Towards a New Zealand Medicines Strategy

Consultation document
Foreword

Medicines have an important role to play in the health and wellbeing of New Zealanders. The medicines sector in New Zealand is a robust one, with a large number of stakeholders carrying out a lot of good, useful work. However, New Zealand lacks an overarching policy direction to bring all of the sector and the systems together under one banner.

This lack of a co-ordinating strategy can leave people worrying whether they are getting access to the medicines they need. It also risks duplication and not making the best use of resources. The commitment to develop a Medicines Strategy arises out of the confidence and supply agreement between the United Future Party and the Labour-led Government.

I am seeking a Medicines Strategy that aligns the sector’s activities and improves the health of New Zealanders. The strategy will be principles-based, and will contribute to achieving the outcomes identified in the New Zealand Health Strategy, the New Zealand Disability Strategy and other population or disease-state strategies.

It is timely to look at medicines in New Zealand as a whole. This consultation document provides a focus for constructive and ongoing dialogue about medicines in New Zealand. It will lead to a Medicines Strategy focused on three objectives:

- quality, safety and efficacy of available medicines
- access to medicines that New Zealanders need regardless of an individual’s ability to pay
- optimal use of medicines.

With the increasing number of high-cost and highly specialised medicines coming through the medicines development, approval and procurement process, changes to our regulatory capacity are clearly needed. Consumer access is another important area of focus for this consultation document. I am particularly looking forward to working on the optimal use of medicines, because this is an area where a lot of good work is under way which the strategy can help bring together and provide a focus for. Optimal use is an area that is often overlooked, but one that can bring significant health gains.

To be a true representation of the medicines environment in New Zealand, the strategy must consider the views of all the stakeholders in the country’s medicines sector. I have been pleased to meet with a wide range of stakeholders over the last few months and have appreciated you sharing your perspectives. I look forward to your continued involvement.

Change takes time and delivering a new strategic direction does not happen overnight. This next phase of work will provide an opportunity for all of us to become involved in enhancing a robust, positive medicines sector in New Zealand. I encourage you to engage in this consultation process as we look towards a New Zealand Medicines Strategy, and I look forward to many useful submissions on the issues raised here, as well as your suggestions for inclusion in the final strategy.

Hon Peter Dunne
Associate Minister of Health
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Executive Summary

Medicines make an important contribution to the health and wellbeing of New Zealanders and they are widely used across community and hospital care settings. The medicines sector in New Zealand involves a large number of stakeholders who undertake a great deal of good work. There is, however, no overarching direction that aligns the sector and the systems that govern the regulation, procurement, management and use of medicines. The Government has signalled its intention to put this overarching direction in place. This consultation document is the first step in the process toward developing a Medicines Strategy for New Zealand.

The document describes how the system works currently, seeks to identify areas where the current system can be improved, and proposes a new strategic direction. Your views are sought on the proposals in this document and they will feed into the development of the Medicines Strategy to be released in 2007.

The health and disability support system aims to improve the health of New Zealanders, support their independence, reduce inequalities between population groups, and operate in a way that people trust. The strategic direction proposed in this document aims to support this high-level aim with the following objectives for the medicines sector:

- quality, safety and efficacy of available medicines
- access to medicines that New Zealanders need regardless of an individual's ability to pay
- optimal use of medicines.

In order to achieve these objectives, the sector needs inputs such as funding to pay for medicines and associated services, appropriate structures, skilled practitioners and information systems. The structures and systems also need to be well understood by the sector and public, be enduring over time, efficient, and able to respond to changes in health priorities.

It is important to acknowledge that the medicines sector already has well-developed systems, structures and highly skilled people working within it. Changes are not proposed to systems that work well. However, the sector is constantly evolving and there is always room for improvements.

It is proposed that the activity of the sector be aligned towards the three objectives above, and that decisions about the detail of its policies, systems and structures be guided by the following principles:

- **excellent systems** – the systems that support medicines use are people-centred, reflect best practice and ensure safety and efficacy
- **equity** – New Zealanders in similar need of medicines have an equitable opportunity to access equivalent medicines, and medicines and other resources are allocated in a manner that reduces inequity of outcome between population groups
- **effectiveness** – the systems are used to ensure the provision of medicines, including the roles and functions of the agencies involved, are effective in contributing to the objectives of the strategy
• **trust and confidence** – the systems are used to ensure the provision of medicines are timely, robust and transparent, and stakeholders (including consumers) understand and have the opportunity, as appropriate, to participate in the decision-making processes used for regulating, funding and managing medicines

• **value for money** – the systems in the medicines sector operate efficiently, and secure the greatest possible value (in terms of efficacy, equity and cost) from medicines, including minimising compliance costs and making choices in a context of acceptance of scarcity and opportunity cost

• **affordability** – the medicines used within the health and disability support system and the structures and processes that support their use are affordable for individuals and the community, and are met within the funding available.

**Figure ES1:** Proposed strategic framework

The medicines sector aims to achieve

<table>
<thead>
<tr>
<th>Quality, safety and efficacy</th>
<th>Access</th>
<th>Optimal use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Through</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sector involvement</td>
<td>System capability</td>
<td>Structures and systems that work well</td>
</tr>
</tbody>
</table>

According to the principles of

| Excellent systems | Equity | Effectiveness | Trust and confidence | Value for money | Affordability |

Applying these principles to the current system, and aiming to improve the quality, access and optimal use of medicines, this document proposes priority areas where improvements could be made.

• Under **quality, safety and efficacy**: the regulation of medicines in New Zealand.

• Under **access**: understanding of decision-making about funding medicines, including how prioritisation decisions are made, how access to high-cost medicines and vaccines is decided, and the process for setting the community pharmaceutical budget.

• Under **optimal use**: increasing the role of pharmacists in ensuring the best use of medicines, improving information-sharing, including the interface between primary and secondary care, and the availability and quality of information given at the time of dispensing.

This document particularly supports the current sector initiatives that aim to improve the optimal use of medicines, and proposes that further action be taken in this area. The public funding of safe and effective medicines cannot achieve the desired health gains if those medicines are not used appropriately and correctly. Your suggestions and views on how to promote the optimal use of medicines are welcomed.
We want your input

The Government wants to know your views about all of the issues raised in this document, and you are encouraged to make a submission to the Ministry of Health. A number of questions are raised throughout the document to help focus your responses. The Government is especially interested in knowing what you think of the overall framework: Do you agree with the objectives and principles, or are there aspects you think should change? Similarly, do you agree with the issues that are identified in the ‘Getting Started’ list? Are there issues that have been missed out and should be addressed as a matter of priority? Are there issues identified that you don’t think are important?

How to have your say

This document is being distributed widely among those with an interest in medicines usage. Further copies are available from the Ministry of Health (see details below), or simply print a copy from the publications section of the Ministry of Health website (www.moh.govt.nz).

You can post, email or fax your submission to the Ministry of Health. Please forward one copy only of your submission to:

Medicines Strategy Consultation  
Sector Policy Directorate  
Ministry of Health  
PO Box 5013  
WELLINGTON

or

e-mail: medicines_strategy@moh.govt.nz

or

fax: (04) 496 2191.

The closing date for submissions is Friday 30 March 2007.

If you are making a submission on behalf of an organisation, please describe the organisation and its interest in medicines usage, identify your position within the organisation, and indicate the extent of any consultation or discussion you have undertaken with your organisation in making your submission. If you are making a submission as an individual, please indicate the reason for your interest in medicines usage (eg, as a consumer, researcher or health practitioner).

Note that your submission and all correspondence you have with the Ministry may be the subject of requests under the Official Information Act 1982. If there is any part of your submission or correspondence that you consider could properly be withheld under the Act, please include comment to this effect along with reasons why you want the information withheld. The reasons for withholding information under the Official Information Act 1982 are contained in Appendix 1.
If you are making your contribution as an individual as opposed to an organisation, the Ministry will omit your personal details from the submission if you include the following statement at the front of your submission and sign it:

‘I do not give my permission for my personal details to be released to persons requesting my submission under the Official Information Act 1982.’

What happens next?

The release of Towards a New Zealand Medicines Strategy is the beginning of the process of developing a Medicines Strategy. All the submissions we receive will be considered and analysed, and a summary of the issues raised will be prepared. The analysis of submissions will inform policy advice to the Government about what the Medicines Strategy should contain and the initiatives that are the first priority to get under way in order to work toward the objectives of the strategy. The Ministry expects that the Government will release its strategy and the priority initiatives in 2007. The work on those initiatives will then get under way.
1. Introduction: Developing a Medicines Strategy

Medicines are an important part of the health and disability support system, and have a significant contribution to make to health outcomes for New Zealanders. They feature in the treatment regimes of many people, are used proactively to prevent illness, and assist with the management of symptoms when cure is not possible. Medicines are used extensively throughout community and hospital care settings. Individuals also have the ability to care directly for their own health with over-the-counter and complementary medicines.

However, medicines carry risks as well as benefits. We must be sure that a medicine is the right treatment for an individual, that the product is safe and that it is used as intended. As with all other treatments, medicines also carry a financial cost – to purchase and administer, and through adverse events or wastage.

Across the sector, District Health Boards (DHBs), the Pharmaceutical Management Agency (Pharmac), the Ministry of Health, Primary Health Organisations (PHOs) and other primary health care providers, professional bodies, industry, and the Accident Compensation Corporation (ACC) are all engaged in activities aimed at increasing the health of New Zealanders including strategies to improve the health gains that can be obtained from medicines.

Box 1: Snapshot of New Zealand medicines

- Approximately 40 million dispensings (provisions of subsidised pharmaceuticals by a community pharmacist) were carried out in 2004/05.
- Between January 2001 and December 2005 the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) approved, on average, 53 prescription medicines for use in New Zealand each year.
- Each year DHBs spend about $1 billion on pharmaceuticals and pharmaceutical services. Of this, in 2005/06 Pharmac administered $582.86 million of spending on pharmaceuticals in the community. In 2006/07 that will rise to $600 million.

This activity is occurring within a changing health and disability support system. The regulation of health practitioners has changed to encourage more flexible use of practitioners’ skills, and with this change has come the extension of prescribing rights to new groups of health practitioners. PHOs provide new care delivery settings, focused on teams and low-cost access to primary health care. Users of health and disability support services are also becoming increasingly immersed in information about how to care for their health and potential treatments.

Alongside these systemic changes, the types of medicines that are available are becoming increasingly sophisticated in targeting individual health conditions, but many of these new medicines come at a high financial cost.

There are also a number of technological and social developments and expectations that are likely to affect the way that medicines are regulated and managed, including:

- an ageing population and accompanying increasing levels of chronic ill health
- advances in information technology systems and a growing demand for accurate and timely information for funding, planning and providing health services, and for clinical decision-making
- the development of new health-screening tools
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1. Introduction: Developing a Medicines Strategy

- newer, more expensive forms of chemotherapy
- robotic surgery
- organ transplants
- multi-slice CT (computerised tomography) and PET (positron emission tomography) scanning, which can be used to diagnose conditions such as heart disease and breast cancer.

Alongside these changes, there is an increasing expectation that access to new health technology and medicines will be publicly funded.

Medicines also need to be viewed in an international context. Medicines are a multi-billion dollar global industry, raising issues for international relations. Regulators are concerned about the flow of medicines internationally and ensuring that the international distribution chain is safe. For example, counterfeit products are a significant concern to both industry and regulators internationally.

Similarly, the development of new medicines through research and development lies beyond the health and disability support sector. The Government’s biotechnology and growth and innovation strategies are key documents that encourage New Zealand-based growth in this area (Ministry of Research, Science and Technology 2003; Office of the Prime Minister 2002).

1.1 Why develop a medicines strategy?

Medicines are used extensively, they require complex systems to support their appropriate use, and the context of health care delivery is changing. It is timely to examine whether improvements can be made to the way we manage and use medicines to ensure we continue to get the best health and disability support outcomes over the longer-term.

This is a complex task, and the Government is beginning this work with the release of Towards a New Zealand Medicines Strategy. This document will lead to a strategy and work programme, which will contain a number of actions. The Government expects that, over time, as the new strategic direction unfolds, additional work will be undertaken.

The World Health Organization (WHO) recommends that countries develop a medicines strategy (WHO 2001). Although the WHO’s recommendation is largely generated by serious concern about access to essential medicines and safety matters in developing countries, it is also important for countries like New Zealand that have a well-developed health infrastructure to ensure that the health gains possible from medicines are realised and that the taxpayer’s investment in medicines is wisely spent.

The WHO identifies the following reasons for developing a Medicines Strategy:

- to present a formal record of aims, values, aspirations, decisions, and medium-to long-term government commitments
- to define the national goals and objectives for the pharmaceutical sector, and set priorities
• to identify the strategies needed to meet these objectives and the various actors responsible for implementing the main components of the policy
• to create a forum for national discussion on these issues.

1.2 What does Towards a New Zealand Medicines Strategy cover?

The terms of reference for the work to develop a Medicines Strategy for New Zealand were released in April 2006. The overall aim is to develop a strategy that will identify where improvements can be made within the existing system and broad policy settings to ensure the best health and disability support outcomes from medicines over the coming years. The full terms of reference are included as Appendix 2.

Towards a New Zealand Medicines Strategy has three main aims:
• to describe the structures and processes of the current New Zealand medicines system
• to propose a set of objectives and principles to guide the policies, structures and systems into the future
• based on those objectives and principles, to propose a ‘getting started’ list of issues that will help to achieve the objectives of the proposed strategy.

In this document ‘medicines’ includes prescription medicines, over-the-counter medicines and complementary medicines. Given the breadth of the issues that arise in this area, Towards a New Zealand Medicines Strategy is largely focused on medicines use within the public health and disability support system. In terms of access, the focus is on community pharmaceuticals.

Towards a New Zealand Medicines Strategy adapts the framework recommended by WHO and focuses on the following objectives:
• quality, safety, efficacy
• access
• optimal use.

1.3 What Towards a New Zealand Medicines Strategy is not doing

New Zealand already has good systems and structures in place to support the quality, access and optimal use of medicines. The New Zealand Medicines and Medical Devices Safety Authority (Medsafe), Pharmac and DHBs have central responsibility for quality and access matters in New Zealand. The optimal use of medicines is not the responsibility of a single agency, and it would not be appropriate for this to be the case. Responsibility in this area rests with individual consumers, health professionals, DHBs, PHOs, and health practitioner registration authorities, in addition to Medsafe, Pharmac and the Ministry of Health.
The aim of the Medicines Strategy work is to build on the existing policies and structures and identify improvements that will enable greater health gains to be realised. It is not aiming to disrupt systems that currently work well, or to revisit issues that have been well examined. Where these contribute to achieving the proposed aims of the strategy they are supported in this document. For example, the Government has recently set out its policy views, or has undertaken work, on:

- establishing the proposed Australia New Zealand Therapeutic Products Authority and the regulatory scheme and systems that will operate under this structure
- the Biotechnology Strategy (Ministry of Research, Science and Technology 2003), which aims to grow the biotechnology sector to enhance economic and community benefits
- the New Zealand Public Health and Disability Act 2000, including legislative exemption of Pharmac from Part 2 of the Commerce Act 1986
- whether New Zealand should continue to permit direct-to-consumer advertising of prescription medicines. Earlier in 2006, the Government undertook consultation on this issue (Ministry of Health 2006a) and it recently released its decisions.

Other therapeutic products such as medical devices, tissue, cellular products, and blood and blood products are outside the scope of the Medicines Strategy work.

1.4 Contributions to date

Following the release of the terms of reference for the Medicines Strategy in April 2006, the Associate Minister of Health wrote to groups across the health sector encouraging their participation in the Medicines Strategy work. Many of these groups subsequently met with the Associate Minister and/or the Ministry of Health. Many also provided written material ahead of the formal submissions process. These contributions have been valuable in setting out the different perspectives on medicines issues and the Government encourages your participation in this formal consultation process.

It is hoped the feedback on this document will help to ensure the Medicines Strategy:
- sets a robust, strategic policy direction for the future
- has buy-in from across the sector
- sets the scene for, and initiates, ongoing constructive and collaborative discussions about medicines use.
2. Setting the Scene: Health and Disability Support System Context

The work toward a Medicines Strategy for New Zealand sits in a broader health and disability system context. This chapter:

- sets out the strategic context for the whole health sector
- provides some key indicators of the current state of New Zealanders’ health
- describes the overarching approach to prioritising the public funding of health and disability support services.

2.1 The legislative context

The New Zealand Public Health and Disability Act (NZPHD Act) 2000 sets the overarching framework for the health system. It identifies key sector structures and the relationships between them, and requires the New Zealand Health Strategy and the New Zealand Disability Strategy to set the direction for the sector. These strategies work together to guide the development and implementation of more detailed service, health issues and population-group-specific strategies and action plans.

The New Zealand Health Strategy identifies seven fundamental principles that should be reflected across the health and disability sector (Minister of Health 2000) (see Box 2).

The New Zealand Disability Strategy is an intersectoral strategy that is relevant across the whole public sector (Minister for Disability Issues 2001). The Ministry of Social Development’s Office for Disability Issues oversees the strategy’s implementation. The New Zealand Disability Strategy identifies 15 objectives, underpinned by detailed actions, to advance New Zealand towards being a fully inclusive society.

Although the New Zealand Health Strategy and the New Zealand Disability Strategy provide the framework for action in the health and disability sector, they do not identify how specific priority objectives or services will be addressed. Population-, service- and disease-based strategies provide more detailed guidance for the health and disability sector – especially DHBs – on how to achieve the umbrella strategies’ goals. These more specific strategies include:

- He Korowai Oranga: Māori Health Strategy
- Primary Health Care Strategy
- Health of Older People Strategy

Box 2: New Zealand Health Strategy: fundamental principles

- Acknowledging the special relationship between Māori and the Crown under the Treaty of Waitangi.
- Good health and wellbeing for all New Zealanders throughout their lives.
- An improvement in the health status of those currently disadvantaged.
- Collaborative health promotion and disease and injury prevention by all sectors.
- Timely and equitable access for all New Zealanders to a comprehensive range of health and disability services, regardless of ability to pay.
- A high-performing system in which people have confidence.
- Active involvement of consumers and communities at all levels. 

(Minister of Health 2000)
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2. Setting the Scene: Health and Disability Support System Context

- New Zealand Cancer Control Strategy
- Healthy Eating – Healthy Action
- Mental Health Strategy.

A key focus is implementing a population health approach, focused on health promotion, prevention and early intervention, while concurrently ensuring that high-quality treatment services continue to be delivered.

Medicines have an important contribution to make in achieving the goals of these other strategies through being accessible and appropriately and safely used. It is crucial to remember, however, that health status and good health outcomes result from a complex interaction between people, their environment, genetics and health services. Medicines are an important element of treatment, but they are only one aspect, and their use must be appropriate in order for gains to be made. Put another way: medicines may not always be the right treatment choice.

2.2 Health status

Overall, the health status of New Zealanders is good. However, general statistics can hide disparities between population groups. Inequalities in the health status between Māori, Pacific peoples and those on low incomes and other population groups remain a concern.

For example, Table 1 summarises the life expectancies of New Zealanders compared with other developed countries. The results are good, but they hide some points of concern.

- Māori life expectancy is significantly lower than the life expectancy for the total population. In 2000–02 Māori female life expectancy at birth was 73.2 years for females and 69.0 years for males, more than eight years less than for non-Māori of both genders.
- Life expectancy for Pacific peoples in 2000–02 was 4.8 years lower than the New Zealand average for males and 4.4 years lower for females.
- Socioeconomic differences are also apparent, with people from more deprived areas experiencing lower life expectancies than people from less deprived areas (Ministry of Health 2006b).

Table 1: International comparison of life expectancy at birth, selected countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Period</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>2004</td>
<td>78.1</td>
<td>83.0</td>
</tr>
<tr>
<td>France</td>
<td>2004</td>
<td>76.7</td>
<td>83.8</td>
</tr>
<tr>
<td>Japan</td>
<td>2004</td>
<td>78.6</td>
<td>85.6</td>
</tr>
<tr>
<td>Netherlands</td>
<td>2004</td>
<td>76.9</td>
<td>81.4</td>
</tr>
<tr>
<td>New Zealand</td>
<td>2004</td>
<td>77.5</td>
<td>81.7</td>
</tr>
<tr>
<td>Sweden</td>
<td>2004</td>
<td>78.4</td>
<td>82.7</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>2003</td>
<td>76.2</td>
<td>80.7</td>
</tr>
<tr>
<td>United States</td>
<td>2002</td>
<td>74.5</td>
<td>79.9</td>
</tr>
</tbody>
</table>

Source: Ministry of Health 2006b

Table 2 provides an overview of the conditions that make the largest contribution to the burden of disease for New Zealanders.
Table 2: Burden of disease in New Zealand: top five conditions ranked by years of life lost and disability-adjusted life years, by sex, 1996

<table>
<thead>
<tr>
<th>Rank</th>
<th>Years of life lost</th>
<th>Disability-adjusted life years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Ischaemic heart disease</td>
<td>Ischaemic heart disease</td>
</tr>
<tr>
<td>2</td>
<td>Road traffic injury</td>
<td>Chronic obstructive respiratory disease</td>
</tr>
<tr>
<td>3</td>
<td>Lung cancer</td>
<td>Road traffic injury</td>
</tr>
<tr>
<td>4</td>
<td>Suicide</td>
<td>Stroke</td>
</tr>
<tr>
<td>5</td>
<td>Stroke</td>
<td>Lung cancer</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Ischaemic heart disease</td>
<td>Ischaemic heart disease</td>
</tr>
<tr>
<td>2</td>
<td>Stroke</td>
<td>Stroke</td>
</tr>
<tr>
<td>3</td>
<td>Breast cancer</td>
<td>Depression</td>
</tr>
<tr>
<td>4</td>
<td>Chronic obstructive respiratory disease</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>5</td>
<td>Colorectal cancer</td>
<td>Chronic obstructive respiratory disease</td>
</tr>
</tbody>
</table>

Source: Adapted from Ministry of Health 2001

1. An indicator of the social burden of fatal health outcomes.
2. A health gap measure of the loss of years of healthy life.

This table illustrates a population-wide perspective, but it is important to remember that there are many other conditions that cause ill health and disability, some affecting very small groups of people. It is often the conditions that affect only a small group of people that are the most challenging to provide treatment services for.

For example, Fabry disease (a rare genetic disorder resulting in major organ failure and premature death) affects an estimated 35 people in New Zealand. Enzyme replacement treatment is available for this condition; however it comes at a cost of approximately $350,000 for each patient each year. This medicine is not publicly funded.

### 2.3 Prioritisation – how health systems decide which services to provide

In meeting the health needs of the population, choices need to be made about which health and disability support services should be provided, and for whom. This includes decisions about which medicines to fund and provide.

Decisions about which medicines should be publicly funded are prioritisation decisions. Prioritisation decisions need to be made across all health and disability support services because the demand for health services and interventions, including medicines, will always be greater than the resources – such as money, time, space and staff – that are available. Choices have to be made about how limited resources will be used and this requires difficult decisions about competing demands for funding.
Prioritisation is most commonly associated with decisions about the allocation of new resources, but it also includes considering the opportunity cost of existing services. Opportunity cost is the value of the service compared to the possible alternative uses of the funding. For example, as the context within which health services operate changes over time, the value of a service or intervention that has historically received funding may decrease in comparison to an alternative. Prioritisation allows resources to be allocated and reallocated to the areas of greatest value.

As with other health services and interventions, prioritisation decisions about medicines occur at a number of levels. The following table identifies the levels at which decisions about medicines occur and the types of decisions that are made. It also identifies the source from which decision-makers derive their decision-making authority.

Table 3: Levels at which decisions about medicines occur

<table>
<thead>
<tr>
<th>Level</th>
<th>Location</th>
<th>Decision</th>
<th>Source of authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macro</td>
<td>Government</td>
<td>The Government needs to remain within its spending limits. Decisions are made about where to spend public money and how much money should go to different public services such as education, police or biosecurity. Vote Health is set in the context of decisions about spending in other government areas and determines the overall resources available within health. Decisions are also made at this level about the overall priorities for Vote Health. The Minister of Health, in consultation with the Ministry of Health, identifies the health priorities and goals that the sector is charged with pursuing.</td>
<td>Macro-level decisions are made by politicians. Their decision-making authority is derived from their positions as publicly elected Members of Parliament.</td>
</tr>
<tr>
<td>Meso</td>
<td>The Ministry of Health, DHBs and Pharmac</td>
<td>DHBs and Pharmac determine, from within the resources that DHBs have, the overall budget for community pharmaceuticals. These decisions are made in the context of the health priorities and goals identified by the Government, and individual DHBs’ priorities identified through their local health needs assessment process. Pharmac, on behalf of DHBs, decides which medicines will receive public funding, the level of the subsidy they receive, and any guidelines or conditions that apply to their prescription. These are listed in the Pharmaceutical Schedule.</td>
<td>Meso-level decisions are made by public sector employees and appointees. Their authority as decision-makers derives from their role in the public sector, or their appointment to a decision-maker role. It is therefore important that the decisions made at this level occur in the context of robust, explicit and transparent processes, and are in keeping with government policy directions and priorities that are set by the Minister of Health in consultation with the Ministry of Health.</td>
</tr>
</tbody>
</table>

1 Vote Health is the Government’s main contributor to publicly funded health and disability services expenditure. Vote Health funds DHBs, the Ministry and other health and disability service providers to purchase or provide: personal health services, public health services, mental health services, disability support services, and independent services (Ministry of Health 2006b).

2 The budget level must be approved by the Minister of Health and therefore falls under both the macro and meso decision-making levels.
<table>
<thead>
<tr>
<th>Level</th>
<th>Location</th>
<th>Decision</th>
<th>Source of authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micro</td>
<td>Prescribers/</td>
<td>Prescribers decide, in the context of the information in the Pharmaceutical</td>
<td>Micro-level decisions are made by prescribing health practitioners. Their decision-</td>
</tr>
<tr>
<td></td>
<td>consumers</td>
<td>Schedule and their own clinical judgement, which medicines they will</td>
<td>making authority is derived from their education and training.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>prescribe to individuals. Prescribers are not bound by the Pharmaceutical</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Schedule, as they can also prescribe medicines that are available in New</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Zealand but are not publicly funded. In this instance the full cost of the</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>medicine is met by the patient. Consumers can also directly purchase</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>medicines and prioritise their personal spending.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adapted from Ministry of Health and DHBNZ 2005.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In the past, both in New Zealand and internationally, prioritisation has occurred using processes that were not based on publicly defined criteria. Often the rationale for these decisions was unclear. Since the late 1980s, however, there has been an increasing focus on ‘explicit’ prioritisation, which involves decision-making according to processes that have been established for the purpose, and which involve clear, publicly available criteria.

Over time, a set of principles has been developed to guide overall prioritisation decisions in the health sector. *The Best Use of Available Resources* (Ministry of Health and DHBNZ 2005) – a resource to assist DHBs with prioritisation – has identified the following list of principles.

- **Effectiveness**: publicly funded health and disability services should be effective, and effective services are those that produce more of the outcomes we desire, such as reductions in pain, the maintenance of daily activities, greater independence and the prevention of premature death.

- **Equity**: services that reduce significant inequalities in the health and independence of New Zealanders are given a higher priority.

- **Value for money**: New Zealanders should receive the greatest possible value (in terms of effectiveness and equity) from public spending on health and disability services.

- **Whānau ora**: this involves considering the three prioritisation principles above from a Māori perspective and recognising that the prioritisation process should enable Māori to participate in, and contribute to, strategies for Māori health improvement and foster the development of Māori capacity to participate in the health and disability sector.
Box 3: Prioritisation in action

SPNIA
The Service Planning and New Health Intervention Assessment (SPNIA) framework is designed to assist DHBs and the Ministry of Health with health services changes that require a collective decision. The first proposal will be considered using this framework in March 2007.

The framework applies to regional and national collaborative decision-making about service reconfiguration and new health interventions (excluding pharmaceuticals). It assesses proposals against:

- expert clinical evidence and health technology assessment
- population health gain
- cost effectiveness
- equity and opportunity cost
- funding stream and affordability
- community acceptability and ethical issues
- service configuration and implementation planning
- priority in relation to other proposals and against past precedents.

(Ministry of Health 2006c)

CLINICAL BEST PRACTICE GUIDELINES

The use of evidence-based guidelines in clinical decision-making is another form of prioritisation that has been supported by the Ministry of Health and the New Zealand Guidelines Group.

For example, in June 2005, the New Zealand Guidelines Group released the New Zealand Cardiovascular Guidelines. These guidelines form a handbook for primary care practitioners and bring together earlier guidelines for cardiovascular risk, diabetes, stroke, arterial fibrillation, cardiac rehabilitation and smoking cessation. The guidelines provide a practical reference for primary care practitioners and include specific consideration of specific at-risk groups, including Māori, Pacific Island people and people with diabetes.

Ethical and legal dimensions of prioritisation

Prioritisation processes inevitably give rise to ethical and legal considerations. The aims of the NZPHD Act 2000 are to strengthen the public health system, achieve the best health and disability support outcomes for New Zealanders, and reduce disparities between population groups. However, the Act acknowledges that the achievement of these aims is limited by the need to prioritise when it states that the objectives (of the Act) ‘are to be pursued to the extent that they are reasonably achievable within the funding provided’ (section 3(2)).

The New Zealand Bill of Rights Act 1990, which applies to actions made by the Government and anyone acting pursuant to a public function, is one avenue for legal challenges to prioritisation decisions about individual patients. The Bill of Rights Act affirms the right to freedom from discrimination on the basis of the grounds identified in the Human Rights Act 1993 (New Zealand). Age and disability are among these. Prioritisation decisions, depending on the criteria on which they are made, could be said to be breaching this right. However, section 5 of the Bill of Rights Act notes that reasonable limits to the rights and freedoms identified in the Bill can apply as long as they are ‘prescribed by law’ and ‘can be demonstrably justified in a free and democratic society’.
While prioritisation of health services is allowed by law, the legality of actual prioritisation processes depends on whether the criteria that form the basis of such processes breach the Bill of Rights Act, and are considered by the courts to be reasonable limits (Manning and Paterson 2005).

When it comes to the ethical considerations associated with prioritisation, the National Ethics Advisory Committee (NEAC) acknowledges that health resources are limited and that prioritisation is therefore a necessity. However, NEAC states that there are ethical advantages to using explicit decision-making processes to reach prioritisation decisions (NEAC presentation on Ethics and the Delivery Pathway at the Ministry of Health’s Multi-Specialty Forum on Elective Services, Queenstown, July 2006).

Prioritisation and trust

Trust and security in the health and disability support system are central aims the Government has for the system, and this is reflected in the Ministry of Health’s Statement of Intent (Ministry of Health 2006d). The Government wishes to be sure that New Zealanders feel secure that they are protected by the system from substantial financial costs due to ill health, and have trust that it performs to high standards, reflects their needs and provides opportunities for community participation.

An important element in gaining this trust is that the public’s expectations of health and disability services are commensurate with what can be delivered within the finite health resources available, and that these services are in fact delivered. Understanding that prioritisation is necessary is critical to managing these expectations (Ministry of Health 2002).

Prioritisation decisions need to be transparent so that the public is aware of the factors that are taken into account when such decisions are made. Decisions made according to explicitly identified criteria will contribute to maintaining and increasing the trust of New Zealanders in the public health and disability sector (Ministry of Health and DHBNZ 2005). Trust in health services is typically associated, among other factors, with a high quality of communication and interaction (Ministry of Health 2002). Stakeholders’ views need to be considered in the prioritisation process and the communication of prioritisation decisions needs to be unambiguous.
3. **Medicines: Current Systems, Structures and Processes**

New Zealand has a well-developed health and disability support sector, which includes well-developed systems, structures and processes to support the safe and effective use of medicines. In turn, the safe and appropriate use of medicines can make a significant contribution to good health outcomes. That said, there is always room for improvement. Before looking towards a new strategic framework, including where the current arrangements may be improved, this section explains how things work now.

### 3.1 The medicines system

There are internationally recognised approaches to providing for the quality of, access to, and optimal use of, medicines, and New Zealand has similar structures to other countries. Figure 1 illustrates the key questions asked in each step of the New Zealand medicines chain. The structural approaches in other countries are summarised later in Chapter 4, and in Appendix 3.

Figure 1 describes the steps as consecutive. In practice, some activities occur concurrently, and even loop back. For example, the price of a medicine at procurement will affect its cost-effectiveness. Similarly, any restrictions imposed on a medicine when a product is approved for entry to the market should be reflected in the way in which the medicine is used/managed in relation to individual patients.

**Figure 1:** Key steps in the medicines chain
3.2 Types of medicines

Medicines are a subset of therapeutic products, and include prescription medicines, over-the-counter medicines and complementary medicines. The medicines system has a particular focus on prescription medicines. The risks posed by the inappropriate use of these products necessitate more controls being placed on their use. They also tend to be higher cost and treat more complex conditions.

A further distinction is made between innovative and generic medicines. Innovative medicines are products that work in new ways to treat ill health. They are developed after long periods of research and testing in clinical trials. Generic medicines are copies of innovative products and are able to be developed when intellectual property protections expire on innovative products. Generic medicines are cheaper. There are also medicines labelled as ‘me-too’ medicines. These are very similar to innovative medicines, often with only slight changes in their formulations.

For example, one study, which rated all the new drugs released in Europe since 1981, concluded that two-thirds of the drugs (66.63 percent) were ‘nothing new’ – mostly being me-too drugs. Less than 3 percent of new drugs offered ‘a real advance’ and only seven of the 2871 medicines assessed received the top rating (Kopp 2004).

There is a similar picture for the United States. In the five years from 1998 to 2002, 415 new drugs were approved by the Food and Drug Administration, of which 14 percent were truly innovative. Nine percent of all drugs were changes to existing medicines. The remaining 77 percent were me-too drugs, classified as not being better than drugs already on the market to treat the same condition (Angell 2004).

That said, recently there has been an emergence of new, high-cost biotechnology and other innovative targeted medicines. These new medicines have the potential to make major advances in the prevention and treatment of previously unmanageable diseases. The medicines are targeted for use in well-defined groups of patients who have specific biological markers. Clear criteria for patient eligibility should therefore be able to be established to both optimise health outcomes and accurately predict the budgetary implications to government and patients if the drug is publicly funded (National Centre for Social and Economic Modelling 2002).

Non-prescription medicines also have an important role to play in the context of self-care. The World Self Medication Industry’s 2006 Declaration on Self-Care and Self-Medication notes that the use of ‘self-care’ products (which include complementary and non-prescription medicines) is ‘already a widely practiced component of self-care’ and that self-care will form a significant part of health care in the future (http://www.wsmi.org/pdf/boarddeclarationselfcare.pdf). The popularity of self-care in New Zealand is demonstrated in the 2002/03 health survey which showed that approximately a quarter of New Zealanders had visited an alternative health practitioner in the last year (Ministry of Health 2004). Ensuring the safety and best use of products used in self-care is therefore increasingly important.
3.3 System structures

Achieving good health outcomes from the use of medicines requires a focus on both the medicines themselves – the products – and the services in which they are used. The structures that support achieving good health outcomes from medicines use include:

- Ministry of Health
- Medsafe
- DHBs
- District Health Boards New Zealand Safe and Quality Use of Medicines Group
- Pharmac
- individual health practitioners
- pharmacovigilance agencies.

The remainder of this chapter is devoted to describing these structures.

Ministry of Health

The Ministry of Health’s overall goal is ‘Healthy New Zealanders’. The Ministry has eight key responsibilities in achieving this goal (Ministry of Health 2006b). These are to:

- provide policy advice on improving health outcomes, reducing inequalities and increasing participation
- act as the Minister’s agent
- monitor the performance of DHBs and health sector Crown entities, such as Pharmac – the Ministry monitors sector organisations against the objectives agreed with the Government, and also monitors the performance of the sector in an international context
- implement, administer and enforce relevant legislation and regulations (eg, the Ministry administers the Medicines Act 1981 and its associated regulations through Medsafe)
- provide health information and process payments (eg, the Ministry processes payments for primary care services and dispensing services)
- facilitate collaboration and co-ordination within and across sectors
- provide nationwide planning and maintenance of service agreements
- plan and fund public health, disability support services and other support services that are retained centrally (with regard to medicines, the Ministry funds public health programmes including vaccination; eg, the Meningococcal B vaccine).

In fulfilling its responsibilities, a key function of the Ministry is supporting the development of the Government’s overall goals and objectives for the sector, which are then given effect to by DHBs according to the needs of the local DHB population.
New Zealand Medicines and Medical Devices Safety Authority: Medsafe

Medsafe is a business unit of the Ministry of Health and is responsible for the regulation of therapeutic products in New Zealand to ensure that, as far as possible, the therapeutic products available in New Zealand can be expected to have greater benefits than risks if used appropriately. Therapeutic products include medicines and related products, herbal remedies and controlled drugs used as medicines. Medsafe is responsible for administering the Medicines Act 1981 and Regulations 1984, and parts of the Misuse of Drugs Act 1975 and Regulations 1977. Medsafe is accountable through the Ministry to the Minister of Health, and its activities are reported as part of the Ministry’s accountability arrangements (e.g., the annual Statement of Intent and Annual Report).

The regulation of therapeutic products is based on the principle that medicines are not ‘ordinary goods of commerce’, because prescribers and consumers cannot ascertain the quality, safety or efficacy of the products simply by examining them. The cost and consequences of product failure through adverse reactions, disability and death will be far greater than the collective cost of regulation to industry, governments and consumers.

This information asymmetry between the manufacturers of medicine and the prescribers and consumers constitutes an example of market failure, where government intervention is necessary to protect the interests of consumers. Medsafe provides this function for the Government by being required to approve medicines before they can lawfully be on the market in New Zealand.³

Medsafe regulation is applied with the intention of ensuring that:

- the benefits of using a product outweigh the risks
- the product consistently produces its therapeutic effect
- people have adequate and balanced information about the use of the product, its interactions with other products and its side-effects, and the risks associated with both taking, and failing to take, the product
- New Zealand plays its role in the international arena to ensure that, globally, therapeutic products are of a sufficient standard
- product development through clinical trials is safely supported.

Medsafe regulates:

- medicines (prescription, over-the-counter and vaccines)
- medical devices (e.g., pace-makers, sutures, syringes, stents)⁴
- blood and blood products

³ There are limited statutory exceptions to this requirement.
⁴ Medsafe’s powers in respect of medical devices are limited to the ability to withdraw unsafe products from the market.
• the advertising of therapeutic products (although there is also a large degree of industry self-regulation in New Zealand)
• clinical trials of medicines.

Medsafe approves, on average, 195 new medicines a year. Between January 2001 and 31 December 2005, Medsafe approved on average per year:
• 53 new prescription medicines
• 54 new generic medicines
• 88 new over-the-counter medicines.

While this is a large number of new products entering the market, regulators assess that only a small percentage of new medicines are truly breakthrough treatments. An approval by Medsafe means that a medicine may be put on the market in New Zealand. It is up to individual companies to decide whether they will place the medicine on the market.

All medicines carry risks, and the consequences of product failure can be very serious. Obviously medicines can also offer significant benefits, and delays in registration while further clinical trials are carried out, or restrictions on use, can limit consumer access. Medsafe, as with medicine regulators in other countries, must balance the need to be risk adverse with the need to progress applications quickly enough to be of most use to consumers.

Medsafe applies both pre- and post-market controls to prescription and over-the-counter medicines, and runs a pharmacovigilance programme (see below).

The four operational areas of Medsafe are:
• evaluation – pre-market evaluation of new and changed medicines and related products, and approving clinical trials
• compliance – monitoring the safety and quality of medicines and medical devices that are on the market by auditing and licensing medicine manufacturers, monitoring compliance with legislation and codes of practice, conducting investigations and prosecutions, and handling complaints and recalls
• medicines control – monitoring the integrity of the distribution chain of medicines and controlled drugs, and drug abuse containment, and investigating post-market activities that do not comply with the requirements of the legislation
• business development and support – developing Medsafe’s operational and strategic policy, managing pharmacovigilance, medicines classification, communication and information services.

Medsafe also classifies medicines, and this affects whether consumers need a prescription to obtain the medicine, and, if a prescription is not needed, where the medicine can be sold. Medicines are divided into:
• prescription medicines (which require a prescription and can only be dispensed by a pharmacist)
• restricted medicines (also known as pharmacist-only medicine, which can be obtained without a prescription but must be dispensed by a pharmacist)
• pharmacy-only medicines (which can only be obtained from a pharmacy).

Medicines in these classifications are listed in schedules to the Medicines Regulations. Medicines that are approved by Medsafe but are not listed in the schedules are unclassified or unscheduled. These are general sales medicines that may be sold from any outlet (eg, aspirin).

Medsafe is also responsible for regulatory activity elsewhere in the medicines supply chain, and is involved in other therapeutic product-related matters. These activities include:

• pharmacy licensing
• licensing wholesalers of medicines
• blood regulation
• working with the Environmental Risk Management Authority in respect of medicines that contain genetically modified organisms or hazardous substances
• the potential to look at applications to undertake specified biotechnical procedures (eg, xenotransplantation)
• providing technical expertise to the Ministry of Health to inform policy development (eg, extending prescribing rights to new groups of health practitioners).

In undertaking its functions, Medsafe receives and considers advice from the following expert advisory committees:

• Medicines Assessment Advisory Committee – which does pre-market assessment of products for safety, quality and efficacy
• Medicines Classification Committee – which makes pre- and post-market recommendations about the classification of medicines
• Medicines Adverse Reactions Committee – which makes recommendations following post-market reviews of adverse reactions monitoring data
• Medicines Review Committee – which is used very rarely to consider objections about recommendations that a medicine not be approved, the issuing of licences (eg, to operate a pharmacy) and requests to carry out clinical trials.

**District Health Boards**

DHBs are responsible for the health of their geographically defined populations. They both fund and provide health and disability support services for the people living in their region, and are allocated funding from Vote Health to do so.

In terms of the proposed Medicines Strategy, DHBs have a central role to play in that they:

• are responsible for improving the health and disability support outcomes for their population in the context of the priorities and goals identified by the Minister of Health in consultation with the Ministry of Health
• provide services and contract others to provide services, including hospital and primary care services
- fund the medicines used by the people in their region, both in the community and in hospitals.

DHBs spend about $1 billion on pharmaceutical and pharmacy products and services each year (DHBNZ 2006) (the expected spend for 2006/07 is shown in Figure 2). District health boards provide hospital services, fund primary care and pharmacy services, and provide support services (e.g., a person taking leflunomide for severe rheumatoid arthritis needs regular monitoring, including a full count blood count and liver function tests, and this is done in a hospital outpatient clinic). These types of costs are not captured in Figure 2, but can be significant.

**Figure 2:** Predicted DHB expenditure on pharmaceuticals and pharmaceutical dispensings, 2006/07 ($ million)

- Pharmaceutical cancer treatments $50.70
- Hospital pharmaceuticals $174.30
- Base pharmacy contract (dispensing fee) $238.40
- Margins on drug costs (pharmacist's margin on wholesale price of medicines (average margin is 4.13%)) $24.78
- Community pharmaceuticals $600.00

Source: DHBNZ 2006

DHBs are accountable for managing within their overall budgets, and their accounts are charged for pharmaceuticals used by their populations.

**Pharmacists and pharmacy services**

There is often a focus on how much is spent on medicines, but it is important not to overlook the role of dispensing services and pharmacists—services that are also publicly funded. Unless a medicine is classified as a general-sales medicine (because it is very low risk), access to the medicine will require an interaction with a pharmacist or a pharmacy, either in the community or in hospital.

Prescription medicines and pharmacist-only medicines must be dispensed by a pharmacist, and pharmacy-only medicines must be sold from a pharmacy.
The role of pharmacists is discussed later in this document, but it is important to note here that DHBs contract for dispensing services for their populations. Dispensing services include providing subsidised pharmaceuticals that are listed in the Pharmaceutical Schedule maintained by Pharmac, and advice on how to use the pharmaceutical correctly. Pharmacists are paid for dispensing pharmaceuticals that are prescribed by a regulated prescriber. The dispensing fee for most pharmaceuticals is currently $5.16 (GST exclusive). A small number of pharmaceuticals receive a higher fee to reflect additional requirements on the pharmacy when dispensing them.

There are approximately 40 million dispensings of subsidised pharmaceuticals per annum, and DHBs spend $225 million on dispensing fees to pharmacists (Ministry of Health 2006b).

**District Health Boards New Zealand Safe and Quality Use of Medicines Group**

In response to concern about the safe and optimal use of medicines, District Health Boards New Zealand (DHBNZ) established the Safe and Quality Use of Medicines Group (SQM) in 2003. The group is interested in the opportunities for improving the systems, technology and processes involved in medication prescribing, dispensing and administration. Specifically, SQM is keen to improve the networking and exchange of information between different organisations and professional groups.

In October 2005, SQM produced the *Safe and Quality Use of Medicines National Strategy*. A similar initiative was undertaken in Australia in 2002, and its National Strategy for Quality Use of Medicines was a key resource in developing the New Zealand approach. The New Zealand strategy provides an outline of the many ways in which health sector stakeholders can improve their use of medicines. SQM specified that its strategy was a menu of ideas and possibilities and was not intended to stifle innovation. The key focus is leadership and co-ordination for the benefit of consumers. The strategy aims to achieve safer, more effective and more appropriate use of medicines so that health outcomes from the use of medicines are improved for the community as a whole (SQM 2005).

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5 Available at ‘www.safeuseofmedicines.co.nz’.
Box 4: Objectives of the Safe and Quality Use of Medicines (SQM) Strategy

The objectives are to:

- promote a culture of safety within the health sector and wider community that supports leadership and co-ordination of safe and quality use of medicines initiatives within all parts of the health sector
- encourage and support more widespread involvement of all DHBs in safe and quality use of medicines initiatives through the establishment and support of active networks, dissemination of information and ideas, and shared learning and review
- maximise outcomes, minimise risks and improve safety associated with medication use by establishing, reviewing and improving practice standards for all aspects of prescribing, dispensing and administration
- identify high-risk medicines and high-risk situations, including those disease states targeted for special input in primary care (eg, cardiovascular disease, diabetes and asthma); and to identify options and advocate for and implement solutions to minimise these risks
- improve the effectiveness and consistency of infrastructure such as systems, processes, technology and information systems used by DHBs in association with medication use
- improve health outcomes for patients who are treated in primary care and DHB hospitals, acknowledging that the interface between these areas requires particular emphasis
- promote a culture of enquiry that fosters audit, monitoring and evaluation, and research into the areas of safe and quality use of medicine
- involve and engage consumers about the safe and appropriate use of medicines and to increase consumer awareness in relation to the level of medication errors in New Zealand.

Source: SQM 2005

Pharmaceutical Management Agency: Pharmac

Pharmac is a Crown entity established by section 46(1) of the NZPHD Act 2000. Its principle objective is to secure for eligible people\(^6\) in need of pharmaceuticals the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided. This is an important role and one that attracts a lot of scrutiny.

In terms of its main functions and responsibilities, Pharmac is:

- accountable to the Minister of Health and has its governance and accountability arrangements described in statute
- required to produce an annual statement of intent and annual report detailing its annual work programme and outcomes achieved
- required to consult
- subject to the Official Information Act 1982
- required to convene expert committees, in particular the Pharmacology and Therapeutics Advisory Committee, and the Consumer Advisory Committee.

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\(^6\) There are eligibility criteria that people must satisfy in order to receive publicly funded (free or subsidised) health and disability services. More information can be found on the Ministry of Health website (www.moh.govt.nz).
Since its inception in 1993, Pharmac has increased the range of medicines that are publicly funded and has controlled increases in expenditure on pharmaceuticals. Pharmac’s impact on price, volume and mix is shown in Figure 3.

**Figure 3:** Subsidy, volume, mix and cost indices

![Figure 3: Subsidy, volume, mix and cost indices](image)

Source: Pharmac 2006a

Although Pharmac is a stand-alone Crown entity, in practice it operates as an agent of DHBs and identifies which medicines should have a public subsidy and be listed on the Pharmaceutical Schedule. Subsidies are then paid by DHBs according to the use of medicines by the population of an individual DHB.

In addition to administering the Pharmaceutical Schedule, and consistent with its statutory functions, Pharmac also:

- promotes the responsible use of medicines, including through its continued implementation of its Māori Responsiveness Strategy
- assists DHBs with national procurement initiatives to facilitate more consistency in the costs of hospital medicines (and some other procurement initiatives)
- manages the exceptional circumstances scheme, which allows for medicines not normally subsidised to be funded for rare and unusual conditions
- administers a range of extremely high-cost medicines (Pharmac 2006a).
The Pharmaceutical Schedule

Pharmac’s central role is to maintain and manage the Pharmaceutical Schedule, which determines eligibility and criteria for the provision of subsidies throughout New Zealand (NZPHD Act 2000, section 48(a)). The NZPHD Act also requires that DHBs act consistently with the Pharmaceutical Schedule (section 23(7)).

The Pharmaceutical Schedule is a list of over 2000 pharmaceuticals and related products that are publicly subsidised for New Zealanders. It is organised by therapeutic groups (and sub-groups), and Pharmac aims to have a fully subsidised treatment available for each therapeutic sub-group. It is important to understand that this approach means that not all medicines that may treat a condition are fully subsidised.

Table 4 shows the changes to the Pharmaceutical Schedule since 1994. In 13 years, 1031 new or enhanced products have been listed, access has been widened for a further 210, and 47 have been restricted. A total of 1132 products have been de-listed since 1994, largely as a result of the tendering process leading to switching to different medicines with the same chemical properties.

Table 4: Listing changes made to the Pharmaceutical Schedule, 1999–2006

<table>
<thead>
<tr>
<th>Decision type</th>
<th>1999/00</th>
<th>2000/01</th>
<th>2001/02</th>
<th>2002/03</th>
<th>2003/04</th>
<th>2004/05</th>
<th>2005/06</th>
<th>Total since 1994</th>
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<tr>
<td>New chemical entity listed</td>
<td>18</td>
<td>20</td>
<td>7</td>
<td>3</td>
<td>15</td>
<td>9</td>
<td>14</td>
<td>169</td>
</tr>
<tr>
<td>New presentation listed</td>
<td>21</td>
<td>13</td>
<td>11</td>
<td>15</td>
<td>27</td>
<td>14</td>
<td>42</td>
<td>304</td>
</tr>
<tr>
<td>New product listed</td>
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<td>45</td>
<td>49</td>
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<td>568</td>
</tr>
<tr>
<td>Total new listings</td>
<td>78</td>
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<td>78</td>
<td>63</td>
<td>91</td>
<td>74</td>
<td>105</td>
<td>1031</td>
</tr>
<tr>
<td>De-restriction or expanded access</td>
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<td>7</td>
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<td>16</td>
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<td>210</td>
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<tr>
<td>Changing access to improve outcomes</td>
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<td></td>
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<td>59</td>
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<td>1132</td>
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</tbody>
</table>

Source: Pharmac 2006a

The Pharmaceutical Schedule also lists some of the pharmaceuticals purchased by DHBs for use in their hospitals, and includes hospital pharmaceuticals for which Pharmac has negotiated national contracts.

Pharmaceutical suppliers apply to Pharmac to have a medicine listed on the Pharmaceutical Schedule once Medsafe has registered the medicine. The Pharmac Board decides which medicines are included on the schedule, the level of subsidy, and any prescribing guidelines and conditions. In some cases, Pharmac sets criteria that need to be met before a medicine will be subsidised. One such mechanism is the Special Authority arrangement, which can be used to target certain medicines to a particular patient group.
The detailed process for listing a pharmaceutical is contained in Appendix 4, and the key points are summarised in Figure 4.

**Figure 4:** Summary of the process for listing a pharmaceutical on the Pharmaceutical Schedule

![Figure 4](image)

*Pharmacology and Therapeutics Advisory Committee*

Note that, in practice, this is not always a purely sequential process. In particular, Pharmac staff may be involved in ongoing negotiations with the manufacturer while the clinical assessment by PTAC takes place.

**Exceptional circumstances schemes**

If Pharmac determines that a medicine cannot be provided through the Pharmaceutical Schedule, it may still be able to be publicly funded in special cases. There are three exceptional circumstances schemes through which public funding may be available:

- **The Community Exceptional Circumstances Scheme** – this is used in circumstances where the provision of a funded medicine in the community is appropriate, but funding from the pharmaceutical budget cannot be provided through the Pharmaceutical Schedule. This scheme requires that the condition (or combination of circumstances) is rare and unusual (occurring in less than 10 cases annually).

- **The Hospital Exceptional Circumstances Scheme** – this is used by DHB hospitals to determine whether a medicine should be funded, to be used in the community, in circumstances where the medication is not on the Pharmaceutical Schedule, is not able to be funded through the Community Exceptional Circumstances scheme and is not a Discretionary Community Supply pharmaceutical. There is no rarity criterion for the Hospital Exceptional Circumstances Scheme, but the treatment applied for needs to be cost-effective to the DHB.

- **The Cancer Exceptional Circumstances Scheme** – this is used by DHB hospitals to determine whether they can fund pharmaceuticals for the treatment of cancer in their hospital or as part of hospital outpatient services, in circumstances where the pharmaceutical is not identified as a pharmaceutical cancer treatment in sections A–H of the Pharmaceutical Schedule.

**How Pharmac makes decisions**

The majority of prescription medicines used in New Zealand are publicly subsidised via Pharmac. The agency’s role in prioritising which medicines are publicly subsidised is crucial to ensuring that the best health outcomes are obtained from medicines and that those outcomes are the best value for money. This section describes the process that Pharmac uses to make its decisions.
The full process is set out in Pharmac’s Operating Policies and Procedures (Pharmac 2006b) and centres on nine decision-making criteria (see Box 5). The criteria are applied to each funding decision, and weighted as Pharmac considers appropriate. In making its decisions and applying the criteria, three key analyses are required:

- an assessment of the relative clinical effectiveness of the medicine
- an assessment of the cost-effectiveness of the medicine
- an assessment of the affordability of the medicine within the budget available.

These criteria may be interrelated. For instance, a change in one, such as the cost-effectiveness of a medicine, may result in a change in another, such as the medicine’s affordability.

**Box 5: Pharmac’s decision-making criteria**

Pharmac makes its decisions based on:
1. the health needs of all eligible people within New Zealand
2. the particular health needs of Māori and Pacific peoples
3. the availability and suitability of existing medicines, therapeutic medical devices and related products and things
4. the clinical benefits and risks of pharmaceuticals
5. the cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services
6. the budgetary impact (in terms of the pharmaceutical budget and the Government’s overall health budget) of any changes to the Pharmaceutical Schedule
7. the direct cost to health service users
8. the Government’s priorities for health funding, as set out in any objectives notified by the Crown to Pharmac, or in Pharmac’s Funding Agreement, or elsewhere
9. such other criteria as Pharmac thinks fit – Pharmac will carry out appropriate consultation when it intends to take any such ‘other criteria’ into account.

**Pharmacology and Therapeutics Advisory Committee**

PTAC has a central role in providing input to Pharmac’s decision-making processes. PTAC is an advisory committee to Pharmac, and its statutory purpose is to provide Pharmac with objective advice on pharmaceuticals and their benefits (section 50 NZPHD Act). PTAC recommends to Pharmac whether a drug should be funded, and provides its view on whether the drug should have a low, medium, high or cost-neutral priority for funding.

PTAC’s members are medical practitioners with broad experience and a particular interest in pharmaceuticals and their therapeutic indications, and well-developed critical appraisal skills. The Director-General of Health, in consultation with the Pharmac Board, appoints PTAC members.

While PTAC is now advisory to Pharmac, the committee has been a feature of the health sector since 1941. It was originally a ministerial advisory committee housed within the then Department of Health, formed to provide advice on the subsidy of pharmaceuticals. When Pharmac was formed in 1993, the committee’s role was aligned with Pharmac’s functions and became an advisory committee to Pharmac.
PTAC provides expert clinical advice on the public subsidy of particular pharmaceuticals being considered by Pharmac. It is advisory only, and the Pharmac Board is not required to accept its recommendations, although PTAC’s recommendations are given serious consideration.

PTAC’s recommendations are based on the nine criteria in Box 5, and its deliberations are informed by the detailed information provided by pharmaceutical companies and supplemented by Pharmac staff if required. Guidelines are available to assist companies in the kinds of clinical data that should be provided to Pharmac and PTAC (Pharmac 2005). The committee can also seek advice from other sources if it considers this necessary. In particular, it is important that PTAC has good information in order to be able to make sound recommendations to Pharmac about such matters as:

- the condition a pharmaceutical is to treat, the severity of the condition and the clinical indications for treatment, including the stage of disease, co-morbidities, whether the treatment is first-line (the main treatment for an illness) or second-line (alternative treatments that are used due to efficacy or, sometimes, cost) and whether the treatment should be used in combination with other treatments
- whether the treatment is preventive, curative, relieves symptoms or is palliative, and the degree of benefit that could be expected (eg, prevention of premature death, prevention of poor long-term outcomes, or improving immediate outcomes)
- other ways the condition could be treated, including other medicines, surgery, preventive programmes or mental health services
- the patient population that could be expected to benefit from the treatment and the burden of disease in the community, and the outcomes the affected population could expect from other forms of treatment
- the impact on outcomes for Māori and Pacific peoples that could be expected from the treatment
- the quality of the evidence that supports the application for a treatment to be funded and the applicability of the evidence in the New Zealand setting.

The health conditions and treatments considered by PTAC are highly specialised, and the committee is supported by specialist sub-committees that cover the following therapeutic areas:

- analgesia
- anti-infectives
- cardiovascular
- cancer treatments
- diabetes
- hormones and contraceptives
- mental health
- clinical aspects of cost–utility analysis
- neurology
- ophthalmology
- osteoporosis
- respiratory
- special foods
- tender medical
- transplant immunosuppressants.

7 Provides advice on Pharmac’s medicines tender supply process.
PTAC regularly seeks advice from the sub-committees with the aim of ensuring there is a sharp focus and high level of expertise in specific health areas/therapeutic groups. At times, ad hoc sub-committees will also be set up to fulfil a specific purpose.

**Cost-effectiveness analysis**

A key part of Pharmac’s role in determining which medicines should be publicly funded is assessing whether a medicine is *cost-effective*. Cost-effectiveness is one of Pharmac’s nine decision-making criteria.

Cost-utility analysis (CUA) is used to determine the cost-effectiveness of a medicine relative to other ways to treat a condition and treatments for other conditions. CUA explicitly looks at the costs and benefits of a medicine using quality-adjusted life years (QALYs). This means pharmaceutical treatments for different areas of health can be compared to one another. Pharmac staff undertake or review suppliers’ CUA analyses that consider both the health benefits and the direct costs of the intervention to the health sector.

The CUA approach also enables Pharmac to compare the cost-effectiveness of treatments for different groups of people. This enables a treatment to be targeted to those who will gain the most benefit from it, and means that resources are not spent on those who have less ability to benefit. For example, outcomes for patients can differ depending on the severity of the underlying disease. CUA enables Pharmac to estimate costs and QALYs for various treatment groups and, as appropriate, to reflect the results in Special Authority conditions.

Although it is a very useful device, CUA is simply one of the tools used by Pharmac to make decisions. All of the nine criteria are considered, and this can mean arriving at a different decision than what would have been reached using CUA alone. For example, Pharmac has listed medicines with cost per QALY values ranging from cost saving with positive health benefits (QALY gains) to $180,000 per QALY. The decision to fund the latter was significantly influenced by other decision criteria, such as budgetary impact and health needs.

CUA is a technical process, and Pharmac consults on the technical detail of its approach and updates its *Prescription for Pharmacoeconomic Analysis* accordingly (Pharmac 2006c).

**Pharmac’s decisions can be questioned**

Pharmac makes difficult decisions about the spending of public funds. It balances the nine decision criteria and makes a judgement about the best use of those funds. These decisions do not always please everyone. Beyond seeking information and clarification about how and why a decision was made, there are two formal channels for questioning Pharmac’s decisions: re-submission and judicial review.

- **Re-submission** – pharmaceutical companies can re-submit an application for funding a pharmaceutical to Pharmac if new evidence has come to light that was not considered during the original application. Pharmac will reconsider the new evidence as a new application.
• **Judicial review** – this involves a review by a Judge of the High Court of any exercise of, or any refusal to exercise, a statutory power of decision, to determine whether that decision is unauthorised or invalid. Judicial review is not the same as an appeal; it is concerned with the process by which a decision is made, not the decision itself. The grounds for a judicial review are set out in Appendix 5. Since its inception in 1993, Pharmac has been subject to eight judicial review proceedings, and has also been involved in civil proceedings and mediation. Of the eight proceedings, Pharmac successfully defended three that went to full hearings; two went part way through the court process (successfully defended by Pharmac at the interim order stage) before being discontinued or settled, and the remaining three were discontinued or settled before going to court.

**Demand-side activities**
Pharmac also has a legislative function to promote the responsible use of medicines in order to optimise prescribing and health outcomes. Maximising health outcomes depends on Pharmac balancing initiatives between the ‘supply side’ (price and quantity influencing through targeted access) and ‘demand side’ (quality and quantity influencing through information, awareness and sector collaboration about the responsible use of medicines).

Pharmac carries out a range of activities through its demand-side team, including:

• He Rongoā Pai, He Oranga Whānau – Whānau Staying Well with Medicines – a pilot training programme for Māori health providers to develop skills and knowledge in communicating to individuals and their whānau the safe and appropriate use of medicines
• Wise Use of Antibiotics campaign
• diabetes education resources for use by primary health sector educators for people with diabetes
• asthma management campaign
• cardiovascular risk management (including the One Heart Many Lives programme)
• gout information for patients
• information about medicine safety and effectiveness.

**Consumer Advisory Committee**
Pharmac is required to have a Consumer Advisory Committee (CAC) under section 50(1)(b) of the NZPHD Act 2000. This committee provides input to Pharmac from a patient or health consumer perspective on:

• initiatives to promote the responsible use of pharmaceuticals
• information to assist patients, particularly educational information
• where appropriate, the implementation of Pharmac’s decisions
• how access to pharmaceuticals could be improved for specific patient groups in terms of specific disease states within existing listed pharmaceuticals
• the use of pharmaceuticals by Māori, Pacific peoples or other groups experiencing inequalities in relation to existing listed pharmaceuticals
• the prioritisation of pharmaceuticals by Pharmac
• any other matters relating to the management of the Pharmaceutical Schedule (Pharmac 2002a).

Under its terms of reference the CAC has eight members, who should reflect different consumer perspectives including the views of different age groups, rural/urban views and different cultural views. In particular, the committee endeavours to have at least two Māori and one Pacific person as members (Pharmac 2002a).

Best Practice Advocacy Centre
The Best Practice Advocacy Centre (BPACnz) is an independent organisation whose role is to promote the responsible use of pharmaceuticals to general practitioners (GPs) and other health professional groups throughout New Zealand. Although it obtains its funding from a number of sources, Pharmac is its principal source of funding and contracts BPACnz to deliver a number of demand-side projects, such as prescription monitoring and educational interventions aimed at improving prescribing, and promoting the safe and optimal use of medicines.

BPACnz’s aims are to:
• develop and distribute resources that provide prescribers with a sound basis on which to review the way they prescribe for and treat their patients
• provide clear, concise and relevant information based on the best available evidence
• use a collaborative and co-operative approach coupled with appropriate marketing and market analysis to ensure BPACnz develops positive programmes targeted to meet the needs of prescribers and patients.

Individual health practitioners
Health practitioners – including doctors, nurses, midwives, dentists and pharmacists – manage medicines daily in their practice. Health practitioners advise on health care, provide direct treatment, prescribe medicines and dispense medicines. They are central to achieving the best health outcomes from the use of medicines. They are also often the people who explain to users of health services how the systems work and what services are publicly funded.

The roles of health practitioners are also changing as the sector aims to make the best use of their different skills. In 2003, Parliament passed the Health Practitioners Competence Assurance Act (HPCA Act). This Act is based on the concept of ‘scopes of practice’ and aims to increase flexibility in service delivery and use the health practitioners’ skills to the fullest extent. The HPCA Act is also centrally concerned with ensuring health practitioners practise safely and within the bounds of their abilities. This approach works well with the Medicines Act 1981, which allows for the extension of prescribing rights to new groups of health practitioners. In combination, this legislative framework provides a real opportunity for more innovative services delivery, and better health outcomes from the use of medicines.
Competencies and scopes of practice

Since the HPCA Act was passed in 2003, different professional groups have been refining their scopes of practice and associated competencies. For example, a key area of current activity is the competency framework for pharmacists being developed by the Pharmacy Council (see Box 6). This type of framework underpins using pharmacists’ skills more effectively to deliver services such as following up with patients to ensure they are adhering to their medicines regimes, and reviewing how patients use their medicines. The competence framework will ensure that individual pharmacists are able to work safely within their scopes of practice. The Pharmacy Council estimates that a large number of pharmacists will take the chance to upskill once the competencies are developed.

Box 6: Scopes of practice and competencies example

**Scope of practice – pharmacist**

The practice of pharmacy includes the custody, preparation and dispensing of medicines and pharmaceutical products; the provision of advice on health and wellbeing, including health screening; and the selection and provision of non-prescription therapies and therapeutic aids. The pharmacist acts as medicines manager, ensuring safe, high-quality use of medicines and optimising health outcomes by contributing to the selection, prescribing, monitoring and evaluation of medicine therapy. The pharmacist researches information and provides evidence-based advice and recommendations on medicines and medicine-related health problems to patients, their carers and other health care professionals.

The practice in this context goes wider than pharmacists directly working with patients, to include teaching, advising, research, policy development and management, given that such roles influence clinical practice and public safety.

**Medicines Management Competence Framework**

The Pharmacy Council’s framework is divided into four levels:

- level A – medicines provision
- level B – medicines use review (e.g., the pharmacist understands the goals of the relevant national health strategies; understands the principles of privacy and consent; builds and maintains an effective relationship with the patient and the health care team; maintains patient records; maintains peer support)
- level C – medicines therapy assessment
- level D – comprehensive medicines management.

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8 Level A refers to competencies described in the current scope of practice of a pharmacist; pharmacists who achieve competencies in levels B and C will have authorisations against their scope of practice; and level D competencies are likely to be set as a new advanced practitioner pharmacist (to be completed during 2007).
Prescribing medicines

In order to protect health and safety, only certain groups of health practitioners can dispense prescription medicines. This is controlled by the Medicines Act 1981. The Government has been extending prescribing rights to new groups of health practitioners where it is safe to do so, and where better service delivery can result. When a professional body wishes to gain prescribing rights, its registration authority (e.g., the Nursing Council) makes a submission to the Ministry of Health. The Ministry then assesses and undertakes consultation on the application on behalf of the Minister of Health, and the Minister and Cabinet decide whether prescribing rights should be extended. The ability to prescribe has recently been extended to nurse practitioners and optometrists.

The relevant professional registration authority ensures practitioners who are prescribing are competent and qualified. It is also up to the authority to determine what medicines it is appropriate for their members to prescribe within the relevant scope of practice and to monitor the prescribing practices of practitioners.

Medical practitioners, dentists and midwives are referred to as ‘authorised’ prescribers as they are authorised to prescribe all medicines on the Pharmaceutical Schedule (except where specific restrictions apply). Nurse practitioners and optometrists are referred to as ‘designated’ prescribers because they can prescribe only a subset of medicines on the Pharmaceutical Schedule.

Pharmacovigilance agencies

Pharmacovigilance uses a range of medical and epidemiological techniques to detect, assess, understand and report on adverse responses to medicines. It is an important part of ensuring the safe and optimal use of medicines.

Medsafe is responsible for overseeing pharmacovigilance activities in New Zealand. Medicine importers and manufacturers have a statutory obligation (under section 41 of the Medicines Act 1981) to report untoward effects of medicines to the Director-General of Health. The University of Otago is contracted by Medsafe to carry out pharmacovigilance activities in New Zealand. The services are provided through two programmes in the New Zealand Pharmacovigilance Centre based at Otago University: the Centre for Adverse Reactions Monitoring and the Intensive Medicines Monitoring Programme.

Centre for Adverse Reactions Monitoring

The Centre for Adverse Reactions Monitoring (CARM) is New Zealand’s national monitoring centre for spontaneous reports of adverse reactions. It collects and evaluates reports of adverse reactions to medicines, vaccines, herbal products and dietary supplements made to it voluntarily by health professionals in New Zealand. It has been operational since the early 1960s, and currently the CARM database holds over 50,000 reports. Despite CARM receiving over 3000 reports of adverse reactions per annum, it is commonly believed that this amounts to less than 5 percent of all adverse reactions that occur.
CARM carries out a number of specific pharmacovigilance functions as part of its contract with Medsafe, including the following.

- **Dangers/warnings**: for severe and life-threatening reactions, it records warning or danger alerts for medicines for individual patients against their unique National Health Index number. When the person is next seen and the system is accessed (usually at a hospital), the information is displayed and incorporated into the facility’s alert mechanism. CARM supports clinical decision-making when unusual symptoms are thought to be therapy-related by providing feedback and advice to a prescriber.

- **Analysis**: regular analysis is carried out to identify any significant patterns of adverse reactions, and potential changes to prescribing advice is undertaken. This data is reported back to Medsafe and considered by the Medicines Adverse Reactions Committee.

- **Collaboration**: CARM collaborates with the World Health Organization’s International Drug Monitoring Programme and contributes anonymised data into the WHO’s database. Through this network, New Zealand has access to international data about adverse reactions, which is used to complement New Zealand adverse reactions data.

- **Reporting**: continued quality reporting of adverse reactions to medicines by practitioners is crucial and the cornerstone of the CARM programme. The World Health Organization rates New Zealand as having the highest quality of adverse medicine reactions reporting per head of population in the world.

### Intensive Medicines Monitoring Programme

The Intensive Medicines Monitoring Programme (IMMP) was established more than 25 years ago. It is a form of prescription medicine event monitoring, where data is collected from pharmacies and from questionnaires completed by medical practitioners about patients taking a specific medicine, to create a prospective observational cohort of up to 10,000 patients taking the selected medicines. The IMMP analyses this data to identify signals of possible previously unrecognised reactions to medicines and to measure the incidence of known adverse reactions. The data is used to construct a risk profile for the studied medicine to help enhance its safe use.

Typically it can take up to five years to collect enough data to have enough statistical power to determine that any new adverse reactions or events reported are more likely to be related to the medicine rather than to the underlying disease or a chance finding. The results are reported to Medsafe for consideration by the Medicines Adverse Reactions Committee and health professionals. The IMMP is funded by Medsafe through its contract with the University of Otago to perform a number of monitoring projects. Medicines currently included in the IMMP are included in Appendix 6.

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Q1. Does this description reflect your understanding of medicines systems, structures and processes? Are there any elements that have not been included that you consider should be?
4. How Do Other Countries Arrange Things?

Other countries are faced with making the same decisions about medicines as New Zealand and have the same key steps in the process:

- assessment of safety, quality and efficacy before entry to the market
- assessment of clinical and cost-effectiveness to determine public funding
- controls on consumer access through medicines scheduling and health practitioner prescribing
- aiming to ensure that medicines are safely and effectively used in the community.

Most countries have centralised the regulatory assessments required, and the approach taken by Medsafe for prescription and over-the-counter medicines generally aligns with international practice. Most countries have also centralised the clinical and economic assessments necessary for evidence-based medicine coverage policy through public subsidies. New Zealand, through Pharmac, has a comparable approach to the pharmaceutical procurement process in Australia, the United Kingdom, the Republic of Ireland and Canada (Morgan et al 2006).

In each of these countries medicines are assessed, through clinical and pharmacoeconomic evaluation, so that drug expenditure is directed towards the most cost-effective and therapeutically beneficial medicines. In each system there is a division between the pre-market registration of a product and the assessments required to determine whether a medicine should be publicly funded. Within the processes to decide whether a medicine should be publicly funded, all countries assess clinical effectiveness and cost-effectiveness, and then make a final decision on whether to fund the medicine.

Despite some differences between New Zealand’s pharmaceutical system and that in the comparator countries (most notably that none of these countries have an explicitly capped pharmaceutical budget), there are a number of similarities of process. There are also common issues that arise in each of these jurisdictions, including the increasing costs of pharmaceuticals, decisions about funding high-cost pharmaceuticals, and ensuring all relevant data is considered when making decisions.

Appendix 3 summarises the registration, evaluation and funding systems of Australia, the United Kingdom, the Republic of Ireland and Canada. Although international comparisons are useful, it is also important to remember that the design of health systems varies internationally, and that New Zealand has unique circumstances (such as being a small country) which mean that overseas models do not always work well here.
5. A New Strategic Direction for Medicines in New Zealand

5.1 Overview

New Zealand currently has a comprehensive medicines system. However, it is not clear that all the parts of that system are working together to achieve the best possible health outcomes from medicines, or that the arrangements will stand the test of time. The key aim of Towards a New Zealand Medicines Strategy is to propose a high-level and strategic framework to guide New Zealand’s medicines policies and service delivery into the future.

The systems needed to support good health outcomes from medicines are complex, and the Government does not propose to set out all the detail of how the individual systems should work – those working within these systems and services are best placed to do that. The Government is concerned, however, to ensure that the systems are co-ordinated and aligned with common goals, as described in the Government’s health goals, and are organised to achieve good health outcomes. The framework proposed in this section is geared to that end.

It is envisaged that the objectives, principles and implementation elements presented here will form the core of the Medicines Strategy to be released in 2007. These elements will then frame policy development and policy implementation across the health and disability sector. If this approach is supported, then the Government can begin applying the strategic direction to the medicines system we have currently and begin identifying where improvements can be made.

The framework in this chapter has been informed by a number of key health sector sources, including:

- the New Zealand Public Health and Disability Act 2000
- the directions set in the New Zealand health and disability strategies
- the objectives set by the Ministry of Health’s Statement of Intent
- WHO guidance on developing a medicines strategy, and international examples of strategies.

In addition, during the last few months, a number of stakeholders have shared their ideas for a strategic framework for the medicines system. These ideas have been valuable, and the Government looks forward to further formal comment on the framework.

Overall, the health and disability support system aims to improve the health of New Zealanders, support their independence, reduce inequalities between population groups, and operate in a way that people trust. Within this broad framework the medicines sector can make an important contribution by ensuring that medicines are of good quality, that people have access to medicines, and that medicines are used to their optimum.

Figure 5 illustrates the proposed strategic framework for the medicines strategy.
The medicines sector aims to achieve through

<table>
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<th>Quality, safety and efficacy</th>
<th>Access</th>
<th>Optimal use</th>
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<tr>
<td>Sector involvement</td>
<td>System capability</td>
<td>Structures and systems that work well</td>
</tr>
<tr>
<td>Knowledge and information</td>
<td>Equity</td>
<td>Effectiveness</td>
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The various aspects of the framework are explained below.

5.2 Objectives

The following objectives are proposed for the Medicines Strategy:

- **quality, safety and efficacy**: medicines that are used in New Zealand are safe, of high quality and are effective – the sector has good systems to support medicines being used safely and in a way that will lead to good health outcomes.
- **access**: New Zealanders have access to medicines they need, regardless of their individual ability to pay and within the Government funding provided.
- **optimal use**: choices about medicines, the ways in which the system delivers medicines, and the ways individuals use medicines are safe and result in the best possible health outcomes.

Later in this document, proposed issues for action are identified under each of these objectives.

5.3 Principles for decision-making and system design

In order to advance these objectives within the structures, policies and processes of the health and disability support system, it is proposed that the Medicines Strategy contain a series of principles to guide decision-making. The principles cannot be considered in isolation, and in some cases they overlap. This reflects the reality of complex health care settings and the systems needed to ensure the safe and appropriate use of medicines. Decisions require balancing sometimes-competing objectives and making judgements using good information. The proposed principles follow.

**Excellent systems**

The systems that support medicines use are people-centred, reflect best practice and ensure safety and efficacy.
Equity
New Zealanders in similar need of medicines have an equitable opportunity to access equivalent medicines, and medicines and other resources are allocated in a manner that reduces inequity of outcome between population groups.

Effectiveness
The systems used to ensure the provision of medicines, including the roles and functions of the agencies involved, are effective in contributing to the objectives of the strategy.

Trust and confidence
The systems used to ensure the provision of medicines are timely, robust and transparent, and stakeholders (including consumers) understand and have the opportunity, as appropriate, to participate in the decision-making processes used for regulating, funding and managing medicines.

Value for money
The systems in the medicines sector operate efficiently and secure the greatest possible value (in terms of efficacy, equity and cost) from medicines, including minimising compliance costs and making choices in a context of acceptance of scarcity and opportunity cost.

Affordability
The medicines used within the health and disability support system and the structures and processes that support their use are affordable for individuals and the community, and are met within the funding available.

5.4 Key elements of implementation
Implementing a robust and sustainable approach to medicines use that is based on the principles above requires:

- cross-sector involvement
- system capability – financial and other inputs
- structures and systems that work well
- knowledge and information.

Cross-sector involvement from stakeholders
Achieving the objectives of the proposed Medicines Strategy and implementing its principles are not the roles of a single agency, professional group or other entity. It requires a sector-wide effort, an understanding of the roles the different parties play, and agreement on a shared strategic direction.
It is important to acknowledge that the stakeholders in the sector have different roles and different perspectives, which can give rise to conflict. This tension is a consequence of the different interests that stakeholders bring to bear. Despite this tension, it is possible for all parties to know and respect the roles that others play and the decisions they make. This is a goal to strive for in itself, and it is hoped that the Medicines Strategy will focus the sector’s efforts in a constructive and collaborative way.

The key sector stakeholders are as follows.

- **Consumers** – the whole system is geared towards improving outcomes for consumers of medicines through the optimal use of affordable, safe, effective, accessible and high-quality medicines. In turn, consumers have a role to play in ensuring that they take and use medicines appropriately, inform others of adverse events, and seek professional guidance when they need advice.

- **Health and disability system** – the Government is concerned with ensuring that New Zealanders’ optimal use of safe, effective and high-quality medicines contributes as much as possible to improving the health of New Zealanders and reducing inequalities between different population groups. The Government wants to be sure that the systems it has in place support this outcome. Various government bodies and government-funded bodies have different roles to play in supporting the achievement of the proposed strategy. The Ministry of Health, DHBs, Medsafe, Pharmac, PHOs, pharmacovigilance organisations, ethics committees and others all need to play their part.

- **Health practitioners** – the role of health practitioners is central to achieving the proposed strategy. Health practitioners interact with consumers in the delivery of health and disability support services, plan treatment, prescribe medicines, and monitor consumer outcomes. Health practitioners are also often the first point of contact for consumers for information beyond an individual’s condition. They frequently provide information about how the health system works, and what treatments are publicly funded and why.

- **Pharmaceutical industry** – the pharmaceutical industry is the key supplier of prescription and over-the-counter medicines. It has a vital role to play in ensuring that medicines are available in New Zealand and that those medicines are safe. For example, the industry’s clinical trials, manufacturing processes and provision of information to consumers all contribute to ensuring that medicines are safe and used to their optimum.

- **Complementary medicines practitioners and manufacturers** – in a similar way to health practitioners and the pharmaceutical industry, complementary medicines practitioners and manufacturers have an important role to play in making products available, ensuring that they are safe and of high quality, and are used appropriately.
5. A New Strategic Direction for Medicines in New Zealand

- **Other government sectors** – beyond the core health sector, other government sectors have both an interest and a role to play in contributing to achieving the goals of the proposed Medicines Strategy. The use of medicines sits in a broader trade and biotechnology context. Other government systems can contribute to the strategy through their policies and their implementation (e.g., the Biotechnology Strategy and the Growth and Innovation Framework, ACC’s purchasing approach, and the Department of Customs border control). Government sectors can also benefit from sharing information about prioritisation and other areas of difficult decision-making.

- **Other governments** – the global nature of the medicines industry and the common goal of governments in seeking to provide access to health care for citizens means the Medicines Strategy also sits in an inter-governmental context. New Zealand needs to work with other governments on safety issues (such as preventing the spread of counterfeit medicines), on supporting research initiatives (such as multi-country clinical trials) and as a good international citizen in terms of access to medicines in developing countries.

**System capability**

The medicines system needs to have a number of key inputs for the objectives of the strategy to be achieved. The core elements include financial resources, workforce and infrastructure.

- **Financial resources** – these are required to pay for the medicines themselves, the services within which medicines are used, and the structures and systems that support their safe and effective use. Financial resources are largely provided through Vote Health and administered by DHBs. In addition to this funding for products and services, financial resources are provided for the administration of organisations such as the Ministry of Health, Medsafe and Pharmac. There are also costs incurred as a result of health practitioner regulation, e.g., for ongoing education and certification. Not all costs are met by government, for example, Medsafe charges fees to industry to process applications for regulatory approval.

- **Workforce** – health practitioners, analysts and others are required to deliver health services, undertake regulatory assessments, make funding decisions, monitor the system.

- **Infrastructure** – physical organisations, information systems and other infrastructure is clearly needed to support the safe and appropriate use of medicines.

**Structures and systems that work well**

In addition to having the necessary capability, it is important that the structures and systems within the sector work well together. The structures and systems need to be:

- **Well designed and efficient** – recognising that any organisational or system design will have difficulties that need to be managed, it is important that the design of the organisations in the sector and its systems are sound and that checks and balances are in place. The system also needs to be designed to operate as efficiently as possible to avoid costs being incurred from unnecessary duplication or compliance.
• Understood by the sector and the public – to avoid duplication, and assist with gaining maximum value, the roles and operations of structures and systems need to be well understood by others in the sector. A good understanding by the public of how the system operates will assist with the public getting the most from the system and having confidence in it.

• Designed to endure over time – changes in structures and systems can be disruptive and costly. Changes in systems and structures also take time to settle down as new relationships and processes are established. A key to ensuring that the systems and structures of the sector are able to endure over time is to make sure that they are designed in a way that allows them to respond to changes in health priorities, new technology or other factors.

The previous chapter described the current structures and systems in the sector. The next chapter proposes where improvements can be made within the existing structures and policy setting to ensure they continue to serve New Zealand well in achieving quality, access and optimal use of medicines.

Knowledge and information
Getting the best out of medicines and having structures and systems that work well requires good knowledge and information, and sharing of that information across the sector. Technology has a central role to play in ensuring that good information is gathered and made available.

• Good information is needed to support Medsafe, PTAC and Pharmac in assessing whether a product should be on the market and whether it should attract a public subsidy.

• The Government and the public need good information about how decisions are made and how medicines are used in order to assess the performance of the system.

• The optimal use of medicines cannot be achieved without good information about evidence-based practice, and information about the extent to which this is implemented.

• Good individual health care, including safe prescribing, is facilitated by good information systems.

• Governments need to share information about the processes for decision-making so that ongoing improvements can be made, shared concerns furthered and efficiencies gained.

• Pharmacovigilance information is a key input to continually monitoring the quality of medicines.

• Governments need to have access to good information in order to facilitate cross-border safety activity.
Q2. Do you agree with the overarching objectives of the proposed Medicines Strategy? If not, why not?

Q3. Are any objectives missing? If so, what are they and why should they be included?

Q4. Do you agree with the proposed principles to guide decision-making? If not, why not?

Q5. Are any principles missing? If so, what are they and why should they be included?

Q6. Do you agree with the key elements of implementation? Are there others you would like to add? Please explain your reasons.
6. **Getting Started**

The previous chapter proposed a strategic framework to ensure that the best health outcomes are obtained from medicines in the coming years, and that sector activity is aligned in a common direction. This chapter now turns to the issues that need to be addressed in order to implement that framework. That is, if we consider that New Zealand’s medicines policy in the future should be explicitly gearing toward the objectives, principles and implementation elements described, where should we begin in order to improve our medicines system?

This question is posed in the context of a complex system where incremental adaptations to align activity with a proposed new strategic direction are more beneficial than sudden changes. Changes to structures need to be very carefully considered given the potential for disruption and financial cost, and the need to re-establish systems and processes.

The issues listed here are not exhaustive. They are issues that have been identified as having the potential to make an important contribution to achieving the objectives of the proposed strategy. They are divided into three main areas.

**Quality, safety and efficacy**

1. Secure a robust and sustainable regulatory capacity for New Zealand.

**Access**

2. Develop a principles-based and collaborative approach to setting the community pharmaceuticals budget.

3. Improve the understanding of public funding decisions about medicines.

4. Examine the criteria to underpin decisions about high-cost medicines for small groups of New Zealanders.

5. Develop a sustainable and robust approach to providing access to vaccines.

**Optimal use**

6. Ensure initiatives are in place to improve the decision-making about medicines, the delivery of medicines, and their use.

7. Introduce mechanisms for enhancing communication and co-ordination between agencies involved in optimal use initiatives, such that information sharing is maximised and duplication is minimised.

The Ministry is seeking your feedback on these issues, their relative priority, the proposals identified to address them, and the infrastructure required to support their implementation – in particular, the systems that might be needed, including ways to strengthen collaboration, communication and information sharing.
6.1 Quality, safety and efficacy

The issues
As we have seen, Medsafe regulates the quality, safety and efficacy of therapeutic products that are available on the market through pre- and post-market controls and pharmacovigilance. The basic framework is sound, but there are a number of significant problems with the current regulatory arrangements in New Zealand:

- they are out-of-date
- New Zealand does not have sustainable capability to regulate complex therapeutic products into the future
- there are gaps in the framework.

The Medicines Act and its regulations are dated and give rise to unnecessary cost and safety risks. For example, the Act is ill-suited to regulating low-risk products, which include complementary medicines, vitamins and minerals, and related products (e.g., fluoridated toothpaste and throat lozenges). The current regulatory framework is designed for higher-risk pharmaceuticals. Under it, low-risk products are subject to unnecessary regulatory hurdles that increase costs for both government and industry.

As a result, New Zealand’s regulatory arrangements are unsustainable. The two key sustainability issues are timeliness of approvals and technical assessment capacity for new pharmaceutical products.

Medsafe currently takes about 36 months to approve a new chemical entity, compared with approximately 18 months in Australia. The new types of prescription medicines (particularly those containing biological ingredients) also require considerable technical expertise to assess them for safety and efficacy. This expertise is in short supply internationally, and access to suitable expertise is increasingly a concern for New Zealand. For example, the assessment of the MenzB™ vaccine had to be outsourced to an overseas regulator to ensure a timely approval, because it was a complex biological vaccine. These complex prescription medicines are expected to increase in volume in the future.

The assessment of generic medicines is also a key issue. Generic medicines are cheaper to purchase, and a reliable stream of new, high-quality generic products is essential to maintain and enhance price competition and to make savings on individual products. Medsafe currently completes 90 percent of its generic applications within three and a half years, with 75 percent being completed within two years. This is slower than in Australia, where the statutory timeline is 255 days. Generic medicines are less technically challenging to assess than new medicines because the assessment process draws on the analysis that informed the decision to approve the original product. Delays in the assessment process for generic medicines can result in the loss of potential savings that could be used to fund other medicines or health services.
The current regulatory framework also has gaps. For example, it does not comprehensively regulate complementary medicines (or medical devices). Under current legislation, complementary medicines fall into one of two categories – dietary supplements (under the Dietary Supplements Regulations) or medicines (under the Medicines Act). Those in the former category are not subject to pre-market approval, which poses a safety concern, and therapeutic claims cannot be made about them, which is a marketing concern. As noted above, products regulated by the Medicines Act face unnecessarily high costs because the Medicines Act is not designed to regulate these low-risk products.

Consumers want to be sure of the quality of the products they purchase or that are used in health care facilities such as DHB hospitals. However, this is not guaranteed under the current system for all products used in these systems (eg, medical devices).

The deficiencies in New Zealand's current regulatory arrangements create problems for the Government in terms of assuring the safety of complementary medicines. The Government has needed to take legal action that may not have been necessary if a more effective regulatory framework was in place. The ability to sustain regulation in the short to medium term is also a significant concern, particularly for complex prescription medicines.

Finally, the poor regulatory framework also affects the industry. The industry is currently unable to make therapeutic or safety claims for many low-risk products, which affects the marketability of those products. The industry also faces unnecessary costs to meet the current regulatory requirements.

A new approach

Aspects of the current regulatory approach, if they remain unchanged, will hamper the achievement of the Medicines Strategy’s objectives. The Government is aware of this and is working to put a new regime in place that enables a sustainable regulatory capacity that can ensure the safety of therapeutic products in the short, medium and long term. The Government’s preferred approach is to establish a joint regulator with the Australian Government.

There would be a number of benefits from such an arrangement, including:

- enabling New Zealand to introduce appropriate risk-based regulation consistent with international best practice, which would mean that low-risk products, such as dietary supplements, will be overseen by less stringent controls than those that apply to prescription medicines
- medicines approved for use in one country would also be approved for use in the other country, helping to limit the licensing and approval costs for the manufacturer and giving New Zealanders and Australians timely access to medicines
- Australia and New Zealand would share technical information about therapeutic products more easily with overseas jurisdictions and would be able to access their technical expertise
- opening up the Australian market to New Zealand therapeutic products, because products will have a recognised regulatory stamp of approval for safety and quality
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6. Getting Started

- international recognition of the joint regulatory stamp of approval, which will open the way for exports of New Zealand and Australian therapeutic products to other countries
- encouraging closer economic ties between the two countries consistent with the Closer Economic Relations Agreement, and resolving the special exemption for therapeutic products under the Trans-Tasman Mutual Recognition Agreement
- an enhanced ability to retain and develop specialist technical expertise, allowing both countries to remain informed of the latest technical developments now and into the future
- ensuring that health and safety objectives are met while minimising costs to businesses and government, and without imposing unnecessary trade barriers
- improving New Zealand’s regulatory scheme, for example, by ensuring consumers are provided with unbiased information about the uses and the risks and benefits of prescription and pharmacist-only medicines, and requiring medicines that present a poisoning threat to children to be provided in child resistant packaging.

Q7. Are there other issues that you consider should be addressed as a matter of priority to improve the quality, safety and efficacy of medicines?

6.2 Access

This document proposes that access to medicines should be an objective of the Medicines Strategy. It also proposes that access be defined as New Zealanders having access to the medicines they need, regardless of their individual ability to pay and within the Government funding provided.

Access to medicines occurs through two processes:
- access to services/health practitioners
- access to individual products.

The Government, through the Primary Health Care Strategy, has recognised the importance of access to primary health care services in improving health outcomes and reducing inequalities (Minister of Health 2001). Access to health services and health practitioners who can prescribe is essential to enable people to access prescription medicines and other medicines on the Pharmaceutical Schedule.

The Primary Health Care Strategy identifies a number of reasons why people may not access primary health care services, including a lack of appropriate information about how to access services, and services being unaffordable. In addition, some people have difficulties physically accessing services.
Removing barriers to access is a key element of the Primary Health Care Strategy. A substantial amount of government funding has been invested in reducing co-payments – the amount that patients have to pay – for GP visits. In addition, PHOs have used Services to Increase Access funding to reduce non-financial barriers to accessing primary health care services.\(^9\)

The implementation of the Primary Health Care Strategy has also resulted in a reduction in the costs of access to medicines. All New Zealanders are eligible to be enrolled in a PHO when they visit a GP. By July 2007 all those who are enrolled will pay a maximum of $3 for each prescription item that is on the Pharmaceutical Schedule. This is considerably less than in comparator countries.

The cost of prescription items that are partially subsidised comprises a co-payment, the manufacturer’s surcharge (the difference between the level of government subsidy and the manufacturer’s price) and any mark-up that the dispensing pharmacy charges.

**Box 7: Costs of prescription items in Australia**

Under Australia’s Pharmaceutical Benefits Scheme (PBS), ‘general’ patients pay the first $29.50 for each PBS item up to a total of $960.10 for the individual and their immediate family, after which they pay $4.70 per item for the remainder of the calendar year. ‘Concessional’ patients – including people on low incomes, sickness beneficiaries and retirees – pay $4.70 per item up to a total of $253.80 for themselves and their immediate family, after which they pay no co-payment for the remainder of the calendar year.

The public subsidy of individual products through listing on the Pharmaceutical Schedule is an important issue for many stakeholders, and one that frequently attracts public attention.

In designing systems, structures and processes to support good access to medicines, all the principles identified in the proposed strategic framework need to be considered, applied and balanced. This document proposes that action on the following four issues will contribute to the access objective of the proposed Medicines Strategy, and that these issues should be progressed first:

- develop a principles-based and collaborative approach to setting the community pharmaceuticals budget
- improve the understanding of public funding decisions about medicines
- examine the criteria to underpin decisions about high-cost medicines for small groups of New Zealanders.
- develop a sustainable and robust approach to providing access to vaccines.

**Community pharmaceuticals budget**

A key issue in the procurement and management of medicines is how to ensure the right (optimal) amount of money is spent on pharmaceuticals. This includes how to make trade-offs between expenditure on medicines and other health services in order to achieve the best health gain for New Zealanders.

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\(^9\) More information on the Primary Health Care Strategy and PHOs is available on the Ministry of Health’s website (www.moh.govt.nz/primaryhealthcare).
Pharmac, through the community pharmaceuticals budget, manages the bulk of expenditure on pharmaceuticals – $600 million in 2006/07. The process for determining the community pharmaceuticals budget is the focus of this section.

**How is the community pharmaceutical budget currently set?**

Funding for community pharmaceuticals is held by DHBs and managed by Pharmac on their behalf. DHBs are accountable for managing within their overall budgets, and their accounts are charged for pharmaceuticals used by their populations. DHBs face the actual costs of spending on pharmaceuticals, and hold and manage their own funds. DHBs can therefore adjust their budget for their own financial management purposes. Each DHB faces incentives to get the best value for the money they spend on pharmaceuticals. The relationship between DHBs and Pharmac is effectively one of Principal – the DHBs and Agent – Pharmac.

Expenditure on pharmaceuticals is determined by price and quantity effects, and Pharmac seeks to influence both through various techniques in its demand-side and supply-side interventions. Pharmac decides which medicines to subsidise, determines access to subsidies, and negotiates with pharmaceutical companies over prices and subsidies.

DHBs and Pharmac work together to agree on the pharmaceutical budget, and make a joint recommendation on the budget to the Minister of Health. The Ministry of Health then advises the Minister of Health on the proposed ‘notional pharmaceutical budget’ put forward by Pharmac and the DHBs. The recommendation to the Minister of Health includes funding for the current year, and indicative funding for the following two out-years. This three-year funding path is designed to assist Pharmac and the industry in their planning by providing a signal about the future level of the community pharmaceutical budget.

Reaching agreement on the community pharmaceutical budget is complex, and DHBs and Pharmac have had difficulty settling the indicative out-year figures in particular. In response, the Minister of Health has agreed that the out-year indications can be a range. This recognises that out-year indications are estimates, and there is invariably a range around any particular figure. In setting the two out-year budgets, the Minister of Health has asked DHBs and Pharmac to recognise the need to:

- maximise the benefits from investment in community pharmaceuticals
- align incentives across the sector
- improve access to existing and new medicines
- ensure that boards remain within overall funding parameters.

Pharmac and DHBs bring different perspectives to the budget-setting process, as follows.

- DHBs, in managing their budgets, consider how best to allocate their funding to achieve their strategic priorities, which are based on an assessment of the health needs of their populations. These decisions involve determining the correct balance of expenditure on pharmaceuticals versus expenditure on other services to achieve their strategic priorities.
• DHBs are funded according to the characteristics of their populations using the population-based funding formula.\(^{10}\) This is adjusted annually by an amount sufficient to fund price and technology growth. DHBs also receive adjustments for demographic changes in their population.\(^{11}\) Any increases in pharmaceutical expenditure need to be balanced against investment in other service priorities.

• Pharmac is expert in managing expenditure on pharmaceuticals, including forecasting growth in demand, likely savings and potential new investments.

The parties consult each other during the budget-setting process and this gives DHBs access to scarce forecasting expertise offered by Pharmac, since it has the best information on the impact of its activities on spending. The process also ensures that the national pharmaceutical expenditure that Pharmac is managing is consistent with DHBs' budgets and priorities.

A new approach

The key issue in setting the budget is how to prioritise expenditure on medicines and other health services in order to achieve the best overall health gain for DHBs' populations. Although the structural arrangements for the budget are in place, improvements can be made to the process.

Having Pharmac manage the notional budget on behalf of DHBs, and allowing DHBs to manage their pharmaceutical expenditure within the whole population-based funding budget allocated to them, works relatively well in practice and is consistent with the overall structures and accountabilities in the sector. Alternatives, such as ring-fencing pharmaceutical expenditure, are not recommended because such arrangements would constrain the ability of DHBs to allocate resources efficiently and effectively across different services; and would remove incentives to identify efficiencies. Also, the ring-fenced funding could only be used for pharmaceuticals, even when greater benefits might be gained from spending money in other areas (eg, preventive care, surgery). Within the existing structural arrangements, there is the ability to improve the way the budget is set, and the principles proposed in this document can be usefully applied to the process.

It would be more helpful if the DHBs and Pharmac discussed setting the budget using consistent principles. There is certainly good will between the DHBs and Pharmac in terms of working together to agree the community pharmaceutical budget. They do, however, consider the budget from quite different perspectives. DHBs have a strong focus on affordability, while Pharmac contributes predictions of beneficial expenditure. These two approaches need to be balanced. At present, the different approaches do not facilitate debate over the forecasting methodology and assumptions about the future. Applying consistent principles would help DHBs and Pharmac to jointly arrive at their best estimate of future expenditure.

\(^{10}\) A description of the population-based funding formula can be found on the Ministry of Health website (www.moh.govt.nz).

\(^{11}\) The allocation of demographic funding to DHBs varies according to whether the overall budget for the DHB matches its fair share of national funding according to the population-based funding formula. Some DHBs are in the process of moving to their fair share and thus may not receive funding increases for demographic growth.
Currently, the Minister of Health approves the community pharmaceutical budget, given its magnitude, and the accountability of Pharmac to the Minister for performing its functions. The Minister of Health has a keen interest in ensuring the best health gains from pharmaceuticals and other health expenditure, and in ensuring that the decisions made by DHBs and Pharmac deliver health benefits in the key areas identified for improvement by government health policy.

The Commonwealth Fund’s recently published *Taking a Walk on the Supply Side: 10 steps to control health care costs* identified the negotiation of pharmaceutical prices as a key step for the United States in managing the amount the US Government spends on health care (Davis 2006). Australian academics such as Stephen Leeder, professor of health policy at the University of Sydney, have also picked up the Commonwealth Fund’s conclusions, stressing the importance of the Australian Government in controlling pharmaceutical prices (Leeder 2005).

A cap on the notional community pharmaceutical budget is appropriate, in terms of managing community pharmaceutical expenditure, providing incentives to both DHBs and Pharmac to ensure value for money from expenditure on pharmaceuticals, and supporting the commercial negotiating environment for pharmaceuticals. Experience internationally where budget ceilings for pharmaceuticals have been removed is that there has often been a corresponding increase in pharmaceutical expenditure (eg, Germany).

It is recommended that DHBs and Pharmac employ a more explicit and transparent process to setting the community pharmaceutical budget, while using the same set of principles or assumptions. The DHBs and Pharmac could then demonstrate to the Minister of Health how these principles have been applied in making a recommendation on the proposed community pharmaceutical budget.

In summary, it is proposed that the budget-setting process build on the current structures and evolve to being principles-based. This entails recommending that:

- DHBs continue to be responsible for managing their pharmaceutical expenditure within the whole population-based funding budget allocated to them, and continue to be charged for the actual pharmaceutical expenditure of their population
- Pharmac continues to manage the community pharmaceutical budget as an agent of DHBs
- DHBs progressively improve their prioritisation work across areas of health spending, with a view to ensuring an optimal level of expenditure on pharmaceuticals
- the notional community pharmaceutical budget remains capped and approved by the Minister of Health
- DHBs and Pharmac continue to collaborate on making a joint recommendation to the Minister of Health on the notional level of the community pharmaceutical budget for the current year and indicatively for the next two out-years (ie, a three-year funding path)
• DHBs and Pharmac explicitly base their recommendations to the Minister of Health on the following principles:
  – *value for money* – including taking into account:
    o forecasts of potential volume growth
    o the potential for new investments
    o government health priorities
    o opportunities for disinvestment
    o maximising the benefits of pharmaceutical spending relative to spending on other health-related services (ie, how effective is spending money on medicines in improving health status compared to other expenditure?)
  – *affordability* – this means ensuring that DHBs are able to remain within their overall funding parameters: the budget must be sustainable, in terms of increased access to medicines, the effects of government priorities (eg, PHOs), and the fiscal impact on DHBs
• DHBs and Pharmac, when they recommend the budget to the Minister of Health, move to providing information on how they have applied the above principles.

As the new approach proposed here becomes imbedded and DHB prioritisation develops, it may not be necessary for the Minister to approve the community pharmaceutical budget. The Minister would need to have confidence in the information provided by DHBs and Pharmac as to how they have arrived at the budget, as the budget will remain significant. While Pharmac is directly accountable to the Minister of Health, in practice, it also operates as an agent of the DHBs. If the Minister were to be removed from the budget-setting process, DHBs would become responsible for deciding how best to allocate funding to all inputs, including medicines, to get the best health outcomes.

**Q8.** Do you agree that the current budget-setting process for community pharmaceuticals is generally working well, in practice, but could be improved by having Pharmac and DHBs use a set of agreed principles to make a joint recommendation to the Minister of Health on the level of the budget? If not, why not?

**Q9.** Do you consider value for money/cost-effectiveness and affordability are useful principles for Pharmac and DHBs to apply in making a recommendation to the Minister on the proposed community pharmaceutical budget? Are there other principles you consider should also be applied? If so, what are these and why should they be considered?

**Q10.** Is a three-year funding path helpful? If not, why not? What improvements do you suggest?

**Q11.** Do you have any other comments on the proposed process for setting the community pharmaceutical budget?
Making decisions about funding medicines

Within the overall budget for medicines determined between DHBs and Pharmac, decisions need to be made about which medicines to fund. This involves prioritising among different medicines, taking into account other ways to treat, and overall health outcomes. These are difficult decisions, which need to be made according to robust criteria. The decisions lead into commercial negotiations between Pharmac and the pharmaceutical companies.

When making decisions about which medicines should be publicly funded, assessments need to be made of the clinical effectiveness (including the risks and benefits) and cost-effectiveness of a medicine, and its affordability. These factors interact with each other, and a change in one can affect the balance across the others.

The central role of the PTAC is discussed in this section, followed by the broader issue of transparency of decision-making.

Pharmacology and Therapeutics Advisory Committee

PTAC plays a pivotal role in the chain of events that leads to a decision by the Pharmac Board to fund, or not to fund, a medicine. PTAC provides advice to Pharmac on pharmaceuticals and their benefits. It is important that this advice is high quality. Important elements of high-quality advice (and ensuring trust and confidence in the overall system) are that the advice is free and frank, and that it is well informed by all relevant factors.

The design of the structural arrangements between Pharmac and PTAC are important to achieving this balance. The two need to be close enough to realise the benefits of sharing information, while being careful that there is no undue emphasis placed on any one factor in decision-making. For example, while the affordability of a medicine is a core concern, making decisions about affordability ultimately fall to the Pharmac Board, not PTAC.

The current system aims to achieve this balance in the following ways.

- Pharmac and PTAC have different roles – the former is responsible for making decisions and negotiating the supply of medicines within a fixed budget; the latter is advisory. Pharmac is not bound by PTAC’s advice or recommendations and the Board may make a different decision. Sometimes this can result from PTAC reviewing funding applications at a different stage in the assessment process from Pharmac. Pharmac may also have a wider range of relevant information before it (eg, cost–benefit data) when it makes decisions. Pharmac may therefore attach a different listing priority or may make a decision that differs from PTAC’s recommendations.

- PTAC members are appointed and removed by the Director-General of Health in consultation with the Pharmac Board. Appointments are made according to the Protocol for the Appointment of Members of the Pharmacology and Therapeutics Advisory Committee. It is important that Pharmac has some involvement in the appointment of members to PTAC because PTAC’s advice is intended to inform Pharmac’s decision-making and Pharmac is well placed to judge the quality of that advice and the requirements of the work.
- Nominations for PTAC membership are called for publicly, and industry, health practitioner groups, consumer groups and others have the ability to make nominations.

- Neither Pharmac Board members nor the Pharmac staff that assist PTAC have any voting rights with regard to recommendations made by PTAC. Only PTAC members have the right to vote on the recommendations they make.

- Members of PTAC and its sub-committees are required to declare any potential conflicts of interest, and the chairperson of these committees may disqualify a member from voting on particular proceedings.

These arrangements allow for PTAC to provide free and frank advice, while not incurring the costs of having the committee as a separate organisation. They also allow for the mutual benefits of a relationship with Pharmac to be realised. The close working relationship that Pharmac currently has with PTAC enables a valuable exchange of information. For example, the attendance of the PTAC chair as an observer at Pharmac Board meetings ensures that PTAC’s views are well understood and allows board members to clarify points of uncertainty. Pharmac board members also frequently ask the PTAC chair for his/her views.

PTAC uses the same decision-making criteria as Pharmac, with PTAC ‘giving weight to each criterion as PTAC considers appropriate’ (Pharmac 2002b). The weight given to each criterion may differ between PTAC and the Pharmac Board according to the expertise of each. For example, PTAC is charged with providing advice on pharmaceuticals and their benefits, and considers cost-effectiveness in this context. PTAC is thus focused on clinical matters, but also considers cost issues. Pharmac is responsible for procuring medicines within the funding available and is therefore weighted toward health gains in the light of budgetary impacts.

Use of the same criteria by PTAC and the Pharmac Board ensures PTAC’s recommendations are based on the same set of factors the Board will weigh up. If PTAC’s criteria were different to Pharmac’s, a further process of integrating PTAC’s advice into a different decision-making framework would be required. Pharmac would probably need to recruit additional clinical experts (or use a further expert committee) to help merge PTAC’s recommendations with other decision-making criteria that Pharmac is required to consider.

Clinical effectiveness and cost-effectiveness

Some stakeholders have questioned whether the quality of PTAC’s clinical advice risks being compromised given that the Committee also considers the cost implications of its clinical recommendations. PTAC is primarily focused on the clinical evidence provided to support a funding application for a particular medicine, incorporating both health needs of patients and the clinical effectiveness of treatment (and alternative treatments), but it also considers the cost of achieving that effectiveness through subsidised access.
However, this broader focus means that PTAC’s advice is not disconnected from the practical reality that, for example, while some medicines are highly clinically effective they may also be highly unaffordable. This broader responsibility comes with the power to consult widely and seek evidence from whatever parties PTAC considers necessary or appropriate.12

PTAC’s approach is consistent with modern clinical practice, where even the most clinically focused health practitioners are aware of the cost and opportunity cost of treatment. Research published by the National Health Committee in 2006 found that:

... a number of managers commented on the increasingly budget-conscious and responsible attitudes expressed by the clinicians they work with. Very few clinicians thought that they could fund any intervention for a patient regardless of the cost of the intervention itself and the impact on the rest of the hospital (National Health Committee 2006).

While PTAC is ultimately a clinically focused committee and interested in improving the health of New Zealanders, resource implications of any decisions are never far from the debate. This is a reality for any prioritisation model.

International comparisons

Australia and the United Kingdom have institutions similar to PTAC to review the clinical effectiveness of pharmaceuticals. In both countries these institutions also consider cost-effectiveness as part of their recommendations.

In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC) manages the Pharmaceutical Benefit Schedule. PBAC has two sub-committees – an economic sub-committee and a drug utilisation sub-committee – which consider major submissions to PBAC.13 PBAC considers the sub-committees’ findings and may seek further external expert opinion. The sub-committees’ findings are not binding on PBAC.

In the United Kingdom, the Technology Appraisal Committee (TAC) considers suppliers’ submissions as well as clinical and cost-effectiveness evaluations, which the National Institute for Clinical Excellence (NICE)14 contracts academic organisations/ universities to complete. TAC provides recommendations to NICE on the basis of this information but NICE is not bound by TAC’s recommendations.

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12 This is subject to confidentiality provisions under the Guidelines for the Pharmacology and Therapeutics Advisory Committee (PTAC) and its Sub-Committees.

13 Major submissions include applications to PBAC to: list a new drug on the Schedule of Pharmaceutical Benefits; request a significant change to the listing of a currently restricted drug (including a new indication or a de-restriction); enable a review of the comparative cost-effectiveness of a currently listed drug in order to change a PBAC recommendation to the Pharmaceutical Benefits Pricing Authority on its therapeutic relativity or price premium; list a new formulation (or strength) of a currently listed drug for which a price premium is requested; or list a new fixed combination product.

14 NICE reviews new and existing technologies (including pharmaceuticals) likely to have significant budgetary impact and where there is controversy over effectiveness. It is the independent organisation responsible for providing guidance on treatments and care of people using the National Health Service in England and Wales.
Summary

Stakeholders need to have trust and confidence that the relationship between PTAC and Pharmac works well and that the decision-making process is robust. In this context, Pharmac is currently updating PTAC’s guidelines and assessing the process for how it obtains advice from PTAC. Consultation would be required for any changes to the guidelines. The next section also addresses options for improving the transparency of the decision-making process to further enhance confidence in it.

Understanding how decisions get made

Understanding how decisions are made is important for public trust and confidence in the decision-making process. This is particularly so where the process involves making difficult choices about which services and products will be provided to the public and which will not (Ministry of Health and DHBNZ 2005). However, making prioritisation decisions is difficult and complex.

The Pharmac Board is appointed to make, on behalf of New Zealanders, difficult judgements and trade-offs about the funding of medicines. These decisions need to be made using a robust and consistent process; it involves applying the decision-making criteria to the specific circumstances of each decision. While confidence can be gained from the same process being followed each time, over time, decisions will inevitably be influenced by changes in the circumstances in which they are made. For example, at any one time, there may be different levels of funding available, different numbers of competing proposals, and differences in the comparative strength of the funding proposals that have been submitted.

Transparency around how individual decisions have been made is likely to show different outcomes over time. Making prioritisation decisions is not a mechanistic process, it involves applying the decision-making criteria to the specific circumstances of each decision using the best information available. The final decision will reflect the best judgement at a point in time about the balance between the decision-making criteria. This is a very difficult process and one that will, necessarily given different circumstances, result in different outcomes for different medicines even where the same decision-making criteria have been used. This fact of prioritisation is often not well articulated or understood.

If stakeholders understand the reasons why, and the basis on which, decisions are made, and if they are engaged in the decision-making process, it increases the likelihood that they will have trust and confidence in the decision makers, and that decisions will be accepted as reasonable. While this is partly due to the ability of stakeholders to affect the decision-making process, transparent decision-making that engages stakeholders can also lead to a greater appreciation of the issues involved in priority setting and recognition of the need for compromises and making difficult decisions.
Low trust and confidence among any stakeholder group does not necessarily mean that a decision-making process is at fault, or that any particular decision should not go ahead but it may signal that further consultation and consideration of the interests of stakeholders is warranted. On the assumption that views have been fully considered, it may, however, also simply reflect that stakeholders’ views, while important, will not always align with the public interest that the decision-making process is designed to protect.

The current process
Some stakeholders have questioned how and why decisions get made, and have raised concern that they do not understand the current processes. The current system contains the following features designed to increase stakeholder understanding of how decisions are made.

- Pharmac’s website advises when it has received an application to fund a medicine.
- Minutes from PTAC meetings are available on the Pharmac website. They provide a simple priority ranking for the funding of medicines, which is designed to be easily understandable. Because PTAC considers commercially sensitive information, the contents of minutes need to be carefully considered. Pharmaceutical suppliers have the opportunity to request that any or all of a minute be withheld under the relevant provisions of the Official Information Act 1982 before it is posted on Pharmac’s website. Pharmac can also decide to withhold any elements of a minute on grounds of commercial confidentiality, and is guided by the principles and withholding grounds of the Official Information Act 1982 in doing so.
- Observers may attend and speak at PTAC meetings, at the discretion of the chairperson and Pharmac’s Medical Director (Pharmac 2002b). Observers may be required to sign confidentiality agreements prior to attending any meeting due to the commercial sensitivity of the information to be discussed. Pharmac board members have attended PTAC meetings on two occasions in the last seven years to observe and understand the committee’s work.
- Pharmac consults on its decision-making processes, such as its Operating Policies and Procedures and Prescription for Pharmacoconomic Analysis (Pharmac 2006b; Pharmac 2006c). It also consults on its decisions to fund or not fund medicines. The Board considers feedback on proposed changes to the Pharmaceutical Schedule from industry, and clinical and patient groups, alongside applications for funding.
- Pharmac’s decision-making criteria are publicly available (see Box 5).
- Pharmac disseminates economic analyses of products to all DHBs on behalf of DHB hospitals as part of the hospital pharmaceutical assessment process. DHBs can access these assessments via a secure website, and the assessments are sent to the pharmaceutical product supplier.
- Pharmac engages with the product supplier when listing a medicine on the Pharmaceutical Schedule. Every listing requires an agreement with the supplier, which covers a range of issues in considerable detail.\textsuperscript{15}

\textsuperscript{15} The kinds of issues covered include: the type of pharmaceutical, price, community and/or hospital listing, special terms of listing of pharmaceuticals, distribution arrangements, change of brand name, assignment, consents, confidentiality, dispute resolution and termination.
• On request (and subject to commercial restraints), Pharmac provides patients and patient groups with updates on the funding status of medicines. Pharmac also meets with members of the public to discuss medicine funding issues when requested.

• Pharmac has a consumer advisory committee and a Māori caucus.

• Pharmac uses opportunities to informally explain its processes and decisions by accepting, where possible, invitations to speak publicly at health professional conferences and teaching sessions, through to suburban patient group meetings. Pharmac engages with the media when announcing funding decisions to publicly explain its decisions.

**Increasing transparency – striking the right balance**

There is an inherent tension between public transparency on one hand and conducting commercial negotiations in order to achieve the best health outcomes on the other. Complete public transparency has the potential to adversely affect both parties in the negotiation although quantifying this effect is problematic. Complete disclosure of commercial information may compromise Pharmac’s ability to retain a competitive pharmaceutical market and so achieve best health outcomes from within available funding. For example, tendering relies on competing pharmaceutical companies not having full information as to what rival companies may be offering. Similarly, Pharmac’s negotiating power would be compromised by publicly committing to funding a specific list of pharmaceutical products prior to negotiating prices. In the interests of securing lower medicine prices and thus improving access to medicines, a degree of flexibility over information disclosure is justified.

Moves to create greater transparency are also likely to have associated costs in terms of time and resources. While transparent decision-making may contribute to the effectiveness of an organisation by promoting stakeholder co-operation, there comes a point at which the marginal gains from transparency are outweighed by the time and resources expended.

The potential long-term effects of complete transparency also need to be considered. If Pharmac was required to explain its decisions in a very detailed way, stakeholders would be likely to focus on specific metrics or hurdles, such as a cost-per-QALY funding threshold. Pharmac may then be criticised for funding one medicine at a particular threshold, but not another at the same level. Taking other decision criteria into account and given other changes in circumstance, such a decision may be appropriate. However, it needs to be recognised that, while the way in which different decisions are reached could be explained, the judgements are subtle in nature.

The desire for transparency in decision-making needs to be balanced against the risk of increasing pressure over time for Pharmac to operate a much more mechanistic decision-making process. Thresholds or particular targets – while well-intentioned – will invariably not be suitable for all circumstances that arise. They can also incentivise pharmaceutical companies to pitch at or around those targets when, in their absence, a better outcome may be possible. Further, a mechanistic process may not, in its strict application, lend itself to commercial negotiations that result in the best use of health funding.
There is no definitive guide for the right level of transparency in a public sector organisation. As outlined above, transparent decision-making is important for public trust and confidence in decision-making processes. However, in seeking greater transparency, this benefit needs to be carefully weighed against the potential costs of compromising commercial negotiations and health outcomes. In addition, there are other checks and balances on Pharmac’s decision-making process that can contribute to trust and confidence. These include the option of judicial review of Pharmac’s decisions, and the Ministry of Health’s role, as the Minister’s agent, in monitoring Pharmac’s performance.

It is clear, therefore, that there are advantages and disadvantages to changes, which need to be weighed up. In addition, the long-term effects of change need to be considered. Subject to this analysis, the Ministry considers there may be opportunities to increase the transparency of the current decision-making processes, including the following options:

- **Option 1**: release a document that describes the reasons for individual medicine funding decisions. This approach has recently been introduced in Australia, where public summary documents of all pharmaceutical funding decisions by the Pharmaceutical Benefits Advisory Committee are published on the Department of Health and Ageing website.\(^{16}\) The documents are one-to-seven pages in length and include a section for the sponsor of the product to comment on the decision. Papers like this could explain the reasoning behind decisions by the Pharmac Board once made, and could identify any additional criteria that Pharmac has considered in the process of reaching its decision. The level of detail and the timing of any documents would need to be carefully considered – including the impact on resources and legal risks. Consideration of this option should be informed by an analysis of the experience of medicines system stakeholders in Australia in relation to PBAC’s public summary documents.

- **Option 2**: publish a summary of the cost-utility analysis on the Pharmac website.

- **Option 3**: widen the opportunities for product suppliers to present information to PTAC.

- **Option 4**: provide fuller responses to those who respond to Pharmac’s consultation on listing particular medicines.

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Q12. What are your views on the options proposed to increase the understanding of decision-making?

Q13. Do you have any further suggestions about the provision of free and frank advice to the decision-making process?

Q14. What, if any, experience have you had of the public summary documents produced in Australia? Do you think the public summary documents assist people to better understand the decision-making process?

Q15. Are there any other options you consider would be useful to pursue? Please describe these and explain how they would increase understanding of decision-making.

Making decisions about high-cost medicines

As noted earlier in this document, although conditions such as cardiovascular disease account for a large part of the burden of disease in New Zealand, there are also much smaller groups that suffer significant ill health. In some cases, there are treatments available for the conditions affecting these groups, but they are often high cost. Decisions about funding high-cost medicines – those with an annual per patient cost of several tens of thousands to over a hundred thousand dollars – often attract considerable attention because they involve decisions about what is, in many cases, the last effective option for people who are very unwell, often with rare conditions.

Pharmac has recently considered how it assesses and funds high-cost medicines. Pharmac undertook this work because it recognised that high-cost medicines are rarely cost-effective and that the application of the cost-effectiveness criteria in the decision-making process makes it unlikely that these medicines will be funded.

As noted in Chapter 3 of this document, the Pharmac Board does not set a threshold for funding medicines. Instead, the Board makes decisions about funding each medicine according to the nine decision-making criteria. Pharmac has funded medicines on the Pharmaceutical Schedule up to $180,000 per quality adjusted life year, however, the average cost per QALY of the medicines it funds has been approximately $7,000 per quality adjusted life year.

Pharmac is charged with achieving the best health outcomes for the population within the funding available. However, the population approach to the provision of services needs to be balanced alongside the Government’s responsibility to perform an insurance function, protecting New Zealand citizens from substantial financial costs due to ill health. This is a difficult balance that has significant implications for people who are affected by conditions for which the treatment costs are prohibitively high and for treatments that may not be very effective.

The current system provides to some extent for these cases through Pharmac’s three medicines exceptional circumstances schemes (described in Chapter 3). In addition, the Special High Cost Treatment Pool administered by the Ministry of Health provides for one-off treatments not otherwise funded by the public health system.
In order to assess the fairness of its current approach to funding medicines, Pharmac commissioned philosophical and economic analyses of how it assesses and funds high-cost medicines. Pharmac will soon be releasing a consultation document that will describe the issues at the heart of decision-making about high-cost medicines and some of the thinking that has informed Pharmac’s work to date in what is a complex area. Pharmac will invite comments on the issues raised in its consultation document.

The Ministry appreciates Pharmac’s work in this complex area and encourages you to participate in its consultation process. The Ministry has a keen interest in Pharmac’s analyses of the issues associated with decisions about high-cost medicines, the outcomes of Pharmac’s consultation, and any decisions that Pharmac makes on the basis of this process.

The Ministry of Health encourages you to read Pharmac’s consultation paper and provide your thoughts on this complicated issue to Pharmac. The Ministry looks forward to Pharmac’s consultation paper and Pharmac’s report on the feedback it receives.

Access to vaccines

General vaccines
Vaccines are an important part of programmes to prevent ill health, particularly in children. Publicly funded vaccines are different from other medicines in a number of respects; notably they are usually given population-wide to healthy people and often protect against a number of conditions. In order to be effective on a population-wide basis, it is necessary for most vaccines to be given to a high percentage of the population.

However, vaccines also have a lot in common with other medicines. As with other medicines, vaccines are subject to a series of decisions before they become available to the community, and key decisions are separated – such as consideration of the clinical and cost effectiveness of a vaccine and the decision to fund the vaccine. The processes used to determine the safety, quality and clinical efficacy of vaccines are also the same as those used for medicines. Medsafe is responsible for assessing the characteristics of any new vaccine and determining whether it should be made available on the New Zealand market.

The publicly funded vaccines the Ministry recommends be provided to patients are set out in the National Immunisation Schedule. Every two years the Ministry of Health’s Immunisation Technical Working Group (ITWG) makes technical recommendations to the Ministry about which vaccines it considers should be listed on the National Immunisation Schedule. The ITWG comprises paediatricians, other physicians, GPs and nurses.

The ITWG considers a range of factors when considering changes to the National Immunisation Schedule. These include New Zealand vaccine-preventable disease epidemiology, advances in vaccinology, the increased availability of combination vaccines, and the sector’s capacity to administer an additional vaccine.
Funding for vaccines on the National Immunisation Schedule is held by the Ministry of Health, which considers the funding and administration implications of the ITWG’s recommendations. Unlike for medicines, there is no dedicated budget for vaccines within which funding decisions are made. While funding for vaccines that are already being used is guaranteed from year to year, funding for new vaccines and price increases of existing vaccines have to be sought from within Vote Health generally. Funding for vaccines on the National Immunisation Schedule is therefore prioritised against spending on other public health initiatives.

A variety of factors determine the cost of vaccine purchases, including:

- changing disease patterns (eg, influenza and meningococcal)
- other changes to the National Immunisation Schedule
- manufacturers’ changes (eg, discontinuation, changed formulation, combined vaccines, polyvalent vaccines)
- New Zealand’s purchasing power on the international market
- the agent’s ability to influence contracts for supply
- currency exchange rates and inflationary factors.

The Minister of Health, under the Health (Immunisation) Regulations 1995, must approve any changes to the National Immunisation Schedule.

Although the Ministry of Health is responsible for funding the actual vaccine, as well as outreach immunisation services and the immunisation co-ordination contract, DHBs pay the ‘immunisation benefit’ – a fee for administering the vaccine – to the vaccine administrator, either a GP or a nurse. DHBs have identified a number of issues associated with planning and funding immunisation services, service delivery, and monitoring immunisation coverage, and are leading a project that involves the Ministry of Health to address these.

The Ministry contracts externally for the procurement and management of vaccines once they arrive in New Zealand. The contractor undertakes tendering, contracting with manufacturers, storage and distribution for all publicly funded vaccines except the influenza vaccine.

Initiatives to ensure the optimal use of vaccines, including vaccine promotion activities and programmes to improve vaccine coverage, are currently undertaken by a range of organisations, including the Ministry of Health’s Public Health Directorate, local public health services, and the Immunisation Advisory Centre. In addition, the New Zealand Pharmacovigilance Centre, through its National Toxicology Group’s Centre for Adverse Reactions Monitoring, monitors reports on all clinically significant events following immunisation.
Influenza vaccine

The management and procurement of the influenza vaccine is the exception to the process described above. Unlike other vaccines on the National Immunisation Schedule, which are only available to people who meet the eligibility criteria, the influenza vaccine is purchased for both the public and private market. The vaccine has been approved by the Ministry of Health for public funding for specific categories of people, but those who fall outside that group are still able to access the vaccine if they are willing to pay for it.

Because DHBs hold the immunisation benefit funding, and the administration of the influenza vaccine is more closely linked to their business, DHBs manage the funding and administration of this vaccine. From 2005, Pharmac has sourced the influenza vaccine on behalf of DHBs.

A new approach

In examining the medicines system, questions have been raised as to whether vaccines for public health benefit should continue to be considered separately from other medicines. This section analyses the decision-making process according to the principles proposed for the Medicines Strategy.

Trust and confidence

As we have discussed above, trust and confidence are encouraged when decision-making processes and criteria are clear. Although information about the ITWG’s decisions may be requested under the Official Information Act 1982, its processes for decision-making are not publicly available or consulted upon. In the absence of such transparency it is difficult for stakeholders to determine how decisions are reached.

Value for money

The ITWG carries out the equivalent role for vaccines as PTAC does for medicines. Both make recommendations on whether the therapeutic products under their consideration should be considered for inclusion on the National Immunisation Schedule and the Pharmaceutical Schedule, respectively. This raises the question of whether it would be more efficient for Pharmac to provide for the ITWG some of the services that are currently provided or contracted for by the Ministry of Health. For example, cost–utility information provided by vaccine suppliers to the ITWG is currently reviewed under contract. Pharmac has considerable expertise in the area of cost–utility analyses, and there may be advantages to making this resource available to the ITWG and thereby potentially reducing the costs of administering the system.

Although DHBs agree with Pharmac on, and fund, the budget for medicine purchases, there is no set budget for the procurement of new vaccines. Instead, as described above, requests for funding for new vaccines are considered by the Ministry of Health alongside those for other public health initiatives. The population-wide nature of immunisation services means that responsibility and funding for vaccine programmes has not been devolved to DHBs.
As with medicines, vaccines are becoming increasingly expensive. It is therefore becoming increasingly difficult to secure funding for new vaccines and for more recent and effective versions of vaccines that have been in use for some time. As an example, the budget for publicly funded vaccines is currently $15.5 million, while it has been estimated that the cost of the new pneumococcal vaccine, if it was recommended for inclusion on the schedule, would be $23 million.

Under the Medicines Strategy work programme, options for the ongoing funding of vaccines, and approaches to prioritising vaccine funding against other health services, could be explored.

The most efficient approach to procuring vaccines is also an issue. The Ministry of Health currently contracts an external provider, and this provider has developed relationships with vaccine suppliers and experience in negotiating the terms of supply. However, Pharmac has gained considerable experience in negotiating for the supply of therapeutic products and medicines. It has been suggested that greater consideration be given to identifying the most appropriate agency to undertake procurement, in order to get the lowest vaccine price and minimise duplication in the system, while still guaranteeing supply.

| Q16. Do you agree that decision-making about vaccines should be more transparent? If not, why not? |
| Q17. Do you agree that consideration should be given to the best arrangements for supporting the Immunisation Technical Working Group process? If not, why not? |
| Q18. Do you agree that options for the ongoing funding of vaccines should be explored? If not, why not? |
| Q19. Do you agree that options for vaccine procurement should be explored? If not, why not? |
| Q20. Are there any other issues you consider are missing and should be addressed as a matter of priority to improve access to medicines? |

6.3 Optimal use of medicines

Optimal use means ensuring that choices about medicines, how the system delivers medicines and how individuals use medicines are safe and result in the best possible health gain. A broad range of activities contribute to ensuring the optimal use of medicines, including:

- considering the most suitable and cost-effective treatment for people, including non-medicinal alternatives
- considering the safety and appropriateness (including risks and benefits) of the medicine choice, and the dose and length of treatment, in relation to the person’s clinical need
- minimising the overuse, under-use and misuse of medicines
- ensuring that people use medicines in the way that was intended by the prescriber
- monitoring the outcomes of medicine use.
Optimal use greatly influences the extent to which New Zealanders benefit from the therapeutic effects of medicines. Despite the significant contribution that optimal-use activities can and do make to achieving the proposed goals of this strategy, they risk being an under-appreciated element of the medicines system. Optimal-use activities are crucial to ensuring that medicines that are assessed as being high quality, safe and efficacious are chosen, delivered and used in a safe way that ensures that their potential to improve health and prevent illness is maximised.

Put another way, optimal-use activities are concerned with ‘fidelity’, which is described as ‘the extent to which the system provides patients with the precise interventions they need, delivered properly, precisely when they need them’ (Woolf and Johnson 2005). This is synonymous with reliability, a concept that is receiving increasing attention internationally because it is recognised that the development of more effective treatments will only result in improved health outcomes if they are ‘delivered reliably to the people who need them’ (Kravitz 2005).

**Box 8: Health and Disability Commissioner case study**

The Health and Disability Commissioner investigates complaints of breaches of the Code of Health and Disability Services Consumers’ Rights. The Commissioner’s publicly available decisions reflect the range of ways that the incorrect prescription, dispensing and administration of medicines can occur, and the sometimes tragic consequences of these events. As an example, in 2004, a GP prescribed a medicine, used in migraine prevention, for a patient who had a migraine. The medicine was not supposed to be prescribed for people who also suffer from asthma, which the patient did. After taking the medicine, the patient suffered a severe asthma attack, went into cardiac arrest, and died.

Source: www.hdc.org.nz (case: 04HDC19938)

Unlike the activities described under the quality and access sections, optimal-use activities are diffuse and are the responsibility of a wide range of people and agencies, including individual prescribers, DHBs, Pharmac and the Ministry of Health.

An important group that has emerged in the sector to provide direction to the activities that fall under the optimal use banner is the DHBNZ Safe and Quality Use of Medicines Group (SQM). SQM stresses that better-designed systems and effective technology are required to ensure that medicines achieve their optimal outcomes.

All groups in the health sector need to work together to ensure the optimal use of medicines, and information sharing is essential to achieving co-ordination. SQM has a particular interest in improving the networking and exchange of information between different organisations and professional groups. To this end, SQM has established a website (www.safeuseofmedicines.co.nz) that displays ongoing work, can be accessed by anyone, and actively encourages DHBs to share information about the optimal use of medicines.

The activities of the SQM group focus primarily on the optimal use of medicines in hospitals. Initiatives to ensure the optimal use of medicines in community settings are currently undertaken by a range of organisations, but no organisation has specifically dedicated itself to co-ordinating this activity.
Optimal-use issues

The process by which drugs are administered to patients includes the following steps (Australian Pharmaceutical Advisory Council 2005):
1. a decision on appropriate treatment
2. decision to prescribe medicine
3. record of medicine order/prescription
4. review of medicine order/prescription
5. issue of medicine
6. provision of medicine information
7. distribution and storage
8. administration of medicine
9. monitor for response
10. transfer of verified information.

A broad range of factors influence whether medicines are chosen, delivered, and used in ways that are safe and enable people to experience their maximum benefit. This section identifies some of the factors that influence the extent to which the potential benefit of medicines is achieved, and in doing so identifies areas in which improvements in the optimal use of medicines could be made.

Safe and appropriate prescribing

Prescribers are responsible for choosing the safest and most appropriate medicines (including the dose and length of treatment) based on an individual’s clinical need. Evidence-based clinical guidelines have been developed to guide prescribers’ clinical decisions about the most appropriate treatment for particular clinical diagnoses. Clinical guidelines aim to ensure that prescribers’ decisions are informed by up-to-date information about the most effective ways of treating specific conditions and preventing ill health in at-risk individuals.

Despite the existence of guidelines, research suggests that people are not always being prescribed the medicines that evidence-based information indicates are most effective. For example, a study of the use of three major types of cardiovascular medications in a New Zealand primary care population in 2000 concluded that more than two-thirds of people in the studied population were not receiving medications recommended in New Zealand and international clinical guidelines (Rafter et al 2005).

More recent research suggests that although the prescribing of statins, one of the recommended medications for cardiovascular disease, has increased since 2000, significant treatment gaps remain – with only 74 percent of people with known cardiovascular disease on aspirin, 65 percent on a statin and 79 percent receiving blood pressure-lowering medication (Sinclair and Kerr 2006).
Research also suggests that prescribers’ decisions about treatment choices may contribute to inequalities in health outcomes, such as those described earlier in this document in terms of life expectancy. Indicators suggest that high-need groups currently under-utilise pharmaceuticals compared to their higher level of need. Research indicates that a lower percentage of Māori with a new diagnosis of chronic respiratory disease receive prescriptions for respiratory drugs compared with non-Māori (Crengle et al 2005). Similarly, research in an Auckland general practice found that Māori with depression were significantly less likely to be treated with antidepressant medication than non-Māori (Arroll et al 2002).

Safe and appropriate treatment choices can only be made when prescribers know what medications an individual is already taking and whether they have previously had any allergic or adverse reactions to medicines. In the absence of this information, a medicine may be prescribed that results in a harmful interaction with a medicine the person is already using, or an allergic response. There are some circumstances in which prescribers rely on people to remember their own medication history and accurately recall what medications they are using. This might be when someone is visiting a different general practice than usual or an accident and emergency clinic, or is having an emergency admission to hospital. Some people find it very difficult to recall what they are taking, particularly those who are on a number of different medicines for more than one condition, or who are very unwell. In these cases, prescribers’ choices may be based on incomplete information.

The interaction between prescription medicines, over-the-counter medicines and complementary medicines is also of concern. People may not always remember to tell their health practitioner about non-prescription medicines that they are taking, and in particular may not think that complementary medicines are of any interest or concern. This is risky. For example, extracts of the plant St John’s Wort have been used for a long time for a range of problems including depression, anxiety and sleep problems. There is good evidence that St John’s Wort can improve the symptoms of mild to moderate depression and it can be purchased from health-food stores and supermarkets. However, St John’s Wort can also interact seriously with other medicines. While there are no reported deaths associated with the use of St John’s Wort there is evidence that it interacts significantly with a number of medicines including those used to treat HIV infection, manage the risk of heart transplant rejection, prescription medicines for depression, and some migraine treatments. The interaction may reduce the activity of the prescription medicines leading to clinically important decreases in its effectiveness (www.cam.org.nz; http://www.medsafe.govt.nz/Profs/PUarticles/sjw.htm).

Medicine reviews ensure that people are receiving and taking the correct medicines and reduce undesirable medicine interactions. This is particularly important for people who are taking a number of medicines that are prescribed by a range of different health practitioners, and who may also be taking complementary and over-the-counter medicines.

Data from The Commonwealth Fund International Health Policy Survey 2005 (see Table 5) indicates half the New Zealand population does not receive a regular review of their
medication from their doctor.\textsuperscript{17} This is the lowest rate of medicine review reported in the survey (The Commonwealth Fund 2005).

The implementation of systems for regular medicine review would be particularly beneficial for hospital and aged-care facilities, where there are large numbers of patients receiving high volumes of medicines.

\textbf{Table 5:} Proportion of respondents who had a medicine review*

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Zealand</td>
<td>50/100</td>
</tr>
<tr>
<td>Australia</td>
<td>51/100</td>
</tr>
<tr>
<td>Canada</td>
<td>56/100</td>
</tr>
<tr>
<td>Germany</td>
<td>59/100</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>53/100</td>
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<tr>
<td>United States</td>
<td>58/100</td>
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</tbody>
</table>

* Respondents who had their doctors (or, in Australia, pharmacist) always/often review and discuss all the different medications used by the respondents, including medicines prescribed by other doctors.

\textbf{Accurate dispensing}

Human error can result in consumers in hospital and community settings being given the wrong medicine for their clinical need.

Table 6 demonstrates that annually 2.5 million prescriptions (9 percent of the total) are prescribed, dispensed or administered incorrectly in New Zealand. While this rate of medication error is equivalent to that of other countries, considerable improvements can obviously be made.

\textbf{Table 6:} Respondents given the wrong medication or wrong dose*

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Zealand</td>
<td>9/100</td>
</tr>
<tr>
<td>Australia</td>
<td>10/100</td>
</tr>
<tr>
<td>Canada</td>
<td>10/100</td>
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<tr>
<td>Germany</td>
<td>10/100</td>
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<tr>
<td>United Kingdom</td>
<td>10/100</td>
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<tr>
<td>United States</td>
<td>13/100</td>
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</table>

* Respondents given the wrong medication or wrong dose by a doctor, nurse, hospital or pharmacist when filling/collecting a prescription at a pharmacy or while hospitalised in the past two years.

\textsuperscript{17} Information about the increasing role of pharmacists in medicines management is included in Chapter 3.
Medicines reconciliation is the process by which the medicines a patient is receiving are checked against their medicines record. The process enables mistakes in the medicines administration process to be identified. While medicines reconciliation has been introduced in some settings in New Zealand, a systematic approach is required to ensure that it occurs reliably in the circumstances in which errors are likely to occur. Included amongst these is the interface between secondary and primary care when people leave the hospital to return to the care of their health practitioner in the community.

**Appropriate use**

The benefit that people receive from the medicines prescribed to them depends on the extent to which they use the medicine in the way the prescriber intended. This is known as ‘concordance’. Commonwealth Fund statistics indicate that almost half of the patient population in New Zealand do not take their medication as prescribed. This is the highest rate of all the countries represented (The Commonwealth Fund 2004).

A range of factors could contribute to this figure, including an inability to read the instructions on the packaging or a lack of understanding about what the instructions mean. Poor understanding of how medicines act to influence symptoms and illnesses can also result in incorrect use. Failing to take medicines according to prescriber’s instructions due to a lack of understanding is termed ‘unintentional non-adherence’.

It has also been identified that some consumers decide to use medicine in a way that differs from the prescriber’s instructions – this is referred to as intentional non-adherence. People adjust their dose or stop taking their medicines to experiment with the effects and side effects of medicines. In addition, people take combinations of medicines that they are not supposed to so that they can participate in certain activities (for example, use of anti-asthma remedies to enable physical activity) (Mossialos et al 2004).

Unintentional non-adherence can be improved by techniques that make it easier for people to remember to take their medicines, and which make explicit the benefits of following the prescriber’s instructions. Clear, simple instructions that are repeated frequently help to promote adherence (Mossialos et al 2004).

Statistics indicate that the clear communication of medicines-related information does not occur as reliably as it should. For example, while New Zealand leads the surveyed countries in explaining side-effects of medicines to consumers, approximately a third of all New Zealanders who receive prescriptions do not have the side-effects of the medications they have been prescribed explained to them (The Commonwealth Fund 2005).
Putting into practice the concept of concordance is essential if intentional non-adherence is to be reduced. Concordance specifies that “medicine taking should be the result of a mutually arrived at agreement between doctor and patient”. This is in contrast to the historical approach in which the patient was expected to comply with their health practitioner’s orders (Mossialos et al 2004). The concept of concordance is aligned with the increasing focus in New Zealand and internationally on encouraging patients to take a more active role in the management of their health. This culture change needs to be imbedded across health care settings and in the population.

**Medicine reactions**

Medicines have to meet certain standards of quality, safety and efficacy before they are approved for use in New Zealand. However, they may still prove to be unsafe and harmful to people who subsequently use them. This can occur because clinical trials of medicines are usually carried out with groups of people who have only the condition the medicine is designed to treat. Participants are selected on this basis to ensure that their response to the medicine being trialled is not confounded by other illnesses or medicines.

Many people in the general population have more than one condition, and are concurrently using more than one medicine. As a result, their responses to medicines may differ to those observed in clinical trials. In addition, clinical trials may be carried out over shorter periods of time than people end up receiving the medicine for, and some harmful effects are identified only after the medicine has been in use for a longer period than the course of the trial.

**Optimal-use initiatives**

The optimal use of medicines – in particular, improved medicines safety – will not be achieved by working the current system harder. It is crucial that there be improvements to the systems that are used to choose, dispense and administer medicines. Both improved systems and the use of effective technology are required to mitigate the impact of human error and harm, and to ensure that people benefit from the therapeutic effects of medicines (SQM 2005).

The following sections indicate the breadth of activity that is being carried out, or considered, in order to address the optimal-use issues described above. Some of these initiatives represent attempts to develop and put in place appropriate systems to ensure the optimal use of medicines. The initiatives include:

- supporting evidence-based prescribing
- reliable and accurate dispensing
- medicines management initiatives
- improved information about medicines
- monitoring
- medicines disposal.
Supporting evidence-based prescribing

Clinical guidelines have been developed to support best-practice prescribing by prescribers. The New Zealand Guidelines Group has adopted a number of strategies to address prescribers not using the clinical guidelines it produces (McKinlay et al 2004). In addition, BPACnz regularly provides information to prescribers on evidence-based health care interventions. The Primary Health Organisation Performance Management Programme, run collectively by DHBs in association with PHOs and the Ministry of Health, incentivises evidence-based prescribing for certain conditions. The programme provides rewards for PHOs that are moving towards targets that reflect best practice (eg, the percentage of people with asthma who are prescribed inhaled corticosteroids).

Despite these initiatives, it has recently been noted that there are few systems ‘that support the meaningful expression of guidelines into regular clinical practice’ in New Zealand (Sinclair and Kerr 2006). Further consideration of how this deficit could be addressed appears to be warranted.

Reducing inequalities

BPACnz has recently produced two bulletins on Māori culture and health to help address an identified gap in medical education about Māori culture. An Introduction to Te Ao – The Māori World (BPACnz 2006) notes the low uptake among Māori of prescribed medication and encourages prescribers to emphasise the importance of medicines and explore Māori consumers' beliefs and understanding in relation to this. The pamphlet also comments on the need to understand rongoā Māori (healing substances produced from native plants) and to consider the interactions between rongoā Māori and prescribed medicines.

Pharmac, acting on its concerns that the benefits of subsidised pharmaceuticals may not be reaching Māori at the same rate as other New Zealanders, has developed a Māori Responsiveness Strategy (Pharmac 2002c).

The strategy is consistent with government health strategies and Pharmac's legislative functions. It aims to ensure that Pharmac is as responsive as possible to Māori, and to improve Māori health.

Box 9 identifies the six strategies that Pharmac is implementing to achieve these aims.

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<thead>
<tr>
<th>Box 9: Pharmac’s six Māori responsiveness strategies</th>
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</thead>
<tbody>
<tr>
<td>1. Incorporating Māori strategic priorities.</td>
</tr>
<tr>
<td>2. Improving the responsiveness of Pharmac’s human resource to the needs of, and issues raised by, Māori.</td>
</tr>
<tr>
<td>3. Improving ethnicity data collection and analysis.</td>
</tr>
<tr>
<td>4. Improving Pharmac’s performance in negotiating with suppliers and assessing new drug applications.</td>
</tr>
<tr>
<td>5. Improving Pharmac’s performance in informing Māori about available subsidised medicines.</td>
</tr>
<tr>
<td>6. Improving Māori representation and participation.</td>
</tr>
</tbody>
</table>

Source: Pharmac 2002c

ePharmacy

ePharmacy is one of the action zones of the Health Information Strategy for New Zealand (Health Information Strategy Steering Committee 2005). The Health
Information Strategy Action Committee has produced an initial proposal of what ePharmacy could include, and many aspects progress suggestions made by SQM aimed at improving the optimal use of medicines. Among these is a national electronic medication record of a patient’s medication history that relevant health practitioners can access at any time. In addition, ePharmacy supports ‘better access to pharmaceutical decision support systems when prescribing pharmaceuticals’ (Health Information Strategy Action Committee 2006).

Box 10: Features ePharmacy may include

1. Health practitioners and other involved parties, including the patients themselves, will be able to access a complete electronic pharmaceutical history, including the National Health Index number, that relates to individual patients, as a form of event summary, as appropriate and within agreed privacy rules.

2. Prescribing, dispensing and other information sharing will be based on an in-built standard medicines terminology and standard schedule that is updated monthly.

3. Hospital and community pharmacy prescribing and dispensing will be reviewed and monitored.

4. Prescriptions will be electronically communicated between prescribers and pharmacies, including:
   a. automating processes to enable smarter transactions to be developed
   b. on-line prescriptions ordering
   c. electronic receipting of authenticated prescriptions at pharmacies
   d. electronic confirmation that prescriptions have been dispensed to prescribers.

5. People will be able to continue to choose their preferred pharmacy to dispense their prescriptions and repeats.

6. ePharmacy information may be used for analysis at local, regional and national levels, including analysis of longitudinal records for individual patients and groups of patients within an agreed privacy, authentication and security framework, for both clinical care and, in an unidentified form, for health planning.

Source: Health Information Strategy Action Committee 2006

Bar-coding

Medicines bar-coding technology that can be used to track medicines as they progress through the system is one system-based solution that can help to address human error in dispensing. Bar-coding of medicines is already used in some areas of community pharmacy in New Zealand and in some anaesthetic departments, but both these systems currently use their own unique bar-coding process.

The Ministry of Health is working on a proposal to ensure all medication is uniquely bar-coded, and that the appropriate systems to use bar-coding technology to improve patient safety are in place. This will allow tracking of medication from manufacture, through distribution, to the administration of the medication to the patient. International examples indicate that bar-coding would help prevent medication errors and ensure better communication between hospital and community pharmacies.
Pharmacists' role in medicines management

The Health Practitioners Competence Assurance Act 2003 reforms and developments can provide opportunities to enhance the roles of health practitioners in delivering health services. One example of this is the increased role of pharmacists in medicines management and the optimal use of medicines.

Pharmacists have a significant role to play in assisting patients to understand their medicines better, to use their medicines more appropriately, to avoid duplication, side-effects and adverse reactions, and to optimise therapeutic outcomes. With the establishment of PHOs there are already initiatives under way to enable pharmacists to have a greater role in medicines management, including:

- pharmacists working alongside GPs on pharmaceutical review and medicines management for patients with chronic conditions
- advisory roles to promote best-practice prescribing
- governance roles
- the promotion and funding of compliance blister packaging (Webster packaging) for patients with chronic conditions.

DHBs are also involved in initiatives aimed at promoting people-centred approaches, including:

- home visits to review medicines management (in conjunction with nursing visits)
- the promotion of blister packaging in rest homes
- health education services for patients, their family and their whānau, including providing information about medicines and their optimal use, and information and advice on maintaining healthy lifestyles
- medicines and clinical information support to health providers, including advice on the appropriateness of the medicine options for a patient and the cost-effectiveness of the medicine options
- clinical review of patients’ treatments and medicines use, and active management of any recommended changes.

With the rescheduling of a number of prescription medicines to pharmacist-only medicines, pharmacists have had an increasing role in developing protocols to ensure that medicines for chronic conditions, such as Xenical, are appropriately managed. With the increase in health practitioners’ prescribing, there is also a greater need for co-ordination and overview of patients’ medicines use. Pharmacists are the common link.

The Pharmacy Council is working on a proposal for highly specialised pharmacists to gain prescribing rights. The Council’s research from Canada and the United Kingdom indicates that pharmacist prescribers are able to improve access to medicines to patients while freeing up medical practitioners to concentrate on aspects of diagnosis and non-pharmacological treatments.
All these initiatives have the potential to reduce the number of prescribed medicines, streamline therapy regimes, reduce duplication of medicines and improve the overall quality of life and independence of people.

**Encouraging the appropriate use of medicines**

Consumers’ expectations about the most appropriate medicine for their symptoms can influence what they are prescribed. However, while consumers have, via the internet, greater access than ever before to information about available treatments, this does not necessarily enable them to identify the most appropriate medicine that will result in the best health outcomes.

Pharmac’s annual Wise Use of Antibiotics Campaign is one example of a programme that aims to influence consumers’ understanding about, and expectations of, appropriate medicines. The aim of the campaign is to remind New Zealanders to use antibiotics appropriately and responsibly and to reduce their unnecessary use. Figures released by ESR in June 2006 show rates of an antibiotic-resistant superbug have levelled off in New Zealand while continuing to climb elsewhere in the world (http://www.esr.cri.nz/news/AntibioticResistanceGrowing.htm.).

**Health literacy**

Health literacy links levels of literacy with the ability to interpret and act on health information. The Pharmacy Guild of New Zealand has developed a paper that provides pharmacists with suggestions about ways to provide information about medicines that is clear and understandable to all patients at the point of dispensing (Pharmacy Guild of New Zealand, 2006). The paper points out that over one million New Zealand adults lack ‘functional literacy’; that is, they are below the minimum level of literacy competence required to meet the demands of everyday life.

Pharmac’s One Heart Many Lives initiative aims to raise the levels of health literacy in relation to cardiovascular disease among population groups that are at greatest risk. The initiative explains the impact the disease will have on the individual and their family/whānau, and describes the steps the individual can take to reduce their cardiovascular risk (including the use of statins).

The Ministry of Health will be developing a health literacy project with a particular focus on the differences in health literacy rates between Māori and non-Māori. The data for this project will be based on the New Zealand results from the International Adults Literacy Survey (IALS) supplied by Educational Testing Services, in New Jersey. This health literacy project is an action point from Whakatātaka Tuarua: Māori Health Action Plan 2006–2011 (Ministry of Health 2006e).
Monitoring and reporting on medicines-related incidents

Monitoring and reporting on medicines-related incidents are key optimal-use activities. Medicines-related incidents include medication errors, as well as adverse drug reactions, which are defined as ‘any response to a drug which is noxious, unintended, and occurs at doses normally used for prophylaxis, diagnosis or therapy’ (SQM 2005). The Centre for Adverse Reactions Monitoring receives reports of adverse reactions to medicines occurring in New Zealand.

The World Health Organization rates New Zealand as having the highest rate and the highest quality of adverse medicine reactions reporting per head of population in the world. The high rate of adverse reactions is attributed to the high reporting rate but is commonly felt to reflect only 5 percent of actual adverse reactions.

Pharmacovigilance activity in the future is proposed to fall under the new regulatory scheme and authority that New Zealand is establishing with Australia. Under the proposed joint regulator it is expected there will be an increase in post-market surveillance. Consultation on how this could be achieved will be undertaken as part of the work currently under way.

The best international practice model that is being developed is based on pharmacovigilance being delivered both before the product enters the markets and after it is approved for use. In this model, companies will submit plans to the regulator for monitoring the safety of their medicine after it is on the market for the regulator to consider prior to approval of the product. Once approved, the company will be responsible for collecting data and reporting it to the regulator, who will then make decisions as to whether the company must perform further research or provide more information to prescribers and consumers.18

In general, there is little or no monitoring and reporting on medicines-related incidents in the primary care sector apart from the national adverse events system, but this tends to record only the most significant events. SQM is considering the possibility of a medication error incident or sentinel reporting system in primary care.

Medicines disposal

The safe and appropriate disposal of unused medicines is an important facet of the optimal use of medicines. The collection and disposal of unused medicines need to be managed in order to reduce the quantities of unused medicines in the community, and to mitigate the impact of waste medicines on the environment (Office of the Auditor General 2005).

18 Details on the proposals for product vigilance are available in a consultation document available from the ANZTPA website (www.anztpa.org).
The safe disposal of medicines is the responsibility of DHBs. For example, MidCentral DHB has funded the Safe and Efficient Disposal of Unused Medicines project (SEDUM) since April 2005. The project is co-ordinated by a local pharmacy, which arranges for:

- receipt of unused medicines from homes and other settings such as aged residential care facilities
- disposal of the medicines in a safe manner
- collection and analysis of information about the unused medicines.

The SEDUM project has been extended so that the findings can be presented to prescribers, with the aim of reducing medicines wastage. One example identified as a result of data collected during the 2005/06 year was the potential to improve practitioner communication with patients about the importance of preventive medicines. This was proposed as a result of the finding that six of the ten most frequently returned medicines were preventive cardiovascular medications (Central Pharmacy and MidCentral District Health Board 2006).

**Advancing optimal use in the future**

As we have seen, optimal-use activities are varied and are carried out by a range of agencies. The DHBNZ Safe and Quality Use of Medicines Group identified a need to co-ordinate the optimal-use activities of the sector and has developed a strategy to guide this work.

The proposed Medicines Strategy, in turn, attempts to set optimal use in the broader context of the medicines chain. This approach acknowledges the integral role that optimal use activities have in achieving the proposed goal and objectives of the strategy, and the contribution made by all the agencies involved in optimal use. Given the widespread use of medicines, improvements in the optimal use of medicines have the potential to result in significant increases in the benefits that people gain from the medicines, and therefore, in their health status.

Given the diffuse nature of optimal-use activities, communication between different agencies and co-ordination of their activities are essential. Both will ensure that the agencies carrying out optimal-use activities are not duplicating work occurring elsewhere. Communication and co-ordination are also necessary to ensure that information about how medicines are chosen, delivered through systems, and used by consumers is used to inform the development of new initiatives. The establishment of the SQM website is an explicit attempt to improve communication about what is occurring in the sector.
The other initiatives outlined in this section provide a snapshot of what the sector is doing to improve the optimal use of medicines. Your views would be welcome on which initiatives you consider should be further pursued to help improve the choice, delivery and use of medicines, including how to improve communication and co-ordination of activities between different agencies, and how to support the use of evidence-based guidelines in clinical practice.

Q21. Where do you think the greatest gains in the optimal use of medicines are to be made?
Q22. Which areas of the optimal use of medicines do you think will have the greatest impact in reducing inequalities in health outcomes between different population groups?
Q23. What other optimal-use initiatives do you consider should be pursued? Why?
Q24. Do you have any suggestions about how to improve co-ordination and communication between agencies involved in optimal-use activities in the sector?
Q25. Do you have any suggestions about how the use of evidence-based guidelines in clinical practice can be better supported?
Q26. Are there any issues missing from the ‘Getting Started’ list on page 40? If so, what are they?

In closing
Medicines are a key element of New Zealand’s health and disability support sector. They are used extensively within services and for self-care and have a significant contribution to make to achieving good health outcomes. They also carry risks and costs and their responsible use requires extensive support infrastructure, systems and policies to be in place.

This document has provided an overview of the current system and proposed that a new strategic framework be put in place to guide its activities into the future. Consistent with the proposed strategic framework, it has also described opportunities to improve the current arrangements. The Ministry welcomes your views on the issues raised in this document, and in particular the proposed strategic framework and ‘getting started’ initiatives. The Government will take into account your suggestions and comments as it develops its Medicines Strategy. It is proposed that this document be released during 2007, along with a set of priority initiatives.

While an initial set of initiatives will be proposed, it is expected that the Medicines Strategy will be in place to guide the sector’s activities over the longer term and to provide a focus for sector collaboration and discussion.
Consultation Questions

Medicines: Current Systems, Structures and Processes

Q1. Does this description reflect your understanding of medicines systems, structures and processes? Are there any elements that have not been included that you consider should be?

A New Strategic Direction for Medicines in New Zealand

Q2. Do you agree with the overarching objectives of the proposed Medicines Strategy? If not, why not?

Q3. Are any objectives missing? If so, what are they and why should they be included?

Q4. Do you agree with the proposed principles to guide decision-making? If not, why not?

Q5. Are any principles missing? If so, what are they and why should they be included?

Q6. Do you agree with the key elements of implementation? Are there others you would like to add? Please explain your reasons.

Getting Started

Q7. Are there other issues that you consider should be addressed as a matter of priority to improve the quality, safety and efficacy of medicines?

Q8. Do you agree that the current budget-setting process for community pharmaceuticals is generally working well, in practice, but could be improved by having Pharmac and DHBs use a set of agreed principles to make a joint recommendation to the Minister of Health on the level of the budget? If not, why not?

Q9. Do you consider value for money/cost-effectiveness and affordability are useful principles for Pharmac and DHBs to apply in making a recommendation to the Minister on the proposed community pharmaceutical budget? Are there other principles you consider should also be applied? If so, what are these and why should they be considered?

Q10. Is a three-year funding path helpful? If not, why not? What improvements do you suggest?

Q11. Do you have any other comments on the proposed process for setting the community pharmaceutical budget?

Q12. What are your views on the options proposed to increase the understanding of decision-making?

Q13. Do you have any further suggestions about the provision of free and frank advice to the decision-making process?
Q14. What, if any, experience have you had of the public summary documents produced in Australia? Do you think the public summary documents assist people to better understand the decision-making process?

Q15. Are there any other options you consider would be useful to pursue? Please describe these and explain how they would increase understanding of decision-making.

Q16. Do you agree that decision-making about vaccines should be more transparent? If not, why not?

Q17. Do you agree that consideration should be given to the best arrangements for supporting the Immunisation Technical Working Group process? If not, why not?

Q18. Do you agree that options for the ongoing funding of vaccines should be explored? If not, why not?

Q19. Do you agree that options for vaccine procurement should be explored? If not, why not?

Q20. Are there any other issues you consider are missing and should be addressed as a matter of priority to improve access to medicines?

Q21. Where do you think the greatest gains in the optimal use of medicines are to be made?

Q22. Which areas of the optimal use of medicines do you think will have the greatest impact in reducing inequalities in health outcomes between different population groups?

Q23. What other optimal-use initiatives do you consider should be pursued? Why?

Q24. Do you have any suggestions about how to improve co-ordination and communication between agencies involved in optimal-use activities in the sector?

Q25. Do you have any suggestions about how the use of evidence-based guidelines in clinical practice can be better supported?

Q26. Are there any issues missing from the ‘Getting Started’ list on page 40? If so, what are they?
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACC</td>
<td>Accident Compensation Corporation</td>
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<tr>
<td>BPACnz</td>
<td>Best Practice Advocacy Centre</td>
</tr>
<tr>
<td>CAC</td>
<td>Consumer Advisory Committee</td>
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<tr>
<td>CARM</td>
<td>Centre for Adverse Reactions Monitoring</td>
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<tr>
<td>CUA</td>
<td>Cost-Utility Analysis</td>
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<tr>
<td>DHB</td>
<td>District Health Board</td>
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<tr>
<td>DHBNZ</td>
<td>District Health Boards New Zealand</td>
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<tr>
<td>GP</td>
<td>general practitioner</td>
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<tr>
<td>HPCA Act</td>
<td>Health Practitioners Competence Assurance Act 2003</td>
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<tr>
<td>IMMP</td>
<td>Intensive Medicines Monitoring Programme</td>
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<tr>
<td>ITWG</td>
<td>Immunisation Technical Working Group</td>
</tr>
<tr>
<td>Medsafe</td>
<td>New Zealand Medicines and Medical Devices Safety Authority</td>
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<tr>
<td>NEAC</td>
<td>National Ethics Advisory Committee</td>
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<tr>
<td>NICE</td>
<td>National Institute for Clinical Excellence (United Kingdom)</td>
</tr>
<tr>
<td>NZPHD Act</td>
<td>New Zealand Public Health and Disability Act 2000</td>
</tr>
<tr>
<td>PBAC</td>
<td>Pharmaceutical Benefits Advisory Committee (Australia)</td>
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<tr>
<td>PBPA</td>
<td>Pharmaceutical Benefits Pricing Authority (Australia)</td>
</tr>
<tr>
<td>PBS</td>
<td>Pharmaceutical Benefits Scheme (Australia)</td>
</tr>
<tr>
<td>Pharmac</td>
<td>Pharmaceutical Management Agency</td>
</tr>
<tr>
<td>PHO</td>
<td>Primary Health Organisation</td>
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<tr>
<td>PTAC</td>
<td>Pharmacology and Therapeutics Advisory Committee</td>
</tr>
<tr>
<td>QALY</td>
<td>quality-adjusted life year</td>
</tr>
<tr>
<td>SEDUM</td>
<td>Safe and Efficient Disposal of Unused Medicines</td>
</tr>
<tr>
<td>SPNIA</td>
<td>Service Planning and New Health Intervention Assessment</td>
</tr>
<tr>
<td>SQM</td>
<td>Safe and Quality Use of Medicines Group</td>
</tr>
<tr>
<td>TAC</td>
<td>Technology Appraisal Committee (United Kingdom)</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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Appendix 1: Relevant Provisions of the Official Information Act 1982

9. Other reasons for withholding official information –

(1) Where this section applies, good reason for withholding official information exists, for the purpose of section 5 of this Act, unless, in the circumstances of the particular case, the withholding of that information is outweighed by other considerations which render it desirable, in the public interest, to make that information available.

(2) Subject to sections 6, 7, 10, and 18 of this Act, this section applies if, and only if, the withholding of the information is necessary to –

(a) protect the privacy of natural persons, including that of deceased natural persons; or

(b) protect information where the making available of the information –
(i) would disclose a trade secret; or
(ii) would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information; or

(ba) protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information –
(i) would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied; or
(ii) would be likely otherwise to damage the public interest; or

(c) avoid prejudice to measures protecting the health or safety of members of the public; or

(d) avoid prejudice to the substantial economic interests of New Zealand; or

(e) avoid prejudice to measures that prevent or mitigate material loss to members of the public; or

(f) maintain the constitutional conventions for the time being which protect –
(i) the confidentiality of communications by or with the Sovereign or her representative;
(ii) collective and individual ministerial responsibility;
(iii) the political neutrality of officials;
(iv) the confidentiality of advice tendered by Ministers of the Crown and officials; or
(g) maintain the effective conduct of public affairs through –
   (i) the free and frank expression of opinions by or between or to Ministers of the Crown or members of an organisation or officers and employees of any Department or organisation in the course of their duty; or
   (ii) the protection of such Ministers, members of organisations, officers, and employees from improper pressure or harassment; or

(h) maintain legal professional privilege; or

(i) enable a Minister of the Crown or any Department or organisation holding the information to carry out, without prejudice or disadvantage, commercial activities; or

(j) enable a Minister of the Crown or any Department or organisation holding the information to carry on, without prejudice or disadvantage, negotiations (including commercial and industrial negotiations); or

(k) prevent the disclosure or use of official information for improper gain or improper advantage.
Appendix 2: Long-term Medicines Strategy Terms of Reference

Aim
The long-term medicines strategy aims to identify where improvements can be made within the existing system and broad policy settings to ensure the best health and disability support outcomes from medicines over the coming years. In doing so, the strategy will focus on the three areas recognised internationally as the key planks for obtaining the greatest benefits from the use of medicines: access to medicines, quality of medicines and the rational use of medicines.

Context
New Zealand has established processes to support access, quality and the rational use of medicines, and policy work has been undertaken recently, or is under way, in a number of key areas that will have a bearing on the development of the strategy. The strategy is aiming to identify areas for improvement that build on New Zealand’s existing infrastructure and recent policy developments.

Medsafe\textsuperscript{19} and Pharmac\textsuperscript{20} are the entities with the central responsibility for quality and access matters in New Zealand. The rational use of medicines is not the responsibility of a single agency; individual consumers, health professionals, District Health Boards, Primary Health Organisations, and registration authorities in addition to Medsafe, Pharmac and the Ministry of Health all have a role to play.

Recent policy developments that have a bearing on the development of the strategy, include the Biotechnology Strategy, the proposed establishment of the Australia New Zealand Therapeutic Products Authority, and the DHBNZ Safe and Quality Use of Medicines National Strategy. Work is also under way on matters such as direct-to-consumer advertising of prescription medicines.

Process and content
The strategy will draw on work by the World Health Organization and other countries. The strategy’s development will begin with an analysis of the current New Zealand system and international trends. The analysis will be informed, among other things, by government and sector stakeholders, including consumer groups.

The analysis will then lead to the development of a draft strategy document for submission, by November 2006, to Ministers and Cabinet prior to formal consultation.

\textsuperscript{19} Medicines and Medical Devices Safety Authority, a business unit of the Ministry of Health.
\textsuperscript{20} Pharmaceutical Management Agency, a Crown entity established under the New Zealand Public Health and Disability Act 2000.
It is expected that the draft strategy document will:

- describe the current system
- summarise trends and their potential impact
- propose a set of high-level objectives
- address a number of more specific issues.

The issues that have been identified to be examined at this stage are focused on access to medicines and include: how prioritisation/rationing decisions are made, access to new/innovative/high-cost medicines (especially for niche groups, eg, rare diseases), and pharmaceutical budgets (eg, Pharmac’s budget is part of DHB budgets, and the strategy could examine how the budget is set, its adequacy, and whether it should be separate or continue to be part of DHB budgets).

As the strategy progresses, other specific matters for further work may be identified.

**Timeframe**

- June–November 2006: development of draft consultation document to be submitted to Ministers and Cabinet seeking approval to be released.
- Early 2007–end of consultation, followed by advice to Ministers on next steps.

**Background**

The long-term medicines strategy is being developed consistent with the commitment between the United Future Party and the Government to examine quality pharmaceutical usage in the health sector, and the role Pharmac should play in implementing the strategy.
### Appendix 3: Medicines Registration, Evaluation and Funding Processes in Australia, UK, the Republic of Ireland and Canada

<table>
<thead>
<tr>
<th>Registration process</th>
<th>Evaluation process</th>
<th>Funding process</th>
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<tbody>
<tr>
<td><strong>Australia</strong></td>
<td>The Pharmaceutical Benefits Advisory Committee (PBAC) manages the Pharmaceutical Benefits Scheme (PBS). PBAC has an economic and a drug utilisation sub-committee, which considers major submissions for listing medicines on the PBS.</td>
<td>The PBAC considers the sub-committee’s findings and recommends to the Minister of Health and Ageing that a medicine is listed (PBAC is the only body that makes recommendations to the Minister). If the Minister accepts the recommendation, the matter is referred to the Pharmaceutical Benefits Pricing Authority to negotiate price.</td>
</tr>
<tr>
<td><strong>Therapeutic goods must be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied.</strong></td>
<td><strong>The Therapeutic Goods Act 1989, Regulations and Orders set out the requirements for inclusion of products on the ARTG, including labelling, product appearance, advertising and appeal guidelines.</strong></td>
<td><strong>The Therapeutic Goods Administration (TGA) is responsible for administering the ARTG.</strong></td>
</tr>
<tr>
<td><strong>United Kingdom</strong></td>
<td><strong>The Pharmaceutical Benefits Advisory Committee (PBAC) manages the Pharmaceutical Benefits Scheme (PBS). PBAC has an economic and a drug utilisation sub-committee, which considers major submissions for listing medicines on the PBS.</strong></td>
<td><strong>The PBAC considers the sub-committee’s findings and recommends to the Minister of Health and Ageing that a medicine is listed (PBAC is the only body that makes recommendations to the Minister). If the Minister accepts the recommendation, the matter is referred to the Pharmaceutical Benefits Pricing Authority to negotiate price.</strong></td>
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### Registration process

<table>
<thead>
<tr>
<th>Republic of Ireland</th>
<th>Canada</th>
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<tr>
<td>Carried out by the Irish Medicines Board (IMB). In determining the safety, quality and efficacy of medicinal products, the IMB draws on the expertise of its assessors and its advisory committee. The IMB reviews the scientific aspects of the application and reaches a conclusion on the likely balance of any benefits versus the risk of the product before arriving at a decision.</td>
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### Evaluation process

Both the UK and the Republic of Ireland are part of the European Union (EU). All medicines are evaluated in the EU through the European Agency for the Evaluation of Medicinal Products (EMEA). In this system, two countries within the EU perform the evaluation and provide this report to the other countries for peer review, before a central assessment committee recommends acceptance or rejection of each proposal. Most licensed drugs and devices are assessed at a local level within the National Health Service. The National Institute for Clinical Excellence (NICE) is asked to look at particular drugs and devices when there is confusion over value or regional prescribing discrepancies. The Technology Appraisal Committee (TAC) considers suppliers’ submissions and assessments of clinical and cost-effectiveness that NICE contracts from academic organisations/universities. TAC makes recommendations to NICE on the basis of this information, but NICE is not bound by TAC’s recommendations. NICE produces a ‘negative list’ of drugs that are excluded from NHS subsidy. (See UK above for a description of evaluation in EU countries.) The National Centre for Pharmacoeconomics reviews the cost-effectiveness and budget impact of individual drugs in response to requests from the Department of Health and Children (DoHC). |

### Funding process

Local primary care trusts must fund all new technologies recommended by NICE. Prices of branded medicines are controlled by the Pharmaceutical Price Regulation Scheme. In addition, there are reserve statutory powers which may be used to control the prices of medicines. The DoHC and the Irish Pharmaceutical Healthcare Association (the industry body) have an agreement for the supply of medicines that governs supply terms, conditions and prices of medicines supplied to the health services. The Republic of Ireland links its drug price by formula to five other European Union member states.
<table>
<thead>
<tr>
<th>Registration process</th>
<th>Evaluation process</th>
<th>Funding process</th>
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<tbody>
<tr>
<td>All therapeutic products sold in Canada are required to be approved by Health Canada's Therapeutic Products Directorate (TPD). The TPD assesses the safety, quality and efficacy of all therapeutic products. The Food and Drugs Act and Regulations stipulates what information a manufacturer needs to provide to the TPD and regulates products once they have been given market authorisation.</td>
<td>The Common Drug Review (CDR) process reviews new drugs and provides non-binding listing recommendations for all participating government drug plans (Quebec does not participate in the process). The CDR does not review generic drugs or new dosage forms of existing medicines; participating federal, provincial and territorial government’s drug plans do this. The CDR contracts individual reviewers to review the clinical and pharmacoeconomic evaluations. The Canadian Drug Expert Advisory Committee considers advice of the reviews and makes a provisional recommendation.</td>
<td>The Patented Medicines Prices Review Board (PMPRB) reviews the prices of new and existing patented medicines and restricts the maximum price for new medicines to be the median price of a group of specified industrialised countries. The PMPRB does not allow the prices of existing patented drugs to increase by more than the Consumer Price Index. The federal government funds hospital pharmaceuticals but not community pharmaceuticals (apart from specific groups, such as First Nations, and veterans).</td>
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Appendix 4: Procedure for Listing a Pharmaceutical on the New Zealand Pharmaceutical Schedule

The process set out in the diagram above is intended to indicate the process that may follow where a supplier wishes to list a new pharmaceutical on the Pharmaceutical Schedule. Pharmac may, at its discretion, adopt a different process or variations of this process.
Appendix 5: Grounds for Challenge Using Judicial Review

Illegality: including

- Improper purpose: The decision has been made outside the purpose or spirit of the Act.
- Relevant/irrelevant considerations: The decision-maker does not take into account relevant considerations or takes into account irrelevant ones.
- Errors of fact: The decision is influenced by some factual error.
- Pre-determined policy: The decision-maker rigidly applies a pre-determined policy without regard to the particular merits of the case.
- Acting under dictation: The decision-makers must make a conscious choice themselves.
- Invalid delegation: The decision-maker has invalidly delegated a power that they ought to exercise to another person or is acting pursuant to an individual delegation.

Unreasonableness: A decision-maker must act in a reasonable fashion and the decision must rely on some reasonable basis.

Unfairness: Broadly speaking, this covers all questions relating to the manner in which a decision is reached. It includes:

- Representations: It is important that the decision-maker gives full opportunity for representations from those affected by the decision to be made.
- Bias: It is the appearance or suspicion of bias that counts. Examples in this context are conflicts of interest by having financial interest in the subject matter or being a relative of the applicant.
- Consistency: There is sometimes an obligation to act consistently with some previous contract or representation.
Appendix 6: Medicines in the Intensive Medicines Monitoring Programme

- clozapine (Clozaril, Clopine)
- olanzapine (Zyprexa)
- quetiapine (Seroquel)
- risperidone (Risperdal)
- celecoxib (Celebrex)
- etoricoxib (Arcoxia)
- rofecoxib (Vioxx)
- valdecoxib (Bextra)
- sibutramine (Reductil)
- Mirena IUS.
References


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References


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