



The National Strategy for Quality Use of Medicines

PLAIN ENGLISH EDITION

The National Strategy
for
Quality Use of Medicines

Plain English Edition

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Introduction

Quality Use of Medicines (QUM) is one of the central objectives of Australia's National Medicines Policy. This document describes Australia's National Strategy for QUM. It sets out the approach and principles necessary to achieve QUM in Australia. The QUM Strategic Action Plan, which is derived from the National Strategy and revised every two years, is a separate document. Together, they are intended to assist the QUM partners—healthcare consumers, health practitioners and educators, healthcare facilities, the medicines industries, the media, healthcare funders and purchasers, and governments—in becoming more aware of the QUM policy framework and approach, and enabling them to integrate their own activities with the National Strategy.

Definition of Quality Use of Medicines

Quality Use of Medicines means:

- *Selecting management options wisely by:*
 - considering the place of medicines in treating illness and maintaining health, and
 - recognising that there may be better ways than medicine to manage many disorders.
- *Choosing suitable medicines if a medicine is considered necessary so that the best available option is selected by taking into account:*
 - the individual
 - the clinical condition
 - risks and benefits
 - dosage and length of treatment
 - any co-existing conditions
 - other therapies
 - monitoring considerations
 - costs for the individual, the community and the health system as a whole.
- *Using medicines safely and effectively to get the best possible results by:*
 - monitoring outcomes,
 - minimising misuse, over-use and under-use, and
 - improving people's ability to solve problems related to medication, such as negative effects or managing multiple medications.

This definition of QUM applies equally to decisions about medication use by individuals and decisions that affect the health of the population.

Quality Use of Medicines and the National Medicines Policy

Stimulated by the World Health Organization (WHO), countries around the world are implementing national medicinal drug policies to ensure the availability of essential, affordable drugs of acceptable quality, safety and efficacy. Australia began to develop aspects of the National Medicines Policy as early as the 1950s. By the 1990s a comprehensive policy was in place, and in December 1999, a formal policy document entitled *Australia's National Medicines Policy* was launched.

The National Medicines Policy (DHAC 1999) aims 'to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved for Australians'. It has four 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.

The National Strategy for QUM is not an isolated strategy. It sits firmly within the framework of the National Medicines Policy (figure 1). The National Strategy acknowledges that the four objectives of the National Medicines Policy are interdependent and that this quality must be recognised and fostered in order to achieve the goal of the National Medicines Policy. For example, it is not possible to have QUM if people cannot afford the medicines they need. Nor is it possible to have QUM if the available medicines are not safe or efficacious, just as it is not sensible to have high quality, efficacious medicines unless they are used appropriately. This interdependence means that activities both within and across the objectives of the National Medicines Policy must be integrated if both the policy and strategy are to continue to develop and be implemented successfully.

Figure 1: Australia's National Medicines Policy

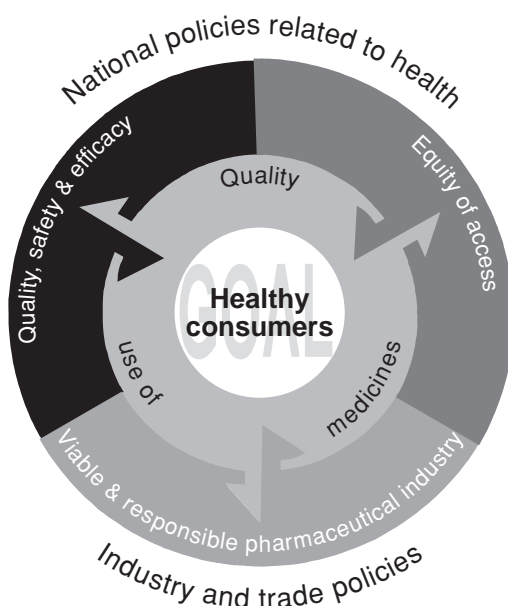


Figure 1 illustrates the interdependence of the four components of Australia's National Medicines Policy. At the centre is the policy goal: to optimise health outcomes. It is encapsulated by the QUM component of the policy, which supports the goal. Like a jigsaw puzzle, the QUM component locks into the other three components of the policy that are essential in enabling and supporting QUM: quality, safety and efficacy; equity of access; and a viable pharmaceutical industry. Figure 1 also depicts the National Medicines Policy in the wider context of national policies to demonstrate that public policy on medicines must be integrated with broader health and trade policies.

Appendix 1 provides a list of the committees and agencies with major responsibilities for the various components of the National Medicines Policy. Appendix 2 provides more detailed information about them.

National Strategy for Quality Use of Medicines

The National Strategy for QUM has been developed to address challenges and barriers to realising all the benefits of QUM and integrating it with the other arms of the National Medicines Policy. The strategy builds on and reaffirms much of the original QUM policy that was first produced in 1992 (DHHCS 1992). It has replaced the original policy in recognition of the National Medicines Policy as the overarching policy framework for medicines in Australia.

The National Strategy details the range of partnerships and the breadth of activity required to achieve its specified goals and objectives. It is envisaged that many organisations and groups will find the strategy and the QUM Strategic Action Plan useful in providing a framework for coordinating and guiding the development and implementation of health policies and programs that affect the QUM.

Goal

The goal of the National Strategy for QUM is to make the best possible use of medicines to improve health outcomes for all Australians.

This recognises that many people maintain their health without using medicines, while for others, medicines play an important role in maintaining health, preventing illness and curing disease.

The term ‘medicine’ includes prescription, non-prescription and complementary medicines.

Objectives

The five objectives of the National Strategy are to:

- improve QUM by healthcare consumers;
- improve QUM by health practitioners, healthcare providers and health educators;
- gain the commitment of the medicines industry (including manufacturers and distributors) to QUM;

- gain the commitment of governments to QUM; and
- improve the commitment of healthcare consumers; health practitioners and educators; the medicines industries; the media; healthcare facilities, funders and purchasers, and governments—commonwealth, state and territory—to working in partnership to achieve QUM.

Principles

The five principles underlying the National Strategy were developed in consultation with all partners and recognise the problems Australia currently faces in achieving QUM. They are:

- *The primacy of consumers*

The National Strategy recognises both the central role consumers play in attaining QUM and the wisdom of their experience. Consumers must be involved in all aspects of the National Strategy.

- *Partnership*

Active and respectful partnerships are essential to achieving QUM in Australia.

- *Consultative, collaborative, multi-disciplinary activity*

To attain QUM, activities must be consultative, collaborative and multi-disciplinary. Therefore, key partners must be involved at all stages in designing, implementing and evaluating QUM programs. At the local level, the value of the healthcare team in achieving QUM needs to be promoted and consumers recognised as active members.

- *Support for existing activity*

Wherever possible, initiatives within and across all groups need to be stimulated and supported, and support given to existing groups that are already developing initiatives. Actions taken to improve QUM should heed the ethical and legal rights, obligations and responsibilities of all partners.

- *Systems-based approaches*

To achieve QUM it is necessary to adopt systems-based approaches that will:

- develop behaviours that support QUM; and
- create a supportive environment that encourages QUM.

Multiple activities and strategies are needed to raise awareness about issues related to QUM. Attitudes, knowledge, skills and behaviours that support QUM need to be developed and maintained. We also need to inspire community, organisational, legal and political efforts to create an environment that supports QUM.

Any undertaking related to QUM should reflect these five principles.

Key partners

The activities of many groups influence QUM. Partnership and cooperation between these groups, and respect for all of them, are central to the National Strategy. The key partners in developing and implementing initiatives to achieve QUM are:

- those who take or consider taking medicines;
- those who prescribe, provide and monitor the use of medicines;
- those who assist people in learning more about health issues and healthcare through information, education and discussion;
- those who provide health services within hospital and community settings;
- those who develop, make, market, distribute and sell medicines;
- those who produce, report, publish and broadcast information about medicines and health matters;
- those in both the public and private sectors who fund and/or purchase the range of health services within which medicines play an important part; and
- the governments who, acting in the public interest, assess and register medicines, monitor their safety and provide equity of access to them.

This requires the involvement of:

- healthcare consumers, their carers, and the general community;
- health practitioners and health educators;
- health and aged-care facilities;
- medicines industries;
- media;
- healthcare funders and purchasers; and
- Commonwealth, State, Territory and local governments.

All partners have their part to play in achieving QUM, with the different partners bearing their responsibilities for QUM in different ways (figure 2).

Figure 2: Responsibilities for quality use of medicines

All partners are responsible for:

- improving medication use by recognising when and where problems exist, identifying factors that contribute to those problems, initiating interventions to improve medication use, and evaluating outcomes;
- enhancing understanding of the risk and benefits associated with the use of all medicines;
- fostering informed debate about the role of medicines in health care; and
- working in partnership to achieve quality use of medicines (QUM).

Health care consumers are responsible for:

- asking for and utilising objective information, resources and services to make decisions and take actions that enable medicines, when they are required, to be chosen and used wisely;
- becoming more aware of the risks and benefits of medicines, the possibility of non-drug options and the importance of a healthy life-style;
- developing skills and confidence to use medicines appropriately and seeking help to solve problems when they arise; and
- becoming more aware of the place of medicines in the broader context of health services and society.

Health practitioners and educators are responsible for:

- assisting people in making informed decisions and learning more about health issues and health care through information, education and discussion;
- becoming more aware of the risks and benefits of medicines, the possibility of non-drug options and the importance of a healthy life-style;
- utilising objective information, resources and services to make decisions and take actions that enable medicines, when required, to be chosen and used wisely;
- continually developing knowledge and skills to use medicines appropriately; and
- becoming more aware of the place of medicines within society.

Health and aged-care facilities are responsible for:

- providing facilities, systems, training opportunities and structures that support staff, health practitioners and consumers in using medicines wisely and that avoid medication errors.

Medicines industries are responsible for:

- continuing to develop safe and effective products to prevent, treat and cure illness or maintain health;
- marketing and promoting products in a way that facilitates quality of use;
- providing good quality, accurate, balanced information and education services that are conducive to QUM; and
- discouraging information and education activities that are not conducive to QUM.

The media are responsible for:

- ethical and responsible reporting on health care issues;
- reporting on medicines accurately and attempting to have errors corrected if they occur;
- being aware of the variety of available information sources on medicines and the limitations of each source;
- being aware of the impact of media reports on the use of medicines in the community;
- being aware of issues relevant to the broad context of medicines use, including risks of medicine use, non-drug alternatives and the cost of medicine use to individuals and society; and
- encouraging dissemination of messages that enhance the quality of medication use.

Health care funders and purchasers are responsible for:

- funding or purchasing services that support QUM; and
- providing appropriate funding mechanisms that give consumers and health practitioners incentives to support QUM.

Governments, their agencies and committees are responsible for:

- developing and implementing the National Strategy for QUM;
- coordinating relevant government programs; and
- investigating and developing appropriate structures, funding mechanisms, legislation and environments that support QUM.

Building blocks

The six building blocks that support QUM are based on evidence and expert opinion about interventions, regulatory efforts and programs to improve medication use. They are:

- policy development and implementation;
- facilitation and coordination of QUM initiatives;
- provision of objective information and assurance of ethical promotion of medicines;
- education and training;
- provision of services and appropriate interventions; and
- strategic research, evaluation and routine data collection.

According to evidence and experience in implementing QUM activities in Australia over the past ten years, these building blocks are necessary in any QUM endeavour. They apply equally to individual practitioners and organisations, community projects, and state and national programs. For example, health practitioner practices and health facilities require:

- policies and protocols that support QUM;
- ways to advance and coordinate activities both within their organisation or practice and with other health professionals and organisations;
- access to information that supports best practice;
- access to education and training that supports best practice;
- the ability to access or provide services and interventions that support QUM; and
- routine evaluation of practices to ensure QUM is being achieved.

Similarly, in any broader community-based, state or national program, the building blocks must underpin activities if they are to deliver QUM. In addition, where appropriate, activities and initiatives must be coordinated with those implemented in the other arms of the National Medicines Policy to ensure an integrated approach to achieving its goal.

The values and ideas on which each of the building blocks is based should inform any QUM endeavour. They are discussed below.

- **Policy development and implementation**

The existence of formal policy and strategy documents are seen as a measure of the commitment of governments and organisations to the National Medicines Policy and QUM. Policy and strategy documents also provide a guide for action to achieve the overall goal.

The National Strategy is an evolving document. It requires constant reflection and revision based on experience and experiment. It needs to be supported by suitable policies or strategic plans within professions, communities, institutions and state and territory governments. QUM principles need to be incorporated into other health-related policies and legislation at Commonwealth, State and Territory levels, and their adoption monitored.

- **Facilitation and coordination**

QUM is founded on the close involvement of groups that set professional standards of practice and understand the needs and concerns of community groups.

A principle of the approach that underpins the National Strategy is to stimulate and support initiatives within local communities or professional and consumer groups, and to support existing groups already developing initiatives. For this approach to succeed, we need mechanisms that facilitate, coordinate and support initiatives at state, regional and local levels in ways that honour this principle.

- **Objective information and ethical promotion**

To make informed decisions, all partners need objective information based on high-quality data. This information should be:

- balanced and accurate;
- informed by evidence and based on agreed standards;
- available in a timely manner;
- accessible and understandable by users;
- provided in a variety of forms suitable for users;
- independently sourced and free of any advertising;
- relevant to the wants and needs of users;
- conscious of the heterogeneity and diversity of the Australian community, including differences across culture, health beliefs, health literacy, skills, education, language, geographic isolation, health status, access to information technology, and socio-economic status;

- evaluated for its usefulness, acceptability and effectiveness; and
- include user groups in its development.

The National Strategy endorses the ethical criteria for promotion of medicines developed by the WHO, which urges each country to:

...develop its own appropriate measures to ensure medicinal drug promotion supports the aim of improving healthcare through the rational use of drugs. (WHO 1988)

- **Education and training**

Appropriate education and training provides the prerequisite knowledge and skills to support QUM. It should occur within a QUM framework as this allows the role of medicines in health to be discussed. Education is equally important for the general public and health practitioners. In developing educational resources and programs, the heterogeneity and diversity of the Australian community must be recognised, including differences across cultures, health beliefs, health literacy, skills, education, language, geographic isolation, health status, access to information technology, and socio-economic status.

- **Services and interventions**

We need to develop effective QUM services and interventions that:

- contribute to better quality care and health outcomes;
- support health professionals and consumers in their decision-making and actions; and
- recognise the heterogeneity and diversity of the Australian community.

They should also recognise that there are certain groups of consumers at greater risk of medication misadventure and on whom the impact of poor medication use is greater. Services for those at high risk of medication misadventure should be given priority.

- **Strategic research, evaluation and routine data collection**

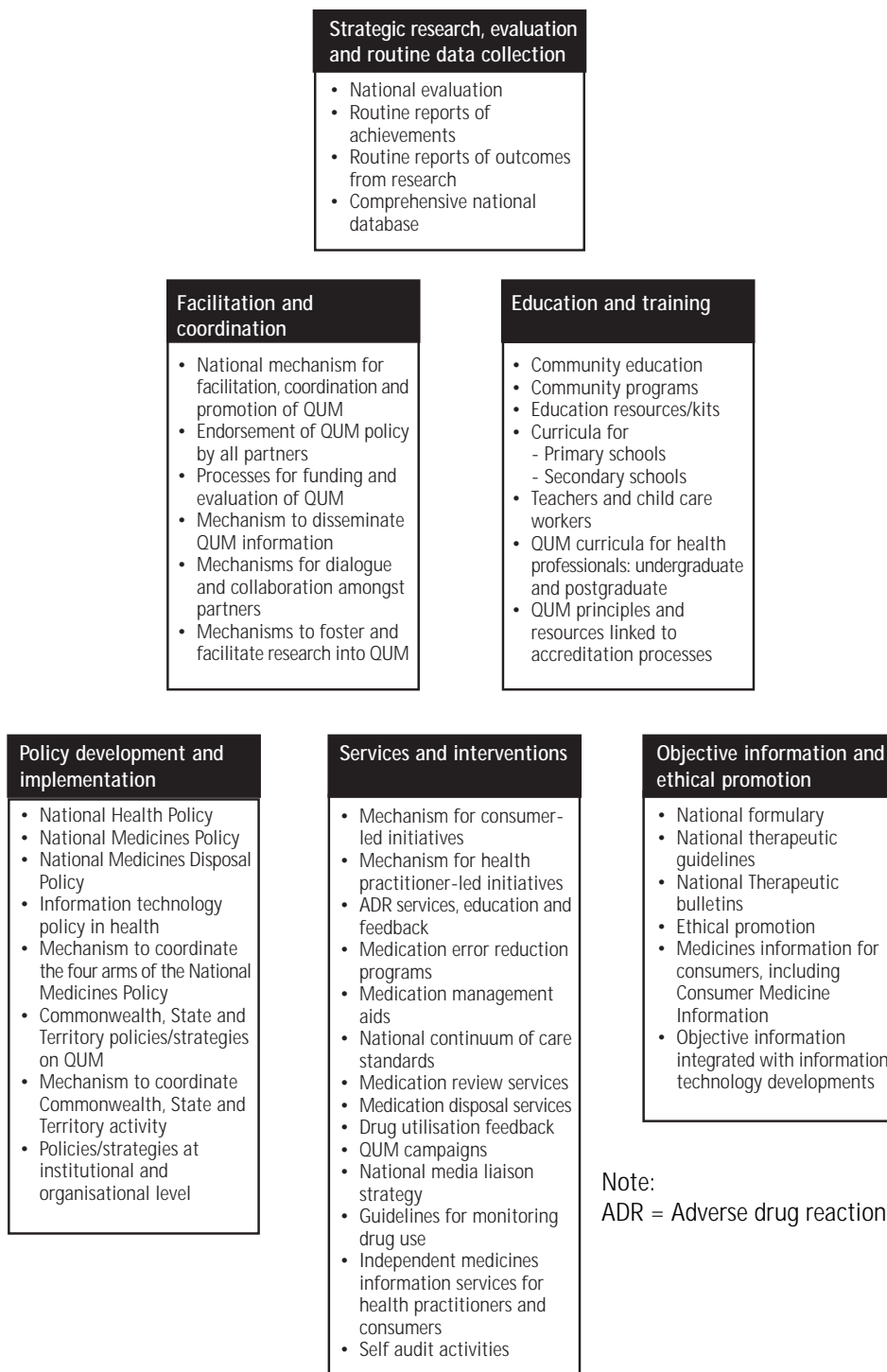
Strategic research is required at all levels to support the development of QUM initiatives. All QUM endeavours require evaluation, whether implemented locally, regionally or on a state-wide or national basis. Evaluation should sit within a quality improvement cycle, with the results used to refine and improve practice. Routine datasets must be established to assist in evaluation, including a comprehensive pharmacoepidemiological database that is patient-linked and contains information on medication use by age, gender and reason for use.

Specific resources and initiatives

These building blocks may consist of different resources or initiatives at local, community, regional, state and national levels. Figure 3 lists specific initiatives and resources considered essential to the National Strategy. Some have been developed; others need to be. There is also need to continually analyse contemporary issues and contexts in new ways and address them with suitable initiatives and resources. Experience in implementing QUM suggests that the approach for developing such initiatives includes:

- gathering evidence about the nature of the problem using reviews, existing evidence or sponsored research where no Australian data exist;
- gathering evidence about effective interventions;
- undertaking larger implementation trials of effective interventions;
- facilitating implementation of successful interventions; and
- evaluation.

Figure 3: Resources and initiatives underpinning the QUM building blocks



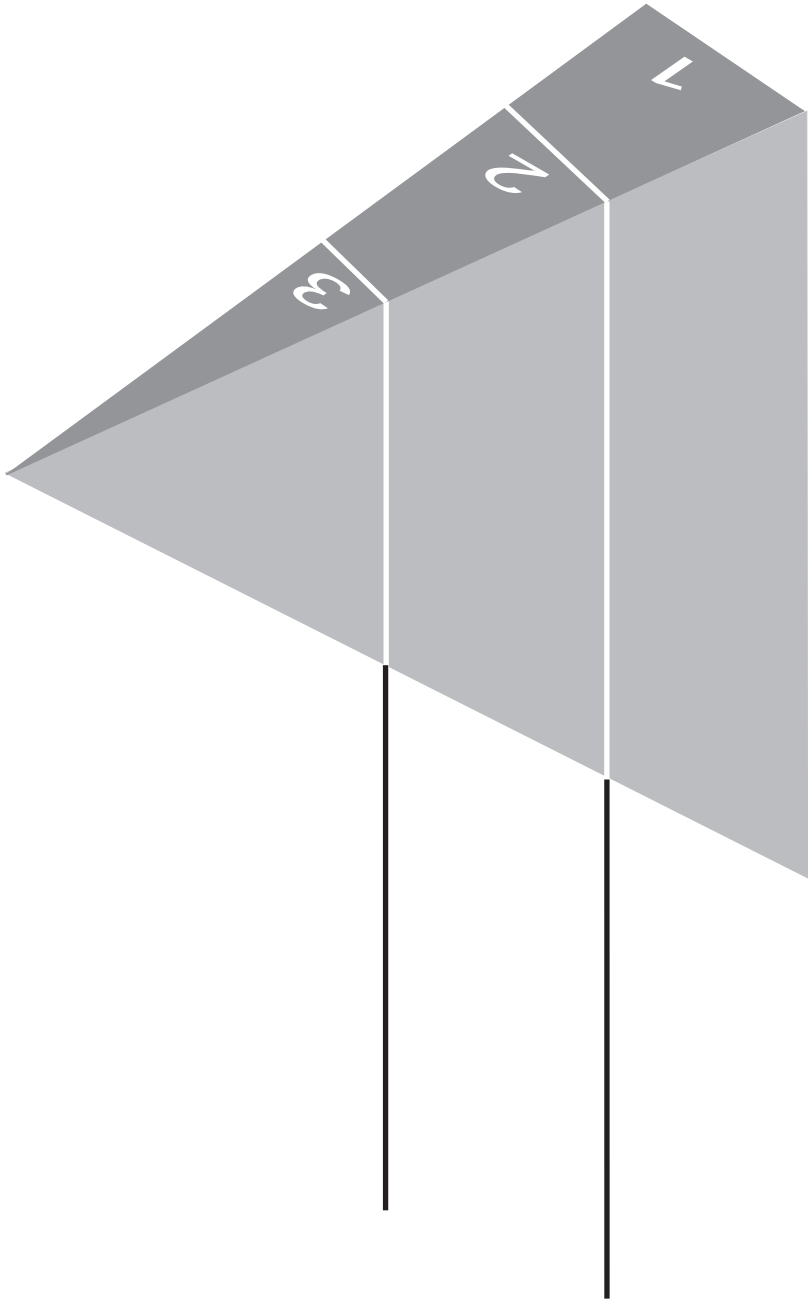
Conceptual framework

The conceptual framework describes the approach for implementing strategies to achieve QUM. It uses principles derived from the education, behaviour change, community development, health promotion, public health and social advocacy literature.

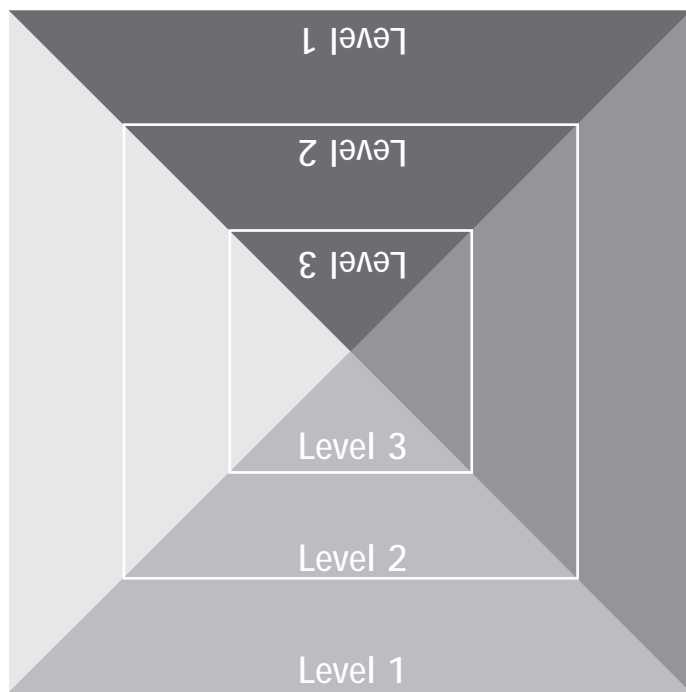
The framework recognises the need to take various perspectives—individual, community development and public health—in planning, implementing and evaluating initiatives to improve use of medicines. This has also been described as a multi-strategic, multi-level, systems approach that:

- involves all groups whose activities influence QUM;
- includes all stages of learning that support and maintain QUM, including the development of awareness, knowledge, skills, behaviour and motivation; and
- addresses all settings within which problems arise and decisions affecting QUM are made.

Such an approach is necessary because individuals and organisations will be at different levels of preparedness to take appropriate actions to achieve and maintain QUM. The different levels are described in figure 4, which depicts the QUM framework as a pyramid.



Each face of the pyramid represents a group of key partners, as shown in figure 5.



The strategies at each level (figure 6) need to be implemented across the range of settings in which problems arise and decisions are made. These settings are:

- individuals and communities
 - individual, inter-personal (e.g. health practitioner–patient interaction);
 - group and community (e.g. self help and community groups, existing social networks, local health services);
 - organisations (e.g. professional organisations, healthcare advocacy groups);
- structures and systems
 - regional (e.g. regional health systems);
 - Commonwealth, State, Territory and local government (e.g. health policy, systems wide implementation, legislative and structural change);
 - international (international trade agreements, WHO policies and programs, international health agreements).



Together, figures 4–6 show how this complex and dynamic framework creates considerable potential for synergies when strategies are implemented across all levels. The implication is that to achieve QUM, multiple strategies must be implemented simultaneously on all levels and involving all groups. If one group is left out of the process, the inter-relationships suffer and outcomes may be compromised. Thus the framework stresses the need for partnership between all the groups represented in figure 5. It also recognises that while strategies need to be developed for individual groups or partners, as a whole, multi-disciplinary approaches are required to achieve and maintain QUM.

Evaluation strategy

A comprehensive evaluation strategy mirrors the conceptual framework for implementing the National Strategy. In keeping with the notion that implementing the National Strategy will initiate change at a number of levels, the evaluation strategy includes evaluation mechanisms at the community (Sansom *et. al.* 1996; Baker *et. al.* 1998), institutional (NSWTAG 1997, 1998) and national (DHS 1995) levels (figure 7). Thus national evaluation is designed to provide an overview of progress towards QUM in Australia resulting from the combination of initiatives implemented by many groups. It uses indicators that:

- provide quantitative data on the implementation of initiatives and their immediate effects, as measured by changes in attitudes, knowledge, skills, and behaviour (DHS 1995);
- determine progress made towards the strategy's goal, as measured by changes in health outcomes associated with medication use; and
- can be used at the community (Sansom *et. al.* 1996; Baker *et. al.* 1998) and institutional (NSWTAG 1997, 1998) levels as part of a quality improvement program around service delivery.

Other evaluation components have been designed for different elements of the National Strategy:

- ongoing programs have their own evaluation component to facilitate and inform future program development;
- research projects relevant to QUM are assessed to identify successful projects and move towards implementing sustainable national and local programs; and
- a qualitative analysis has been designed to enhance understanding of the successful processes surrounding strategy development and implementation.

Figure 7: QUM evaluation strategy



This sophisticated and comprehensive approach provides routine monitoring of the implementation and effect of the QUM National Strategy, with the results informing future strategy planning and development.

Conclusion

Initiatives promoting QUM, supported by other initiatives implemented within the National Medicines Policy framework, have been remarkably successful. For example, among other things, they have resulted in better use of non-steroidal anti-inflammatory drugs and antibiotics. Importantly, this has led to improved health outcomes, with reductions observed in hospitalisations and deaths associated with the adverse effects of these medicines. However, despite these improvements, problems with medication use are still significant in Australia, with estimates suggesting 80,000 hospital admissions per annum are associated with medication-related problems, many older people at significant risk of medication misadventure, and emerging and increasing antibiotic resistance. There is much to be done.

The National Strategy for QUM describes the principles, building blocks and approach that will lead to better health outcomes for Australians. It makes a significant contribution to the overall workings of the National Medicines Policy. The implementation and evaluation of the National Strategy for QUM will yield substantial benefits in healthcare services and the wider community through better health outcomes, better medicine use, increased national productivity and quality of life. It will be on these end points that the success of the National Strategy will be judged.

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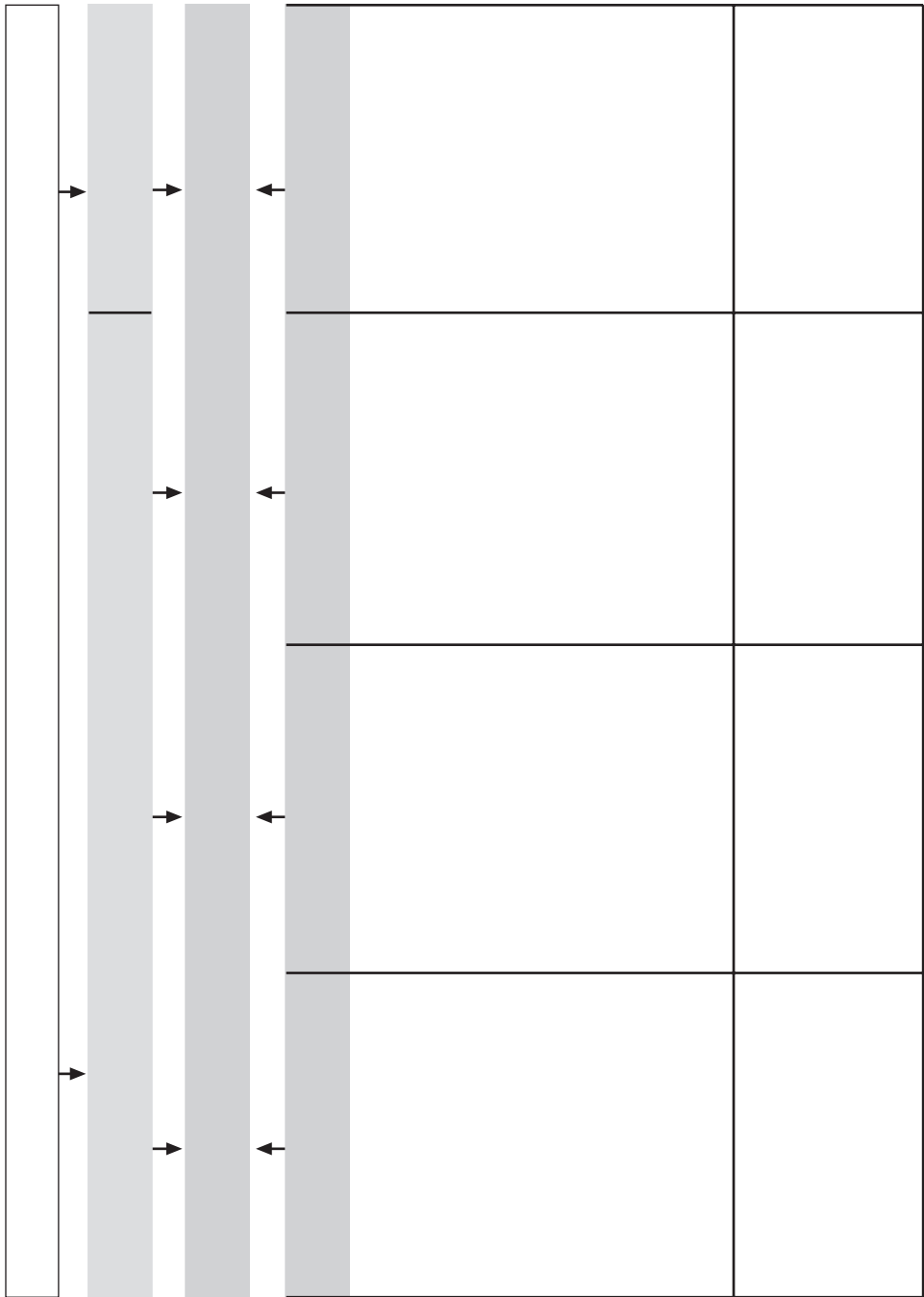
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Appendixes

1 Committees and agencies with major responsibilities for the various components of the National Medicines Policy

Figure 8 depicts the committees and agencies with major responsibilities for the various components of the National Medicines Policy. This listing is not intended to be exhaustive. It seeks to identify major committees and agencies only. It is acknowledged that the responsibilities and activities of the committees may cover more than one component of the policy, but for simplicity the committees have been listed by the component of the policy under which they were established or for which they bear primary responsibility.

It is acknowledged that healthcare practitioners, professional organisations, consumer agencies, registering authorities and the pharmaceutical industry also have responsibilities under the National Medicines Policy. It is also acknowledged that there are many other players that are not listed and whose primary responsibility is not to the National Medicines Policy, but whose responsibilities and subsequent activities have a major impact on the National Medicines Policy. Examples include the Department of Finance and Administration, the Australian Taxation Office and the Australian Competition and Consumer Commission.



(Source: adapted from an unpublished diagram by Dr Ken Harvey, School of Public Health, Latrobe University, 2000)

2 National Medicines Policy and Quality Use of Medicines Structures

Pharmaceutical Health And Rational use of Medicines Committee

The Pharmaceutical Health And Rational use of Medicines (PHARM) Committee is a multidisciplinary committee that provides expert advice to the Minister for Health and Ageing and the Department of Health and Ageing on the Quality Use of Medicines (QUM).

The PHARM Committee is appointed by the Minister for Health and Ageing. The Committee has 12 members who are experts drawn from the areas of general practice, pharmacy, nursing, pharmaceutical industry, consumer issues, health education and behavioural science.

The Committee's terms of reference are to:

- provide advice on quality use of medicines to Government and to other bodies;
- promote and review the implementation of the National Strategy for Quality Use of Medicines;
- prioritise and encourage quality use of medicines educational activities in collaboration with health professionals, industry, consumers and Government;
- recommend proposals for funding under the Quality Use of Medicines Evaluation Program (QUMEP);
- evaluate the outcomes of completed QUMEP funded activities; and
- consider quality use of medicines matters referred by other relevant committees including the Pharmaceutical Benefits Advisory Committee and the Australian Pharmaceutical Advisory Council.

Australian Pharmaceutical Advisory Council

The Australian Pharmaceutical Advisory Council (APAC) provides the primary forum for the engagement of all stakeholders in discussion, debate and resolution of issues arising from the application of the National Medicines Policy.

The structure and members of the Council reflect this role. Its members are the organisations and entities that have a major stake in the application and implementation of the policy.

APAC's mission is:

Through a partnership approach, promote, influence and assist in the implementation of the National Medicines Policy in Australia.

This involves:

- advising and making recommendations to the Minister on identified priority issues;
- identifying specific issues where success is dependent on cooperation between specific stakeholders;
- monitoring outcomes; and
- evaluating effectiveness.

National Prescribing Service

The National Prescribing Service (NPS) is a non-profit, incorporated organisation, independent of government and the pharmaceutical industry. The NPS works in partnership with health professionals, government, industry and consumers, all of whom are represented in its membership. The NPS:

- works with others to provide nationally coordinated prescribing initiatives;
- provides independent information about medicines to prescribers and consumers;
- delivers messages about drug therapy to prescribers using strategies such as:
 - prescription analysis and feedback
 - peer review
 - self-assessment of prescribing behaviour
 - academic detailing
- encourages and supports cross-discipline and cross-sector collaborations that promote quality use of medicines;
- offers incentives that support quality prescribing in Australia; and
- undertakes ongoing evaluation of its strategies.

Pharmaceutical Benefits Advisory Committee

The Pharmaceutical Benefits Advisory Committee (PBAC) is an independent statutory body established on 12 May 1954 under section 101 of the *National Health Act 1953* to make recommendations and give advice to the Minister about which drugs and

medicinal preparations should be made available as pharmaceutical benefits. No new drug may be made available as a pharmaceutical benefit unless the PBAC has so recommended.

The PBAC is required by the Act to consider the effectiveness and cost of a proposed benefit compared to alternative therapies. In making its recommendations, the committee, on the basis of community usage, recommends maximum quantities and repeats. It may also recommend restrictions as to the indications where PBS subsidy is available. When recommending listings, the Committee provides advice to the Pharmaceutical Benefits Pricing Authority (PBPA) regarding comparison with alternatives or their cost effectiveness.

Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) is a division of the Commonwealth Department of Health and Ageing and is responsible for administering the provisions of the Therapeutic Goods Act. The Therapeutic Goods Act, Regulations and Orders set out the requirements for inclusion of therapeutic goods in the Australian Register of Therapeutic Goods, including advertising, labelling, product appearance and appeal guidelines.

The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard. At the same time the TGA aims to ensure that the Australian community has access, within a reasonable time, to therapeutic advances. Overall control of the supply of therapeutic goods is exercised through three main processes:

- pre-market assessment;
- licensing of manufacturers; and
- post-market vigilance.

Contact information

Further information about QUM can be obtained from the following sources:

- Australian Pharmaceutical Advisory Council:
apac@health.gov.au
- National Medicines Policy Section, Department of Health and Ageing:
Telephone: (02) 6289 8023
- Pharmaceutical Health And Rational use of Medicines Committee:
pharm@health.gov.au
- Website:
<http://www.health.gov.au/pbs/natmedpol.htm>