

Medicines New Zealand

**Contributing to good health outcomes
for all New Zealanders**

Citation: Associate Minister of Health, Minister of Health. 2007.
*Medicines New Zealand: Contributing to good health outcomes
for all New Zealanders.*
Wellington: Ministry of Health.

Published in December 2007
by the Ministry of Health
PO Box 5013, Wellington, New Zealand

ISBN: 978-0-478-31254-6 (Print)
ISBN: 978-0-478-31255-3 (Online)
HP 4452

This document is available on the Ministry of Health website:
<http://www.moh.govt.nz>

Ministers' Foreword

Medicines are a key part of the health and disability support system and make significant contributions to the lives of New Zealanders. They are used to treat a wide range of diseases and disorders and in some cases can be used to replace invasive procedures. Ultimately, medicines contribute to New Zealanders' opportunities to maintain their independence and enhance their quality of life.

The medicines environment has changed significantly over the years. New products offer expanded treatment options, New Zealanders are increasingly taking more responsibility for their own health and there is growing awareness of the risks of inappropriate medicines use. These are heartening trends, but we must continue to ensure that the medicines system can respond to change. Health practitioners and people using medicines must work together to establish treatment regimes that are appropriate to individual circumstances, including ensuring that treatment regimes are well understood. The system needs to recognise that individuals may vary from population norms, people need access to good information about medicines (including explanations about the cost of health services directly related to medicines) and the overall system must be affordable for taxpayers.

The process of developing *Medicines New Zealand* began in 2005 under the confidence and supply agreement between the Labour-led Government and the United Future Party. The work was initiated because it was apparent that the medicines system was not serving New Zealanders as well as it could and lacked an overarching strategic direction. The consultation document *Towards a New Zealand Medicines Strategy* was released in December 2006. It described how the medicines system in New Zealand currently works, proposed a new strategic direction and identified areas where improvements could be made.

We have consulted widely on the proposals and are pleased to launch *Medicines New Zealand* and *Actioning Medicines New Zealand*. We would like to take this opportunity to thank all of you who have made significant contributions to the development of these documents and we look forward to your ongoing participation in their implementation. We were particularly struck by the constructive discussions during the consultation process and the willingness to be open and frank about the operation of current systems. This open and constructive approach bodes well for the future and the realisation of the objectives of *Medicines New Zealand*.

Medicines New Zealand is intended to provide a strategic framework that supports sound decision-making over time. It is principles-based and aims to deliver a transparent and coherent approach to medicines issues in New Zealand. It has the potential to draw together the agencies and stakeholders that make up our medicines system and provide them with a platform to build a sustainable system that ensures equitable access to safe, quality medicines that are used in the most effective ways possible.

Our medicines system grapples with complex issues, but New Zealand does not do this alone. Internationally, issues such as how to determine the right level of investment in medicines versus other health services are the subject of ongoing debate. There are no simple answers.

Medicines New Zealand aims to ensure that the decisions made about prioritisation and funding are as transparent as possible, understood and open to debate. It is important for New Zealanders to have confidence that the medicines system is fair, even if they do not always agree with all of the decisions made.

Ensuring equitable and affordable access to medicines is a central concern for the medicines system, but so are issues of quality and optimal use. New Zealand needs to address the inadequacies in its regulatory arrangements to ensure medicines are safe. There is also great potential to improve health outcomes by improving the way medicines are used.

Medicines New Zealand is supported by *Actioning Medicines New Zealand*. *Actioning Medicines New Zealand* sets out the key initiatives that will take the first steps toward achieving *Medicines New Zealand* outcomes and contribute to larger health and disability support system outcomes: improvements in New Zealanders' health; improved independence and participation; reduced inequalities between population groups; and greater trust and security in the health and disability system. Progressing *Actioning Medicines New Zealand* is what will make the strategy real and make a difference to New Zealand communities.

Medicines New Zealand builds on the feedback from the sector and the public and aims to change the New Zealand medicines environment for the better. It is important that all stakeholders continue to contribute, achieve and aspire to building a world-class medicines system for New Zealand that will ensure the best health and disability outcomes from medicines in a changing world.



Hon Peter Dunne
Associate Minister of Health



Hon David Cunliffe
Minister of Health

Contents

Ministers' Foreword.....	iii
Introduction	1
Aim of the strategy	1
Making it real.....	1
Background.....	2
The medicines system in New Zealand	3
<i>Medicines New Zealand: The Strategy</i>	4
Health and disability system outcomes	6
<i>Medicines New Zealand: Outcomes</i>	7
Quality, safety and efficacy.....	8
Access	10
Optimal use	12
Guided by Principles	14
Implemented through Excellent Systems	15
Cross-sector collaboration and stakeholder engagement.....	15
Structures and systems that work well.....	16
System capability.....	16

Introduction

Aim of the strategy

Until now, there has been no overarching policy direction aligning the medicines sector and the systems that govern the regulation, procurement, management and use of medicines. In 2005 the Government signalled its intention to put this overarching direction in place. This strategy, *Medicines New Zealand*, is the result.

Medicines New Zealand is an aspirational document. It articulates the overarching framework and desired outcomes for the medicines system in New Zealand. It provides a common strategic direction to draw together the agencies and stakeholders that make up our medicines system. This strategy is intended to inform decision-making over the long term and to deliver a world-class medicines system for New Zealanders.

Medicines New Zealand provides the platform for a medicines system that:

- delivers equitable access to safe, quality medicines that are used in the most effective ways possible
- is transparent, accessible and trusted by stakeholders
- delivers affordable medicines that meet the needs of New Zealanders and is sustainable for New Zealand.

To achieve these outcomes, the agencies and stakeholders in the New Zealand medicines system need to:

- acknowledge and respect each other's roles and expertise
- be committed to working collaboratively to bring about good health outcomes through medicines.

Making it real

Medicines New Zealand is supported by an action plan, *Actioning Medicines New Zealand*. *Actioning Medicines New Zealand* is intended to be a living document that continues to reflect health priorities, needs and emerging issues over time. It is not an exhaustive list of initiatives for the medicines sector, but highlights key activities, some of which specifically respond to feedback received during the consultation process.

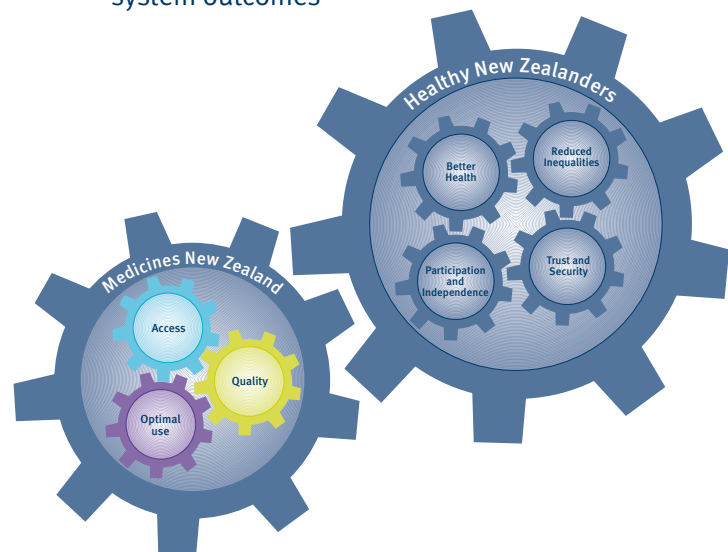
Background

Medicines are an important part of the health and disability support system, making a significant contribution to health outcomes for New Zealanders. They play a role in the health care of many people and are used extensively throughout the community and in hospital care settings. Medicines can prevent ill health, are a critical element in many treatment regimes, support people to maintain their independence and enhance the quality of life of many New Zealanders. Individuals also have the ability

to care directly for their own health through lifestyle choices and with non-prescription and complementary medicines.

Alongside their benefits, medicines also carry risks and challenges. Individuals make decisions about when to self-medicate with non-prescription or complementary medicines and/or when to seek professional advice. Good-quality information enables people to make decisions about medicines, use them safely and get the maximum benefit from them. Challenges for the wider health and disability system include ensuring that New Zealanders have access to safe, quality medicines and that health practitioners prescribe, and individuals use medicines effectively. Medicines also need to be affordable for individuals and their overall costs sustainable for the health sector.

Figure 1: The three elements of *Medicines New Zealand* and their link to the wider health and disability system outcomes

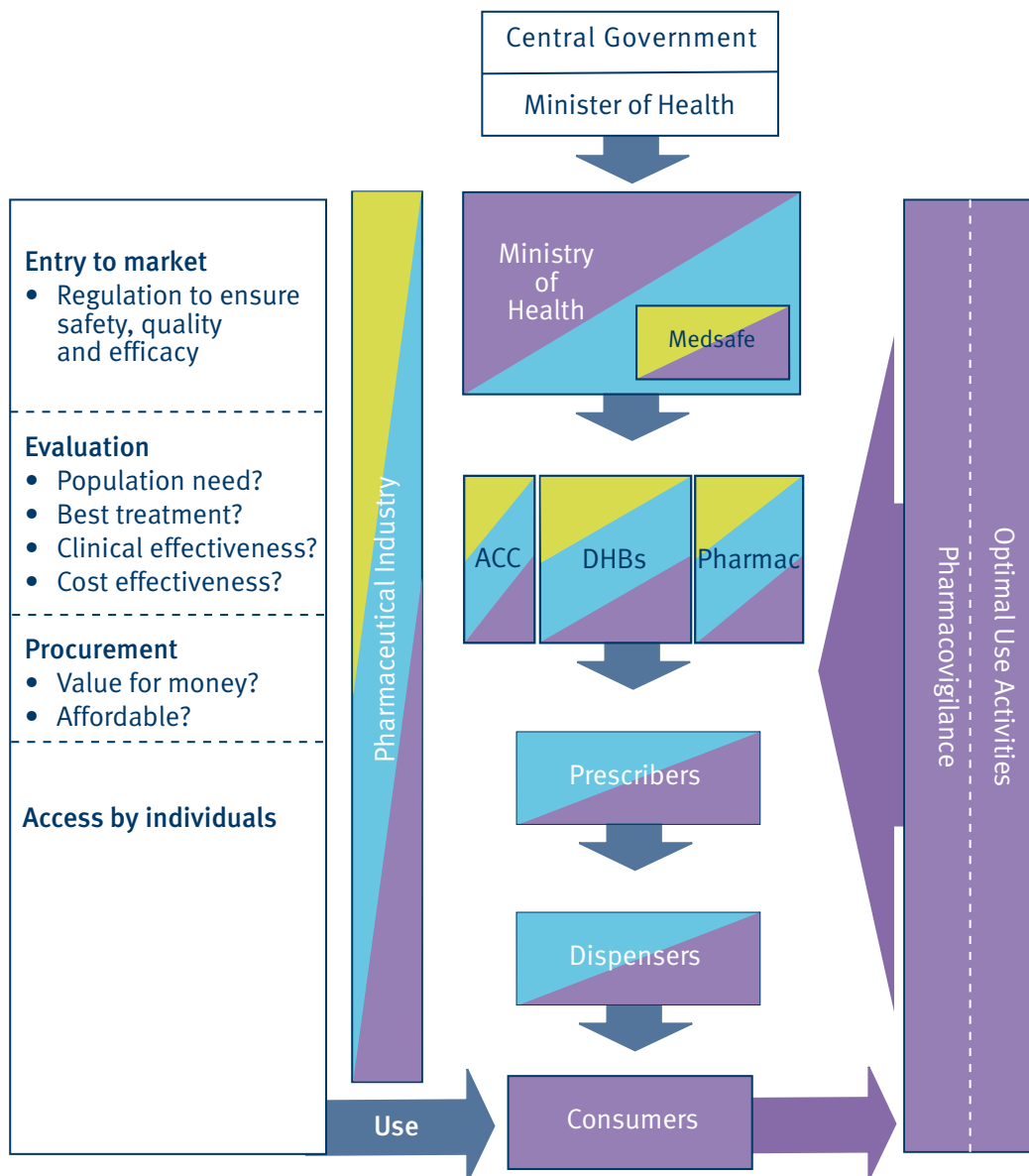


For the purposes of *Medicines New Zealand*, medicines include prescription medicines, non-prescription medicines and complementary medicines.

The medicines system in New Zealand

Achieving good health outcomes from the use of medicines requires a focus on the medicines themselves (the products), the health and disability services in which they are used and the people who are using them. Figure 2 provides a pictorial summary of the New Zealand medicines system.

Figure 2: The New Zealand medicines system



The agencies and groups with responsibility for pharmacovigilance and optimal use activities overlap and include Medsafe, the Medicines Adverse Reactions Committee, the Centre for Adverse Reactions Monitoring, the Intensive Vaccines Monitoring Programme, the Intensive Medicines Monitoring Programme, the Best Practice Advocacy Centre, the Safe and Quality Use of Medicines Group, the Quality Improvement Committee, Primary Health Organisations (PHOs) and other health care providers. (A detailed description of the role and functions of the agencies listed are described in *Towards a New Zealand Medicines Strategy* which can be found online at www.moh.govt.nz.)

The medicines system is made up of a range of agencies and stakeholders, each of which has various functions relating to the quality, safety and efficacy; access; and optimal use of medicines. This complexity can give a perception of fragmentation, however it would be difficult for one agency or stakeholder group to deliver all the functions necessary in a medicines system. Responsibility for various functions is purposely spread across the medicines system. This can at times create tensions, but also provides the checks and balances necessary in a robust and accountable medicines system. Examples of these checks and balances include the process to determine the community pharmaceuticals budget (District Health Boards (DHBs) and Pharmac work together to make a joint recommendation on the level of the budget, which must then be approved by the Minister of Health) and the role of Medsafe in regulating the therapeutic products available in New Zealand.

A number of key components of the current medicines systems and structures are still relatively new. DHBs have been in place since 2001, following the passage of the New Zealand Public Health and Disability Act in 2000. Although Pharmac has been a feature of the health and disability system since the 1990s, Pharmac, the Pharmacology and Therapeutics Advisory Committee and the Consumer Advisory Committee only took their present form in 2000. These reforms represent fundamental changes to the medicines system and relationships are continuing to evolve. Some of the benefits of these changes are only now being realised.

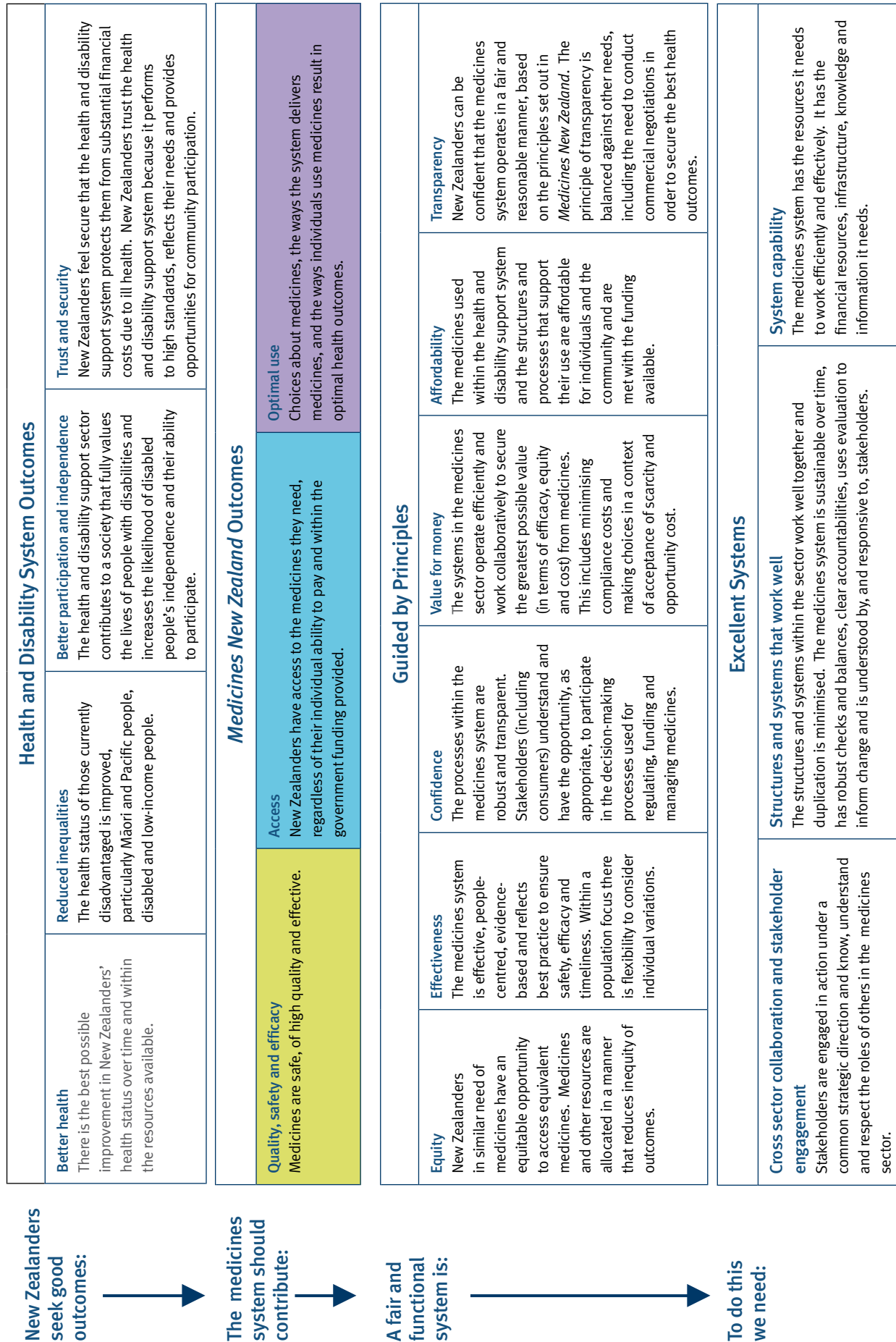
Change is disruptive and should be undertaken only if it results in a significant improvement. The current structural arrangements are sound, but there is room to improve. This strategy builds on existing structures and policies to align them with the objectives and goals of *Medicines New Zealand*. *Medicines New Zealand* is intended to be a platform for the agencies and stakeholders that make up the medicines system to build relationships and create a cohesive, effective and responsive medicines system.

Medicines New Zealand acknowledges and reflects the significant contributions made by stakeholders during the consultation process, including government agencies, health practitioners, the medicines industry, consumer groups, Māori and Pacific peoples and other New Zealanders.

Medicines New Zealand: The Strategy

The major components of *Medicines New Zealand* are described next. A summary of how they fit together is provided in Figure 3 on the next page.

Figure 3: Medicines New Zealand



Health and disability system outcomes

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. Reflecting this, *Medicines New Zealand* is informed by:

- the New Zealand Public Health and Disability Act 2000
- the New Zealand Health Strategy
- the New Zealand Disability Strategy
- government-agreed health objectives, as outlined in the Ministry of Health Statement of Intent
- stakeholder (including consumer) feedback
- World Health Organization guidelines on developing and implementing national medicines strategies.

Medicines policy also interacts with and plays a role in achieving the outcomes of other strategic health policies and is in turn informed by them. Examples of related health strategies include the Primary Health Care Strategy, He Korowai Oranga: Māori Health Strategy, Health Targets: Moving towards healthier futures and the New Zealand Cancer Control Strategy.

Medicines New Zealand contributes to achieving the following health and disability system outcomes:

Better health

There is the best possible improvement in New Zealanders' health status over time and within the resources available.

Reduced inequalities

The health status of those currently disadvantaged is improved, particularly Māori and Pacific people, disabled and low-income people.

Better participation and independence

The health and disability support sector contributes to a society that fully values the lives of people with disabilities and increases the likelihood of disabled people's independence and their ability to participate.

Trust and security

New Zealanders feel secure that the health and disability support system protects them from substantial financial costs due to ill health. New Zealanders trust the health and disability support system because it performs to high standards, reflects their needs and provides opportunities for community participation.

Medicines New Zealand: Outcomes

New Zealanders will have a medicines system that:

- **delivers quality medicines that are safe and effective**
- **provides access to the medicines they need**
- **ensures that medicines are used effectively.**

The following sections describe these outcomes and their characteristics.

Quality medicines that are safe and effective

New Zealand has a sustainable, efficient and effective regulatory system that is consistent with international best practice and ensures that safe, quality medicines are available to New Zealanders in a timely way. The quality, safety and efficacy of our medicines are assured through the regulation of products before they reach the market and effective post-market monitoring. This includes ongoing monitoring of their effects, particularly adverse responses to medicines once they are on the market.

To do this effectively New Zealand needs:

- a modern regulatory system that:
 - applies risk-based regulation consistent with international best practice. Lower-risk products (for example, most complementary medicines) will be subject to less stringent controls than those that apply to prescription medicines
 - has, or can access, the technical expertise necessary to assess the safety and efficacy of new medicines
 - where possible, is compatible with international regulatory requirements. This will reduce duplication and unnecessary restrictions, facilitating early access to new medicines
 - ensures pre-market assessment of medicines is timely and not unnecessarily costly
 - is based on constructive working relationships between the regulator and the medicines industry
 - updates the risk/benefit profiles of medicines in light of post-market information
- collaborative and co-ordinated pharmacovigilance activities that:
 - capture and analyse information through the regulatory system. Proactively make this information available and take timely action in response to adverse events
 - provide effective post-market monitoring (including monitoring the outcomes of medicines use for children and of non-prescription and complementary medicines) in line with international best practice. This will provide ongoing medicines safety assessment

Quality, safety, efficacy

Goal 1

New Zealand has a sustainable, efficient and effective regulatory system that is consistent with international best practice. It ensures that quality, safe and effective medicines are available to New Zealanders in a timely way.

Goal 2

Working relationships between the regulator and the medicines industry are constructive and based on trust.

Goal 3

Pharmacovigilance activities are supported by input from all stakeholders, including consumers, health practitioners and the medicines industry, to achieve post-market monitoring in line with international best practice.

- provide people with unbiased information about the uses and the risks and benefits of medicines, recognising that some risks arising from new medicines may not yet be apparent
- seek input from all stakeholders, including consumers, health practitioners and the medicines industry
- actively disseminate information about new safety concerns to other governments and the World Health Organization.

Access: New Zealanders have access to the medicines they need

New Zealanders have access to the medicines they need, regardless of their individual ability to pay and within the government funding provided. This does not preclude New Zealanders or health care providers' right to choose and pay for medicines that are not funded by government.

Access to medicines is achieved through:

- access to health practitioners and services
- access to individual medicines.

The key mechanism facilitating access to affordable medicines in the community is the Pharmaceutical Schedule. The Pharmaceutical Schedule determines eligibility and criteria for the provision of medicines subsidies throughout New Zealand and aims to have a subsidised treatment available for each therapeutic sub-group of medicines.

The price for medicines listed on the Pharmaceutical Schedule is negotiated by Pharmac, on behalf of DHBs. The budget for community pharmaceuticals is negotiated between DHBs and Pharmac and is approved by the Minister of Health. In determining the community pharmaceuticals budget, consideration is given to community expectations about access to medicines, the contribution of medicines to health outcomes and areas of particular need. The amount spent on medicines is balanced against other health needs and, within medicines, choices about which medicines are funded.

To enable New Zealanders to access the medicines they need, balanced against other health needs and considering affordability for New Zealand:

- stakeholders, including consumers, will have the opportunity to provide information and perspectives that will contribute to Pharmac's decision-making processes and will be provided with guidance on how to do so
- opportunities for ongoing consultation with stakeholders (including consumers) will identify areas of need and community expectations that will contribute to decisions about medicines
- medicines funding decisions will be as transparent as possible and based on sound information and evidence
- the community pharmaceuticals budget-setting process will move towards a principles-based approach
- the medicines budget-setting process will consider access to innovative new medicines, low-volume or special formulations and high-cost medicines for small groups of New Zealanders
- where opportunities arise, and considering cost-effectiveness and affordability for New Zealand, innovative use will be made of medicines
- taking account of and balanced against other health priorities, the medicines system will have the capacity to respond to individual variation, within a population focus
- health practitioners will be aware of, and responsive to, the particular needs of Māori, Pacific people, disabled and low-income people and children, including defined processes and mechanisms to achieve improved outcomes for these groups

- physical access barriers including, for example, geographical barriers are considered and minimised in policy and medicines service design
- there is a nationally co-ordinated decision-making, funding and procurement programme for vaccines that builds on the strengths of the national immunisation programme and the health and disability sector.

In the community, access to medicines, health practitioners and services is supported through the Primary Health Care Strategy. This support reflects the Government’s recognition of the importance of access to primary health care services in improving health outcomes and reducing inequalities. Key elements of the Primary Health Care Strategy are reduced prescription costs for New Zealanders enrolled in a PHO and lowered fees to see primary health care practitioners.

Access to medicines is further supported, for eligible people, through:

- the Pharmaceutical Subsidy Card, which allows prescriptions for the cardholder and named family members to be filled at reduced or no charge
- the High Use Health Card, which provides additional assistance with the cost of doctor’s visits and prescription charges for people who face high general practitioner (GP) and prescription costs as a result of ongoing health needs
- the Community Services Card, which assists families on low to modest incomes with the costs of GP visits and prescriptions charges
- the Disability Allowance, which assists with costs associated with disability, including the cost of medicines and prescription charges
- in the case of a personal injury covered by the Accident Compensation Corporation (ACC), part or all of the costs of medicines to treat the injury are covered by ACC. This can include community pharmaceuticals co-payments, part-charges and, where approved, the full cost of medicines not on the Pharmaceutical Schedule
- personal insurance coverage.

Building on these existing initiatives, *Medicines New Zealand* seeks to make access to medicines and the system that makes decisions about the public funding of medicines, simple and seamless. This will support people to access the assistance they are entitled to – wherever they are in the medicines system.

Access

Goal 4

Stakeholders, including consumers, will have the opportunity to provide information or perspectives that will contribute to Pharmac’s decision-making processes and will be provided with guidance on how to do so.

Goal 5

New Zealanders understand and can access information about the medicines system including, where appropriate, information about medicines funding decisions and related health and disability system prioritisation criteria.

Goal 6

Medicines are affordable for individuals, the community and the health and disability system and meet the needs of New Zealanders.

Goal 7

Taking account of and balanced against other health priorities, the medicines system is responsive to individual variation, within a population focus.

Goal 8

Health practitioners will be aware of, and responsive to, the particular needs of Māori, Pacific people, disabled and low-income people and children, including defined processes and mechanisms to achieve improved outcomes for these groups.

Goal 9

Physical access barriers including, for example, geographical barriers are considered and minimised in policy and medicines service design.

Goal 10

New Zealand will implement a nationally co-ordinated decision-making, funding and procurement programme for vaccines that builds on the strengths of the national immunisation programme and the health and disability sector.

Optimal use: medicines are used to their best effect

Optimal use greatly influences the extent to which New Zealanders benefit from the therapeutic effects of medicines. Optimal use activities are crucial to ensuring that medicines that are assessed as being high-quality, safe and effective, are chosen, delivered and used in a way that ensures their potential to improve health and prevent illness is maximised. Optimal use activities also reduce wastage, enabling resources to be used more effectively.

Each of the three elements of *Medicines New Zealand* (quality, safety and efficacy; access; and optimal use) requires a commitment to collaboration between stakeholders and co-ordination of activities to achieve the desired outcomes. This is particularly true in the case of optimal use. Optimal use activities are diverse and are the responsibility of a wide range of people and agencies, including health practitioners and medicines consumers. Activities in this area also need good systems, for example, those envisaged by the Health Information Strategy for New Zealand (2005) and associated initiatives, to enable secure electronic transmission of information.

Behaviours and practices to support optimal use need:

- prescribers and other health practitioners to:
 - consider the most suitable and cost-effective treatment options, including non-medicinal and non-prescription alternatives
 - consider the safety and appropriateness (including the risks and benefits) of medicine choice in relation to clinical need
 - develop medicines plans that are mutually agreed with their patients
 - work collaboratively with other health practitioners and services to provide continuity of care and share up-to-date information on medicines risks and benefits and best practice treatment options
 - make services more available and provide treatment in a way that recognises the needs of individuals, including cultural differences
- medicines consumers to:
 - be active participants in their health management
 - be able to make informed decisions about medicines
 - understand the best way to use medicines (are ‘health literate’) and know where to go for information and support
- the medicines system to:
 - monitor and disseminate information to minimise the over-use, under-use, misuse and inappropriate disposal of medicines
 - provide effective regulation and post-market monitoring, in line with international best practice, to ensure ongoing assessment of medicines safety

- have systems to support optimal medicines use practices, including safe medicines systems such as child-safe packaging and at-the-bedside medicines verification systems
- monitor and evaluate the outcomes of medicines use.

Getting the best from medicines (optimal use) requires:

- robust medicines monitoring and reporting systems
- that consumers, health practitioners and medicines dispensers have access to timely and accurate information and education about medicines, how to take them and their use
- that prescribers have access to quality information about best practice treatment approaches
- that effective use is made of the skills of all health practitioners, as envisaged by the Health Practitioners Competence Assurance Act 2003
- that health providers (organisations and individuals) recognise that Māori and Pacific people may have specific perspectives and approaches to medicines use. To be effective, health services need to be whānau-inclusive and recognise specific attitudes and approaches to medicines use, including the use of traditional medicines such as rongoā Māori
- a collaborative and co-ordinated approach to ensure that optimal use activities are aligned and integrated across the medicines sector
- systems that make best use of electronic technology
- a culture of safety built on:
 - education for health practitioners and people using medicines
 - systems and technology to mitigate the impact of human error, including consideration of medicines safety practices for children
- that high-risk medicines and high-risk situations are identified and strategies enacted to minimise the likelihood of adverse events
- that special attention is given to the optimal use of antibiotics in light of the public health impacts of antibiotic resistance
- that particular attention is given to the interface between primary and secondary care services to ensure continuity of care and safe medicines use.

Optimal use

Goal 11

Information about medicines is collected and disseminated in a timely manner to ensure health practitioners and people using medicines have access to accurate, unbiased information and education about medicines, how to take them and their use.

Goal 12

People using medicines take an active role in making decisions about, and managing, their health care. Medicines plans are mutually agreed with health practitioners.

Goal 13

Robust and integrated systems support and monitor best-practice prescribing and the optimal use of medicines, including safe medicines use practices.

Goal 14

Māori and Pacific people receive health care services that meet their needs, are whānau-inclusive and recognise their specific attitudes and approaches to medicines use, including the use of rongoā Māori.

Guided by Principles

Achieving the *Medicines New Zealand* outcomes (quality, safety and efficacy; access; and optimal use) requires making policy decisions about a wide range of issues. Policy decisions that advance *Medicines New Zealand* will be principles-based, including decisions around setting the community pharmaceuticals budget. The principles described below cannot be considered in isolation and in some cases overlap. Decisions about medicines can and do require balancing competing objectives and making judgements using good information. This reflects the reality of complex health care settings and the systems needed to ensure the safe and appropriate use of medicines.

Equity

New Zealanders in similar need of medicines have an equitable opportunity to access equivalent medicines. Medicines and other resources are allocated in a manner that reduces inequity of outcomes.

Medicines New Zealand acknowledges the special relationship between Māori and the Crown. Strategies to achieve equity for Māori under *Medicines New Zealand* will recognise and build on the strengths and assets of Māori.

Effectiveness

The medicines system is effective, people-centred, evidence-based and reflects best practice to ensure safety, efficacy and timeliness. Within a population focus there is flexibility to consider individual variations.

Confidence

The processes within the medicines system are robust and transparent. 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 work collaboratively to secure the greatest possible value (in terms of efficacy, equity and cost) from medicines. This includes 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 with the funding available.

Transparency

New Zealanders can be confident that the medicines system operates in a fair and reasonable manner, based on the principles set out in *Medicines New Zealand*. The principle of transparency is balanced against other needs, including the need to conduct commercial negotiations in order to secure the best health outcomes.

Implemented through Excellent Systems

Implementing a robust and sustainable approach to medicines use requires excellent systems. Our medicines system will be people-centred, reflect best practice and actioned through the following:

Cross-sector collaboration and stakeholder engagement

Different agencies and stakeholders, jointly or alone, have responsibility for advancing the outcomes of *Medicines New Zealand*. Achieving these outcomes requires collaboration, an understanding of the roles that different stakeholders and agencies play and a clear, agreed strategic direction. *Medicines New Zealand* acknowledges that stakeholders have different roles and perspectives. This can give rise to conflict. Regardless of this tension, all parties know and respect the roles that others play and the decisions they make.

All New Zealanders are stakeholders in the medicines system. To effectively participate in achieving *Medicines New Zealand* outcomes, stakeholders need to have a clear understanding of how the medicines system operates and have confidence in it. This will be supported through accessible information about the medicines system, including medicines system decision-making criteria. The medicines system will actively seek stakeholder input and support stakeholders in providing their feedback. Key stakeholders include:

- people who use medicines
- the health and disability sector (for example, the Ministry of Health, DHBs, Pharmac, PHOs and non-government organisation providers)
- iwi representative groups
- disability sector organisations and disability consumer organisations
- health practitioners, their regulatory authorities, professional organisations and training providers
- the pharmaceutical industry, including the innovative medicines industry, the generic medicines industry and the non-prescription medicines industry
- complementary medicines practitioners and manufacturers
- other government agencies, such as the Ministry of Research, Science and Technology, the Ministry of Social Development and ACC
- other governments.

Structures and systems that work well

The structures and systems that make up the New Zealand medicines system are sound. This does not mean they cannot improve. Agencies and stakeholders within the medicines system will continue to refine their internal processes and the ways they work together to ensure they deliver the best health outcomes possible from medicines. Structures and systems will have the following characteristics:

- **well-designed and safe** – any organisation or system design will have difficulties that need to be managed. Acknowledging this, organisational design will be sound, management practices for safe medicines systems will be in place, there will be appropriate checks and balances and clear accountabilities, and organisations will be well connected domestically and internationally.
- **responsive to citizens** – agencies and other stakeholders within the medicines system will support and include consumers to take an active role in medicines treatment decisions and will provide opportunities for consumers to contribute to medicines funding decisions.
- **efficient** – the system will operate as efficiently as possible to gain the maximum value from medicines and medicines funding. Duplication of activities and unnecessary compliance costs will be minimised.
- **enduring over time** – changes in structures and systems can be disruptive and costly. It takes time for new structures and systems to bed-in as new relationships and processes are established. That said, structures in the medicines systems need to be responsive to changes in health priorities, new technology, the outcome of evaluation and other changes in the health environment.

System capability

In order for our medicines systems and structures to work well and deliver *Medicines New Zealand* outcomes, they must be supported by the following:

- **financial resources** – the medicines system will have the resources it needs to enable systems and structures to carry out their functions. Funding decisions will demonstrate value for money and ongoing improvement in overall system performance. Funding for medicines will be determined through a principles-based budget-setting process and strike a balance between the objectives of promoting health status, access and affordability.
- **workforce** – there will be a skilled and educated health workforce. Health practitioners will support people to access, safely use and gain maximum effect from medicines. Health practitioners will identify the needs of particular population groups and act to ensure they have equitable access to the medicines they need, notably Māori, Pacific people, disabled and low-income New Zealanders. Those accessing non-prescription medicines and complementary medicines will be supported by good quality advice and information.

The medicines system will have an expert health workforce, including analysts, to deliver necessary health services, undertake regulatory assessments, make funding decisions and monitor and evaluate the medicines system to ensure it delivers *Medicines New Zealand* outcomes.

- **infrastructure** – physical organisations, information systems and other infrastructure will support the safe and appropriate use of medicines.
- **knowledge and information** – getting the best from medicines and having structures and systems that work well requires good knowledge and information. We also need the technology to share that information. The medicines system will collect and disseminate high-quality information to:
 - support Medsafe, the Pharmacology and Therapeutics Advisory Committee and Pharmac in assessing whether a medicine should be on the market and whether it should attract a public subsidy
 - inform the Government and New Zealanders about how decisions are made and how medicines are used so that they can assess the performance of the medicines system
 - enable people to make informed decisions about, and optimal use of, medicines
 - inform optimal-use strategies and evidence-based practice
 - inform the development of systems and practices for the safe use of medicines
 - support best-practice prescribing and health care
 - inform and refine decision-making processes
 - enable robust pharmacovigilance systems, ensuring access to safe, quality medicines for New Zealanders
 - contribute to cross-border information sharing to facilitate safety throughout the supply chain.

Excellent systems

Goal 15

Stakeholders are aware of, understand and respect the roles of others in the medicines sector.

Goal 16

People understand how the medicines system works, can participate in it and gain maximum benefit from medicines.

Goal 17

Stakeholders in the medicines system are guided by a common strategic direction and work collaboratively to achieve *Medicines New Zealand* outcomes.

Goal 18

The roles and functions of agencies within the medicines system are aligned to enable them to deliver *Medicines New Zealand* outcomes effectively and efficiently and to minimise duplication.

Goal 19

The medicines system has the capability it needs to deliver *Medicines New Zealand* outcomes effectively: financial resources; workforce availability and skill sets; infrastructure; and knowledge and information.

Goal 20

The systems within the medicines sector work well and contain appropriate checks and balances and clear accountabilities.

