily expensive medicines in situations where there are cheaper alternatives which work just as well for that patient.

By reducing overuse and inappropriate use of medicines, implementing the principles of quality use can help to ease pressure on the costs of providing access to medicines, making it more feasible to ensure good access in the longer term.

Potential underuse also needs to be addressed, despite Government concerns about the costs involved in the use of more expensive, newer medicines.

In particular, there are substantial access barriers and evidence of underuse of medicines by Aboriginal and Torres Strait Islander peoples. Partnership commitments to address the issues (eg Framework Agreements on Aboriginal and Torres Strait Islander health) are required.

Alternatively, the appropriate use of medicines may on occasion mean higher utilisation and thus more expenditure on medicines.

### ***Access and a viable medicines industry -***

Subsidisation schemes which ensure access also ensure that any medicines eligible for subsidy have a good opportunity for achieving a market share in Australia. On the other hand, the price control exerted by the PBS can limit the profitability of the medicines industry.

A locally based industry maximises the opportunities for reliable and cost-effective supply of medicines in Australia. A viable medicines industry can assist access by ensuring the availability of essential medicines and by facilitating the availability of niche market medicines, wherever possible.

### ***Quality use of medicines and a viable medicines industry -***

Efforts to ensure quality use of medicines can have various effects on industry. For some diseases where medicines appear to be underused (eg preventive asthma medicines), quality use can in fact increase sales and therefore company profitability. However, in some cases, reducing overuse of certain medicines would reduce their sales.

Product promotion which aims to achieve maximum market share can lead to irrational use. The information needs to be factual and balanced for the practitioner and the consumer.

The provision of good information about use of medicines should assist quality use and reduce adverse events, which may in turn assist the industry by reducing company liability. The industry has recognised the benefits of good information about medicines through the provision of Consumer Medicine Information.

A viable medicines industry is an important player in assisting quality use of medicines, by supporting research and development, continuing professional education, ethical promotion, and the availability of appropriate information about medicines for consumers and health practitioners.