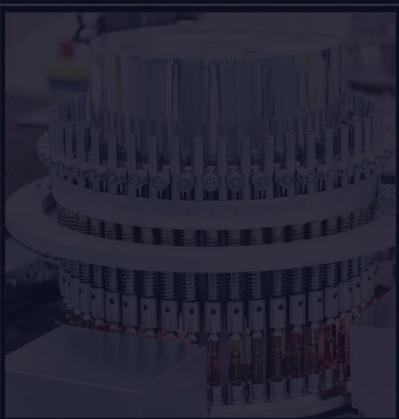


A ROADMAP FOR INDIAN COMPANIES



PHARMA INDUSTRY IN NEW ZEALAND

RESEARCH BY:

India 
New Zealand
Business Council



SUPPORTED BY:

HIGH COMMISSION OF INDIA,
WELLINGTON, NZ

Contents

India New Zealand Business Council, in collaboration with the Indian High Commission, presents a research paper on the scope and structure of the Pharma industry of New Zealand.

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NEW ZEALAND HEALTH STATISTICS

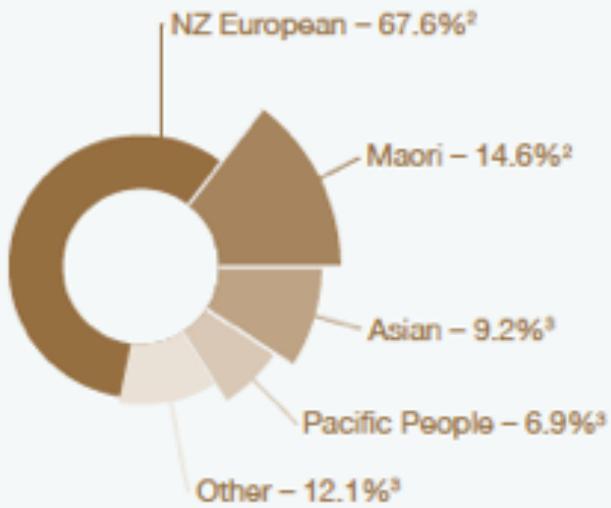
CURRENT POPULATION

4,433,492
(4.4 million)¹

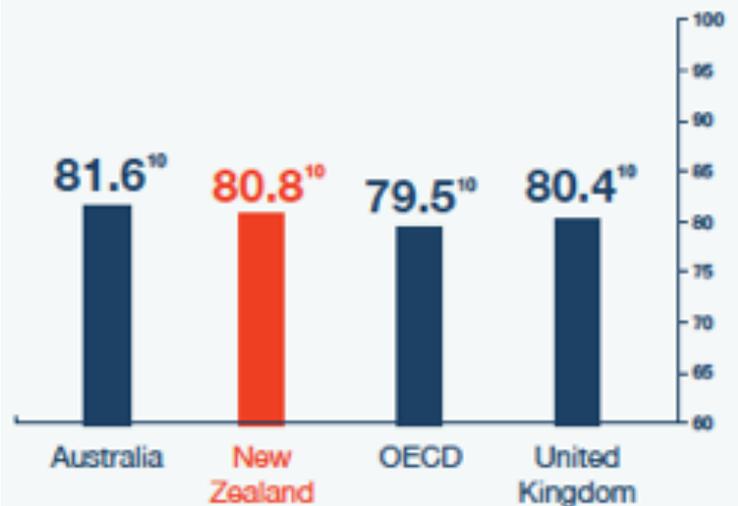
PROJECTED POPULATION

5.5 Million
by 2061¹

ETHNIC BREAKDOWN



LIFE EXPECTANCY AT BIRTH



Main Causes of death / Health Risks in NZ

1. CARDIOVASCULAR DISEASE STATISTICS

40% **90** mins

Cardiovascular disease (heart, stroke and blood vessel disease) is the leading cause of death in New Zealand, accounting for 40% of deaths annually.

Every 90 minutes a New Zealander dies from coronary heart disease (16 deaths a day).

In New Zealand, it is estimated that the number of people diagnosed with diabetes exceeds 200,000 people (predominantly type 2 diabetes).

There are also about 100,000 people who have diabetes but have not yet had it diagnosed.

Within the New Zealand population, the prevalence of diabetes in Maori and Pacific populations is around three times higher than among other New Zealanders.

2. DIABETES STATISTICS

>200,000

Approximately one in two New Zealanders are obese or overweight.

44.7% of Maori adults are obese.

57.9% of Pacific adults are obese.

One in twelve children (aged 2 to 14 years) are obese (8.3%).

One in five children are overweight (20.9%).

3. OBESITY STATISTICS

1 in **2**

Cancer is a leading cause of death in New Zealand accounting for 29.4% of all deaths.

Every day around 51 people are diagnosed with cancer in New Zealand and there are 22 cancer deaths.

4. CANCER STATISTICS

51 People diagnosed with cancer per day

Main Causes of death / Health Risks in NZ

5. SMOKING STATISTICS

2025

New Zealand is aiming to be smoke-free by 2025.

One in five New Zealanders older than 15 smoke.

It is estimated that 5,000 people in New Zealand die prematurely from smoking each year - this equates to around 12 people a day dying from smoking.

New Zealand has the second highest prevalence of asthma in the world (after the UK).

One in six New Zealand adults and one in four children experience asthma symptoms (approximately 600,000 kiwis).

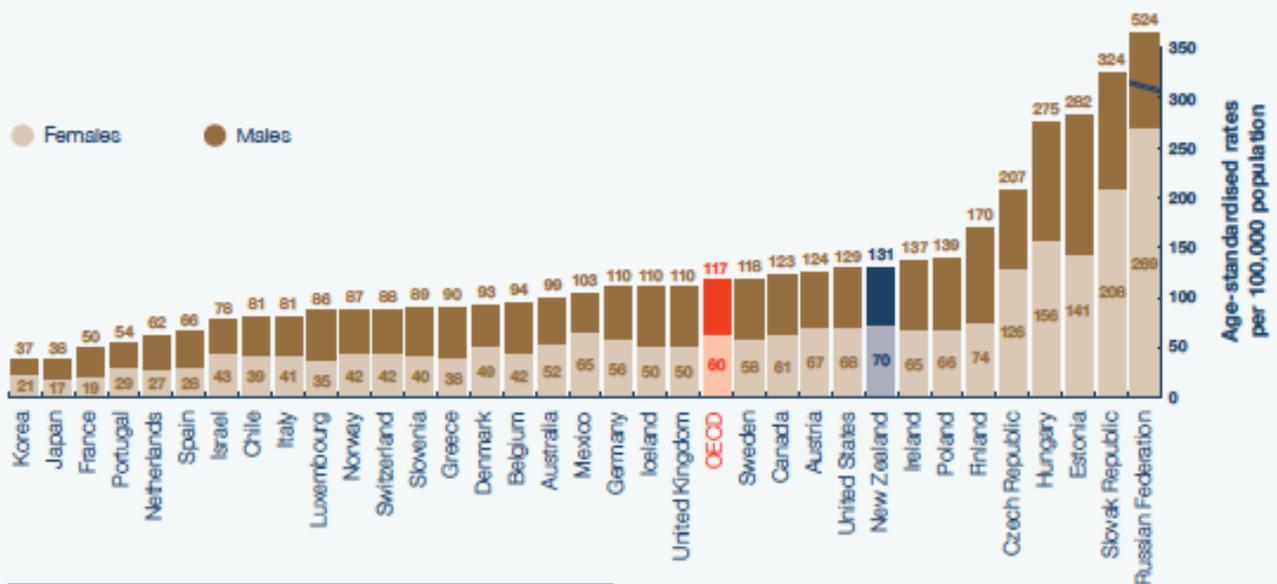
6. ASTHMA STATISTICS

1 in 6 Adults

1 in 4 Children

The Health of New Zealand vs the OECD

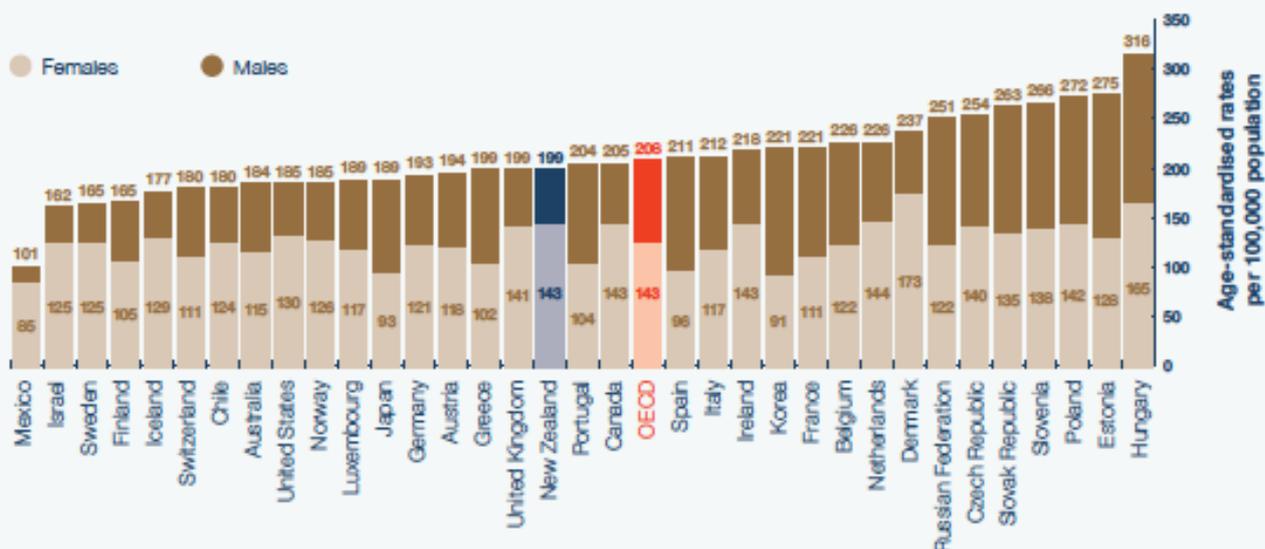
ISCHEMIC HEART DISEASE MORTALITY RATES, 2009 (OR NEAREST YEAR)



Source: OECD Health Data 2011; IS-GBE (2011).
<http://dx.doi.org/10.1787/888932523348>

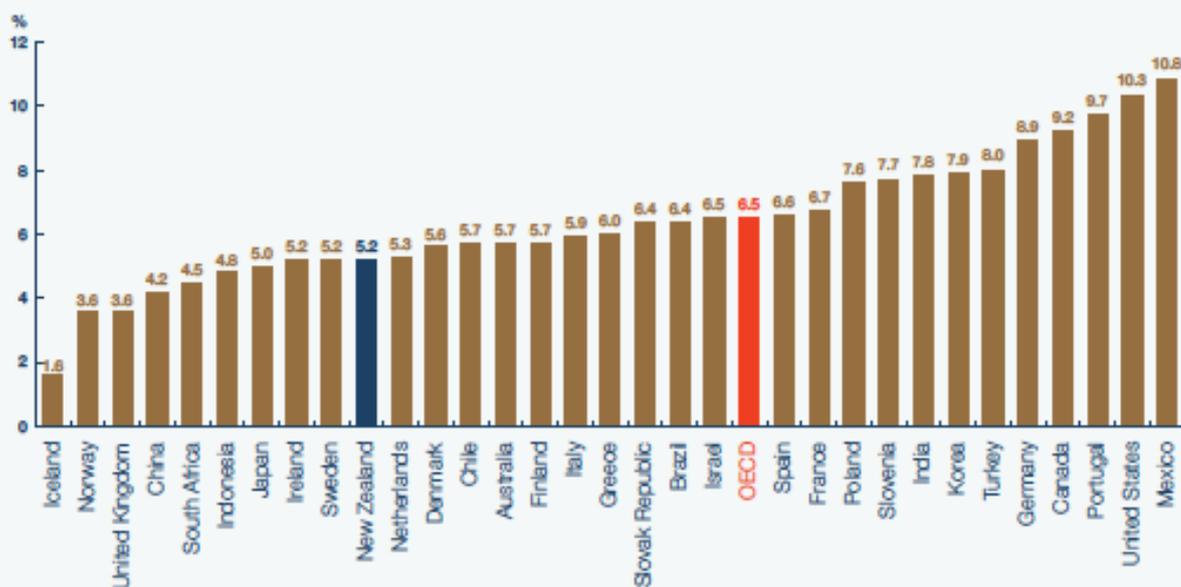
The Health of New Zealand vs the OECD

ALL CANCERS MORTALITY RATES, MALES AND FEMALES, 2009 (OR NEAREST YEAR)



Source: OECD Health Data 2011; IS-GBE (2011).
<http://dx.doi.org/10.1787/888932623424>

PREVALENCE ESTIMATES OF DIABETES, ADULTS AGED 20-79 YEARS, 2010



Note: The data cover both Type 1 and Type 2 Diabetes.
 Data are age standardised to the World Standard Population
 Source: IDF 2009. <http://dx.doi.org/10.1787/888932623747>

The New Zealand Health and PHARMAC Budgets

THE PHARMAC BUDGET EQUATES TO APPROXIMATELY 5% OF THE TOTAL NEW ZEALAND HEALTH BUDGET.

New Zealand Health Budget¹

Year	Budget (\$Bn)
2009/2010	13.40
2010/2011	14.00
2011/2012	14.40
2012/2013	14.70

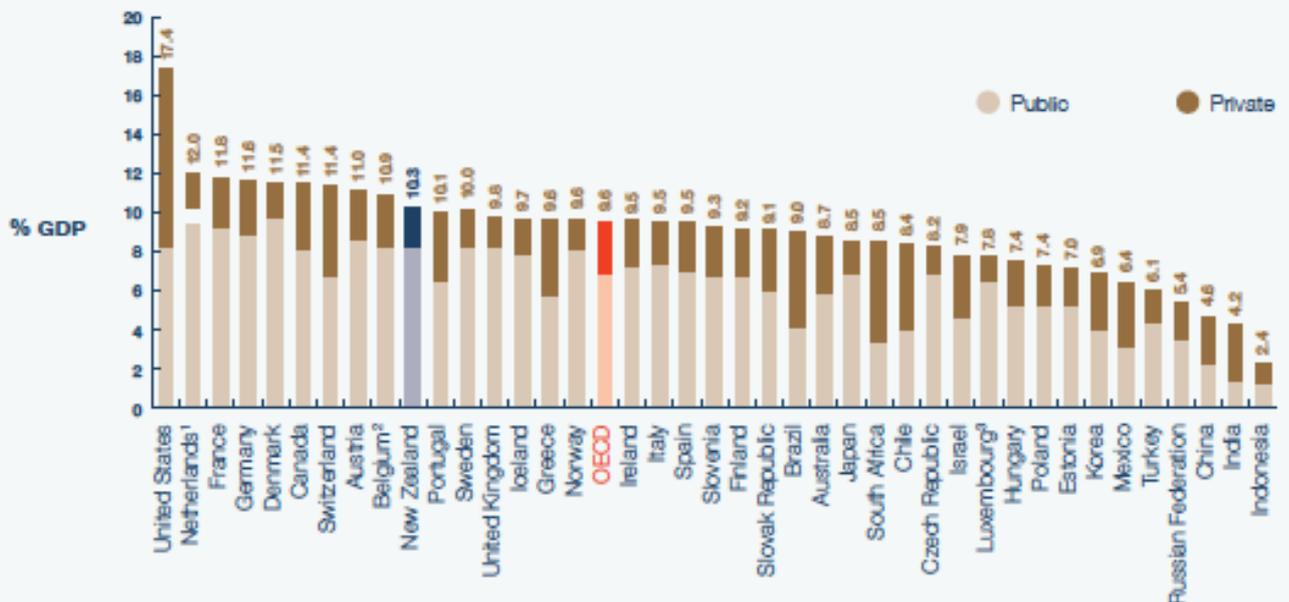
PHARMAC Budget²

Year	Budget (\$Mn)
2009/2010	694.0
2010/2011	710.0
2011/2012	778.0
2012/2013	748.5

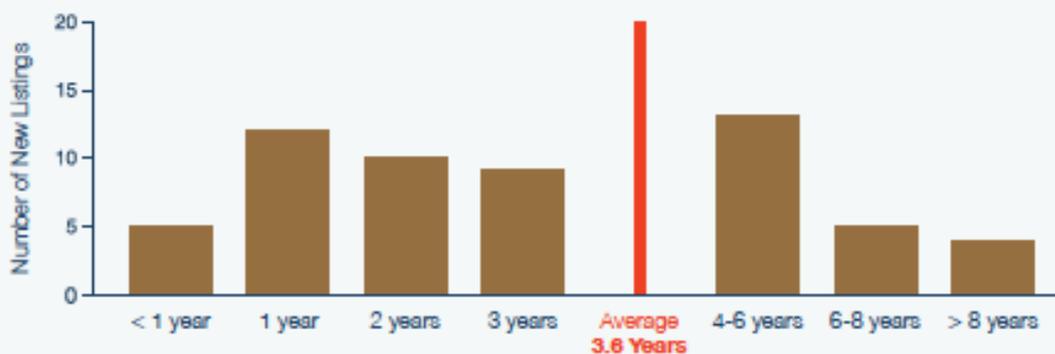


Medicines play an important part in maintaining the health of New Zealanders. 41.1 Million funded prescriptions were written between July 2011 and June 2012 and 3.3 million New Zealanders benefited from these medications.

TOTAL HEALTH EXPENDITURE AS A SHARE OF GDP, 2009 (OR NEAREST YEAR)



NEW ZEALAND HAS DELAYED ACCESS TO NEW MEDICINES COMPARED TO AUSTRALIA.



Delays in PHARMAC listing of medicines relative to Medsafe approval (2000 - 2010)²

R&D is a Long and Costly Process

25,000

compounds start in the laboratory³

25

go to clinical trials³

5

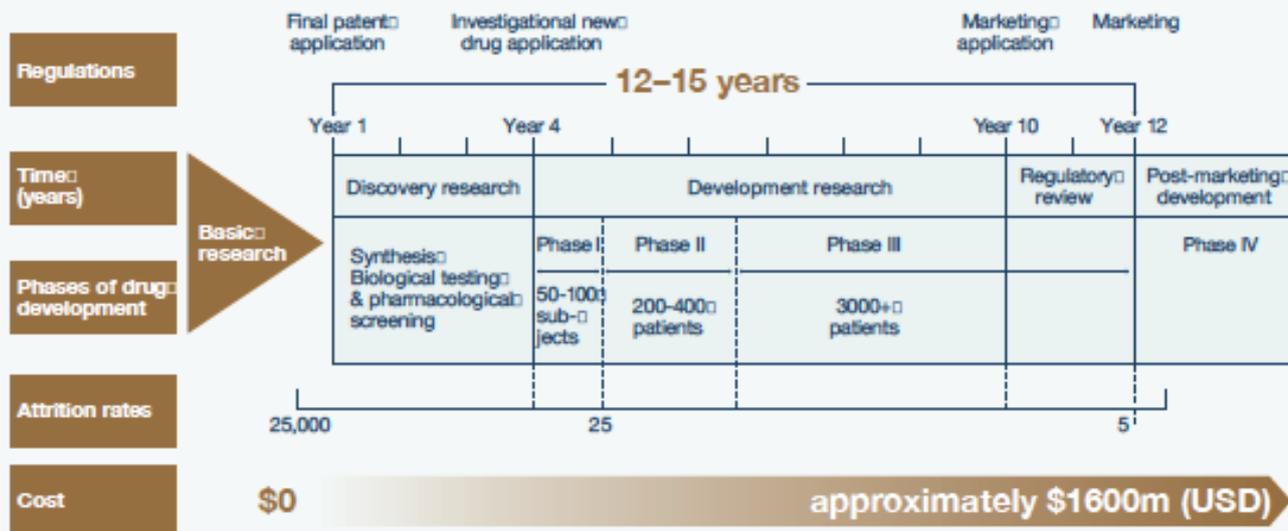
make it to market³

1

recoups investment³

The development of a new pharmaceutical takes between 12 and 15 years.¹

Only 5 of 25,000 compounds tested in the laboratory are actually approved by regulatory authorities following clinical testing.²

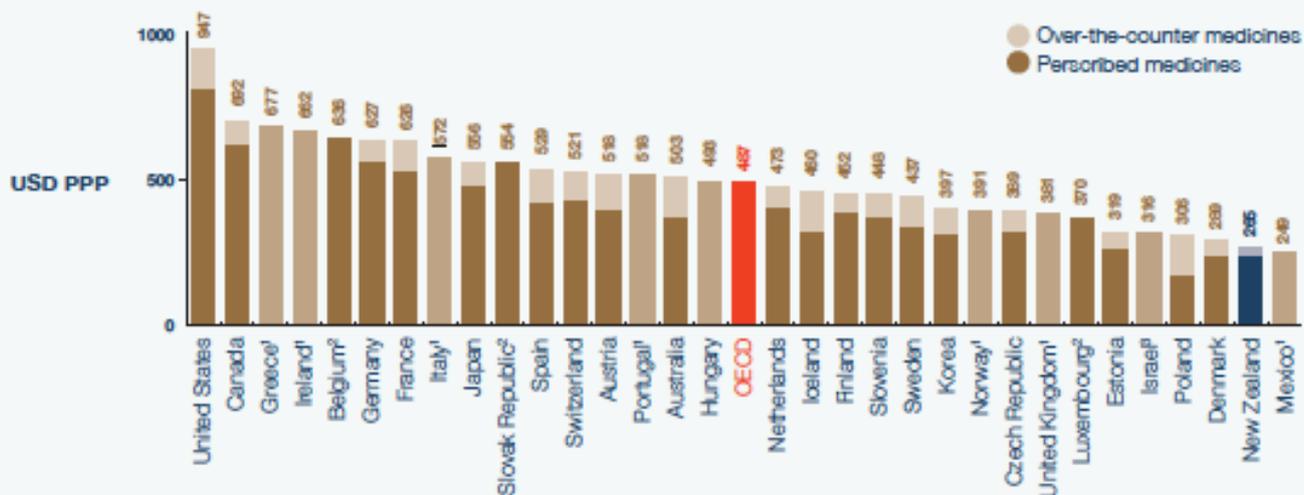


New Zealand ranks

31st out of 32 Countries

in the amount they spend on pharmaceuticals as a share of GDP

EXPENDITURE ON PHARMACEUTICALS PER CAPITA, 2009 (OR NEAREST YEAR)



- 1 USA
- 2 Spain
- 3 France
- 4 Denmark
- 5 Australia
- 6 Switzerland
- 7 Canada
- 8 UK
- 9 Austria
- 10 Norway
- 11 Germany
- 12 Italy
- 13 Sweden
- 14 **New Zealand**

Uptake of New Medicines in New Zealand is Slow.

New Zealand's overall ranking for the uptake of new medicines¹

New Zealand's Medicines Landscape

Medicines New Zealand believes New Zealanders deserve better access to medicines when they need them.

Coming last out of 20 comparable OECD countries for access to new and innovative medicines reflects a harsh reality – New Zealand is a first world nation with second-rate access to leading health interventions.

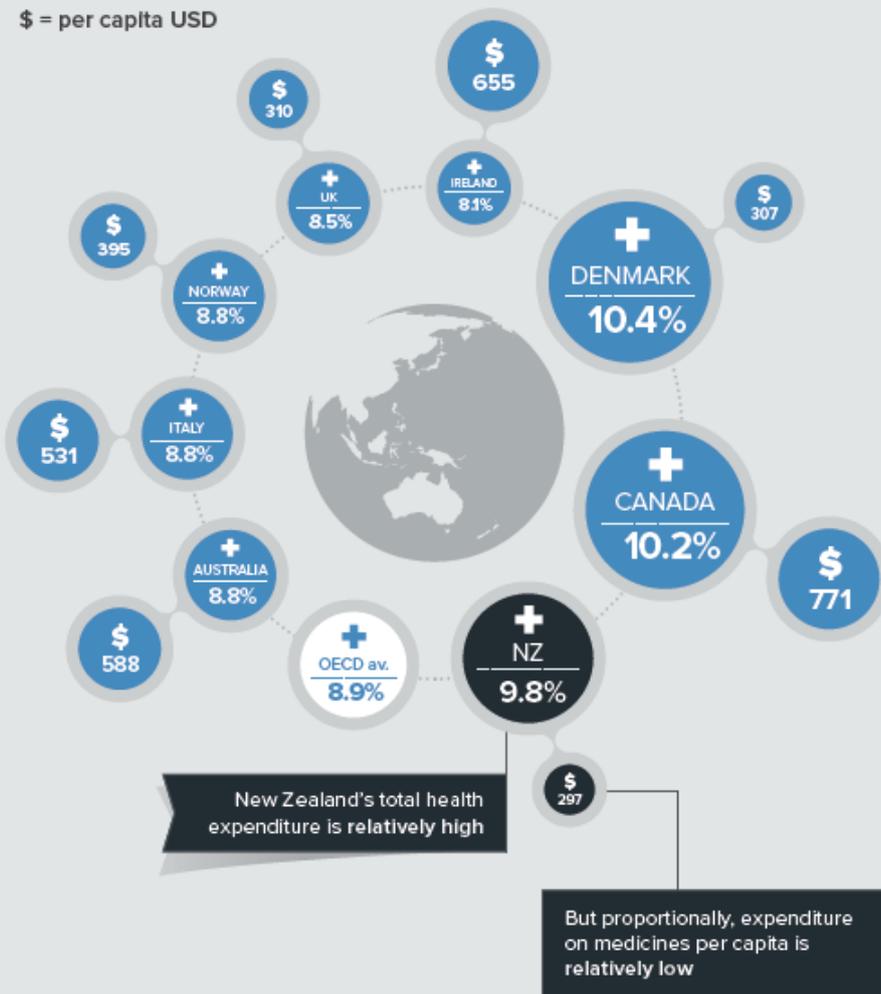
Medicines are an important part of the overall health equation for New Zealand. Our aging population and increase of chronic diseases mean rapidly rising healthcare costs. We believe continuous investment in the best medicines when patients need them is crucial in helping the Government better manage healthcare solutions and costs.

Government, industry, and New Zealanders should be in partnership to ensure we can have longer and healthier lives.

Hon Heather Roy | Medicines New Zealand Chair | 2015

New Zealand's health expenditure compared to the rest of the world based on OECD data and health spend per capita (USD)

\$ = per capita USD



Innovative medicines contribute to an increase in life expectancy*

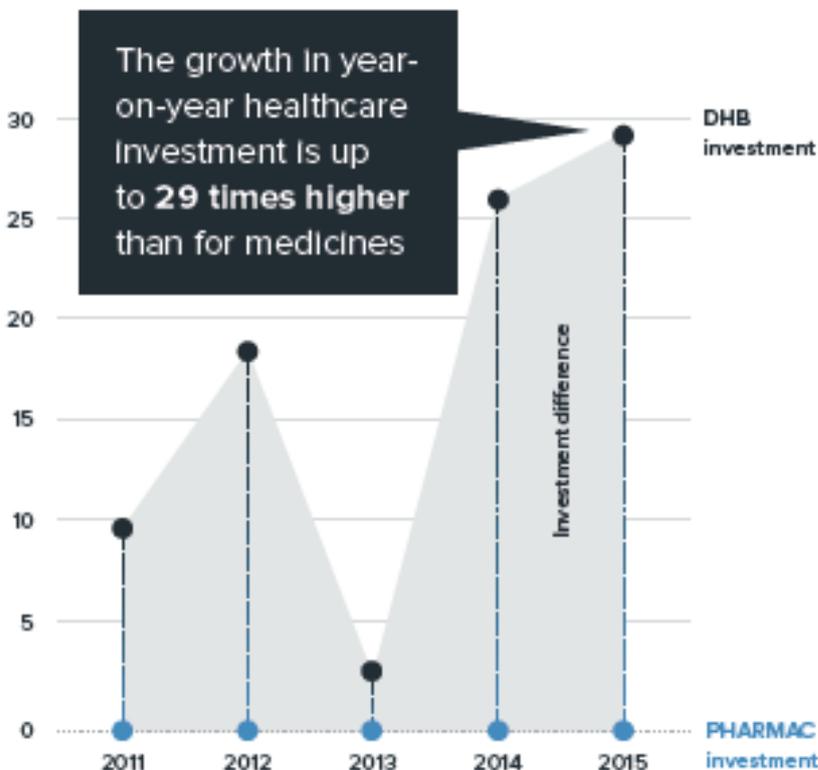


* Measured by the effect of the vintage (year of US FDA approval) of prescription drugs used by elderly American patients.

The Pharmac:DHB investment difference

Why the discrepancy?

Healthcare investment is increasing, while investment in medicines is not, despite medicines lowering total future healthcare spending, reducing the length of stays in hospital, preventing and treating chronic illnesses, and improving life expectancy.



Diabetes is on the rise

1st



United States

2nd



New Zealand

New Zealand is second to the United States in the years of life lost to diabetes.

There are

7 PTAC
recommended
type II diabetes
medicines

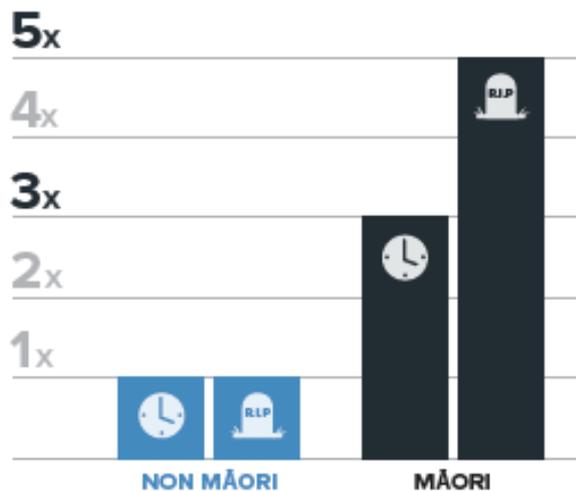
waiting for funding.



To see the detailed waiting list visit
www.medicinesnz.co.nz

Diabetes is most common among Māori and Pacific Islanders

Māori are 3 x more likely to develop diabetes type II than non-Māori, and are more than 5 x likely to die from it.



The number of people with diabetes grows by nearly
40 people per day

Health interventions help people with diabetes live longer healthier lives than those without support.

The medicines waiting list is too long

What is the waiting list?

Following a Pharmacology and Therapeutics Advisory Committee (PTAC)* recommendation and PHARMAC** in-house evaluation, an internal priority list of medicines is generated from which potential investment options are then chosen.

PHARMAC does not publish this list, nor the process by which it is subsequently reprioritised for final funding decisions.

Medicines New Zealand actively updates this waiting list to increase transparency around PHARMAC decision making, timelines for listing, and help with budget forecasting.

* PTAC is PHARMAC's primary clinical advisory committee. PTAC's role is to provide objective clinical advice to the Board of PHARMAC.

** PHARMAC is the New Zealand government agency that decides which pharmaceuticals to publicly fund in New Zealand.

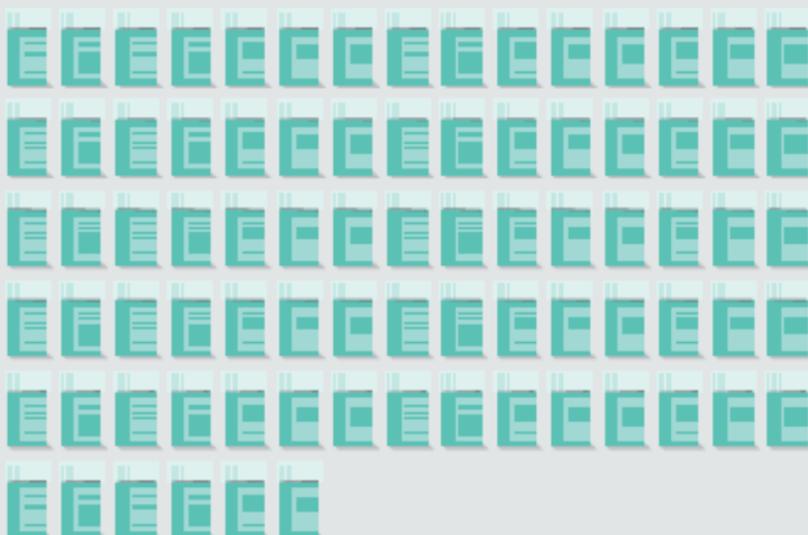
There are:

109

PTAC
recommendations for

81

medicines yet
to be funded



2.7 YEARS

IS THE AVERAGE
WAITING TIME



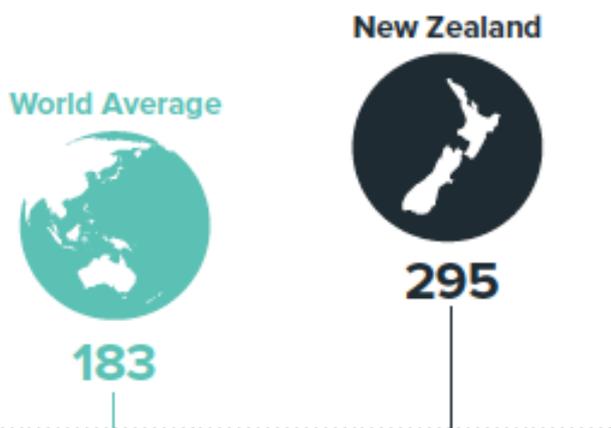
12 YEARS

IS THE LONGEST WAITING TIME
FOR A MEDICINE

New Zealand has high cancer rates

Average cancer rate

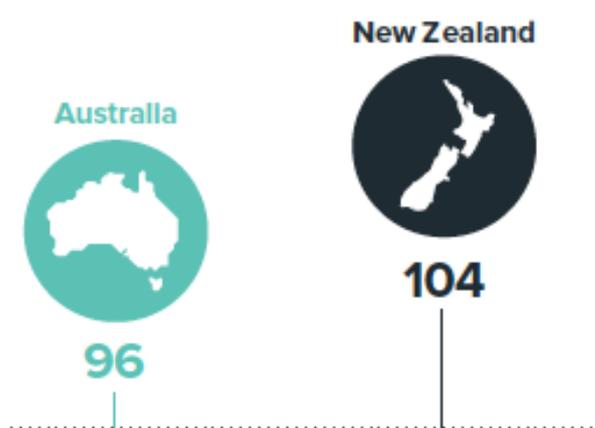
New Zealand's average cancer rates are over 62% higher than the world average.



ASR rate per 100,000
All cancers excluding non-melanoma skin cancer rates

Cancer mortality rate

New Zealand's cancer mortality rate exceeds Australia's average by 8%.



ASR rate per 100,000
All cancers excluding non-melanoma skin cancer mortality rates

New Zealand only invests 0.8% on cancer medicines

New Zealand cancer facts

13th highest rate of all cancers in the world	9th highest rate of colorectal cancer	4th highest rate of colorectal cancer in women	19th highest rate of breast cancer	18th highest rate of prostate cancer
Highest incidence rate of melanoma skin cancer in the world	Lung cancer is the leading cause of cancer deaths	Colorectal mortality rates are almost double the world average	Melanoma skin cancer rates are more than four times the world average	New Zealand mortality rates exceed the overall world average

Māori have poorer health outcomes

Life expectancy is less for Māori than non-Māori

MĀORI MEN



3x
more likely
to die from
lung cancer

3.5x
more likely
to die from
liver cancer

1.5x
more likely
to die from
prostate cancer

2.5x
more likely
to die from
stomach cancer

MĀORI WOMEN



1.5x
more likely
to die from
breast cancer

2x
more likely
to die from
cervical cancer

4x
more likely
to die from
lung cancer

Health burdens for Māori



Māori make up 27% incidences of cancer



12% of Māori families with ill children cannot afford prescription costs



Māori children are 1.5 x more likely to develop asthma and are 3 x more likely to be hospitalised with eczema



The total cancer mortality rate is 1.5 x higher for Māori than non-Māori.

Māori are 5 x more likely to:



Wait longer for chemotherapy



Have less lymph nodes removed



Require emergency surgery



Die after elective surgery

Overview of the NZ health system

Health and disability services in New Zealand are delivered by a complex network of organisations and people. Each has their role in working with others across the system to achieve better health for New Zealanders.

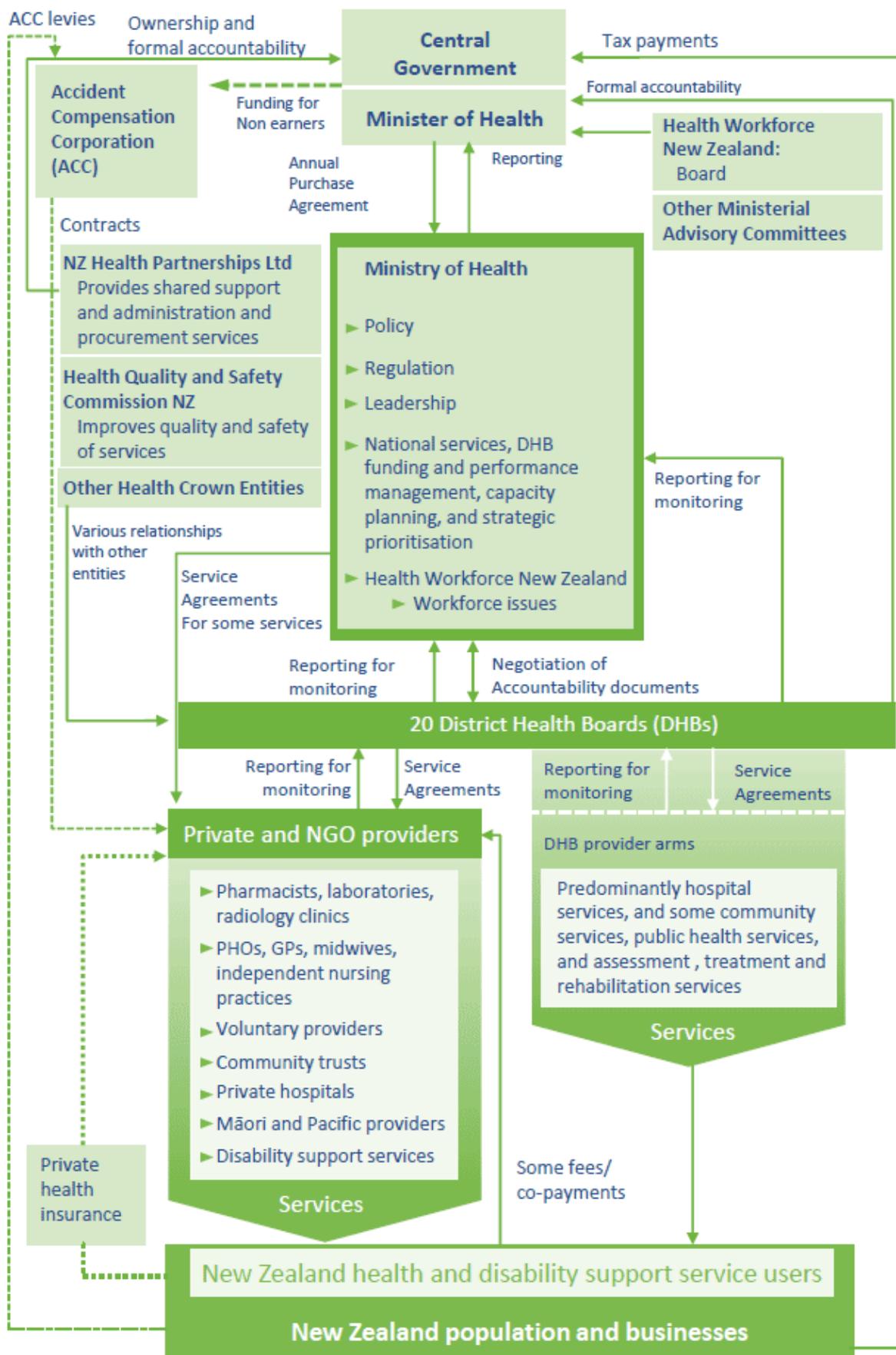
A complex system, working together

The Minister of Health (with Cabinet and the government) develops policy for the health and disability sector and provides leadership. The Minister is supported by the Ministry of Health and its business units, and advised by the Ministry, the strategic prioritisation function, Health Workforce New Zealand and other ministerial advisory committees.

Most of the day-to-day business of the system, and around three quarters of the funding, is administered by district health boards (DHBs). DHBs plan, manage, provide and purchase health services for the population of their district to ensure services are arranged effectively and efficiently for all of New Zealand. This includes funding for primary care, hospital services, public health services, aged care services, and services provided by other non-government health providers including Māori and Pacific providers.

Please see overview of the whole system on next page.

The structure of the New Zealand health and disability sector



District health boards: Overview

District health boards (DHBs) are responsible for providing or funding the provision of health services in their district. Disability support services and some health services are funded and purchased nationally by the Ministry of Health.

Board membership

There are 20 DHBs in New Zealand and each DHB is governed by a board of up to 11 members. DHB boards set the overall strategic direction for the DHB and monitor its performance.

The Minister of Health appoints up to four members to each board, and the board's chair and deputy chair. Seven members are publicly elected every three years at the time of local government elections. The Minister can also appoint Crown monitors to boards, in certain circumstances.

Objectives and roles of DHBs

The New Zealand Public Health and Disability Act 2000 created DHBs. It sets out their objectives, which include:

- improving, promoting and protecting the health of people and communities
- promoting the integration of health services, especially primary and secondary care services
- seeking the optimum arrangement for the most effective and efficient delivery of health services in order to meet local, regional, and national needs
- promoting effective care or support of those in need of personal health services or disability support.

There are currently 20 DHBs in New Zealand. They are required to plan and deliver services regionally, as well as in their own individual areas.

Public hospitals are owned and funded by DHBs.

About PHARMAC

What is PHARMAC?

PHARMAC is the New Zealand government agency that decides which pharmaceuticals to publicly fund in New Zealand. PHARMAC makes choices about District Health Boards' (DHBs) spending on vaccines, community and cancer and other hospital medicines.

Background:

PHARMAC was created in 1993 to ensure that New Zealanders get the best possible health outcomes from money the Government spends on medicines used in the community. Since then our role has expanded to include cancer medicines, vaccines, and haemophilia treatments, which are all funded by District Health Boards through the Combined Pharmaceutical Budget (CPB). PHARMAC also makes decisions about the medicines funded in DHB hospitals and negotiates national contracts for medical devices used in hospitals. They work towards budget management of hospital medicines and medical devices in the longer term.

PHARMAC has four main functions:

1. Managing the Pharmaceutical Schedule

Consisting of about 1900 Government-subsidised community pharmaceuticals, 2600 medicines used in public hospitals, and 20,000 hospital medical devices (August 2016)

2. Promoting the responsible use of medicines

3. **Managing the Named Patient Pharmaceutical Assessment policy** for patients in exceptional circumstances

4. Engaging in research as required

We are guided by a number of laws, regulations and Government guidelines, and Medicines New Zealand – the Government's strategy for the medicines system, as well as our own internal decision-making framework and the Factors for Consideration.

Managing within budget

PHARMAC manages a Combined Pharmaceutical Budget (CPB) and also holds further funding (CPB and Hospital Discretionary Pharmaceutical Funds (DPF)). The CPB DPF enables PHARMAC to manage up to two percent variation in the expenditure figure which allows a long-term approach to spending decisions. The CPB DPF may be supplemented by DHB underspending in combined pharmaceuticals in any financial year and may also be used to pay DHBs if there is any collective overspend in combined pharmaceuticals.

The CPB is set each year by the Minister of Health, on the advice of District Health Boards and PHARMAC. The CPB includes funding for community medicines and some medical devices, hospital cancer medicines, haemophilia treatments and vaccines.

PHARMAC forecasts the level and cost of growth in demand for products already listed, and then decides what additional pharmaceuticals (medicines and some medical devices) to fund,

negotiates prices, sets subsidy levels and conditions, and ensures spending stays within budget. The list of subsidised pharmaceuticals is published in the Pharmaceutical Schedule.

PHARMAC also manages the cancer medicines DHBs must have available. Funding for hospital cancer medicines has been part of the CPB since 2011/12.

PHARMAC is not able to spend more than the budgeted amount by law, so they try to keep spending as close as possible to the target figure while remaining under it.

New Zealand Pharmaceutical Schedule

All of PHARMAC's funding decisions are listed in the Pharmaceutical Schedule. It tells people what funded medicines and devices are available, what level of subsidy a particular item has or the price to be paid.

However, the subsidy is the amount for the pharmaceutical paid to the pharmacist, and is not the amount of money the patient pays. That amount (known as the co-payment) is set by Government and is free for children under the age of 13 years and usually \$5 per item for each family's first 20 items each year. A small number of medicines require payment of an additional manufacturer charge on top of the patient co-payment. There are some other costs that pharmacists may charge for additional services and they will explain these to you at the time.

AS WELL AS MANAGING FUNDING, PHARMAC
ASSESSES & PRIORITISES
VACCINES, ALONGSIDE OTHER
PHARMACEUTICALS

AND WORKS WITH SUPPLIERS
ACROSS THEIR FULL PRODUCT
PORTFOLIOS TO OBTAIN THE

\$ BEST VALUE \$

For medicines the Pharmaceutical Schedule includes what formulation a medicine is available in, how much can be prescribed at one time and what, if any, restrictions are in place.

Anyone can look at the Schedule at: <http://www.pharmac.govt.nz/about/your-guide-to-pharmac/factsheet-14-pharmaceutical-schedule/>

Guide to PHARMAC: What they do and How they do?

PHARMAC's place in the health system

PHARMAC's role within the New Zealand health system is to make decisions on which medicines and medical devices are funded in order to get the best health outcomes from within the available funding. Their effectiveness depends significantly on the work of others.

In the medicines area they need pharmaceutical companies to supply effective products and Medsafe to approve medicines as safe and effective to use, and manufactured to good quality standards. They also rely on prescribing decisions, dispensing services and consumer feedback to get the best health outcomes from medicines. In the medical devices area they rely on suppliers, clinicians and DHB specialist staff, device users and Medsafe to share their knowledge and perspectives.

Medicines New Zealand is the Government's strategy for the medicines system. It defines three main outcomes for the medicine system:

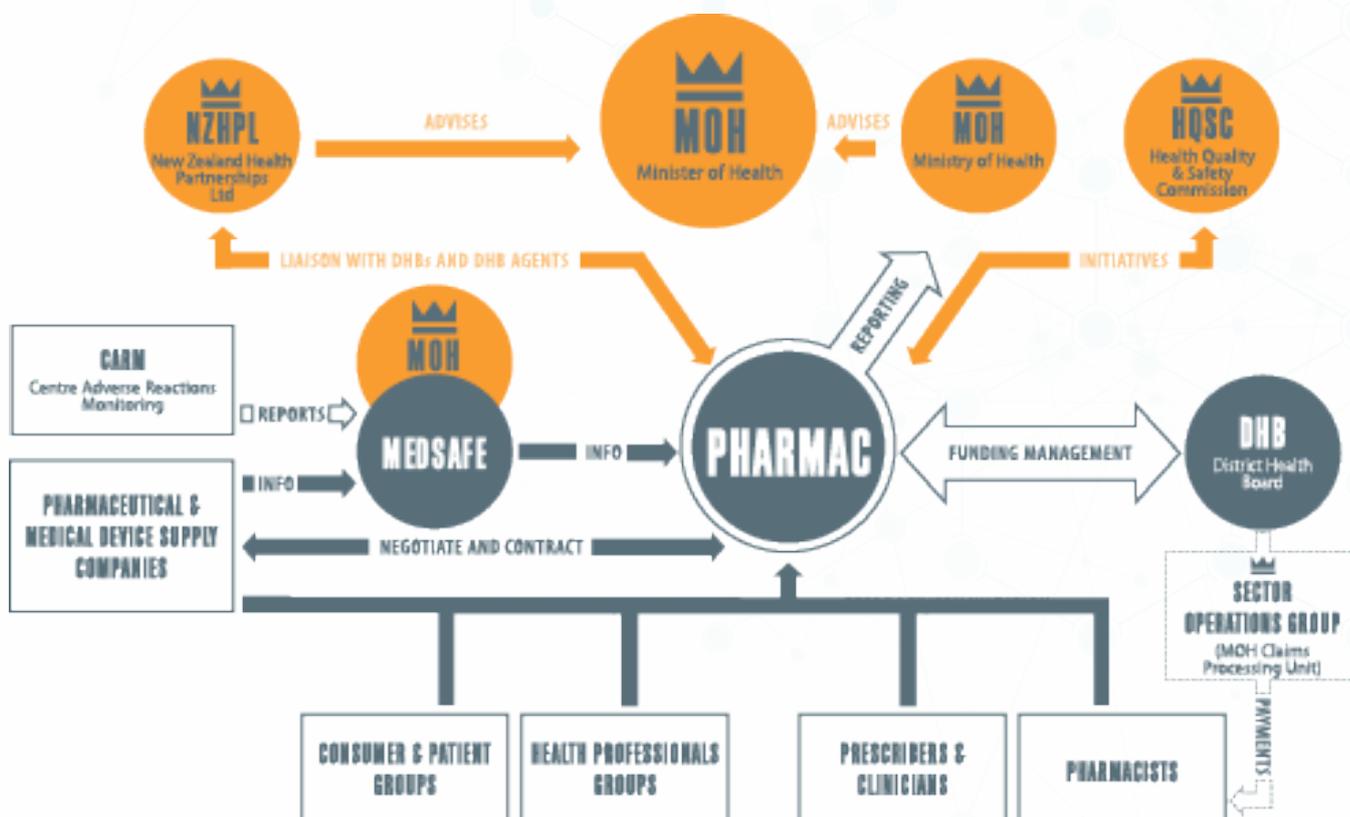
Access: New Zealanders have access to the medicines they need, including equity of access to medicines

Optimal use: medicines are used to their best effect

Quality: medicines that are safe and effective.

PHARMAC's work focuses on access and optimal use of medicines.

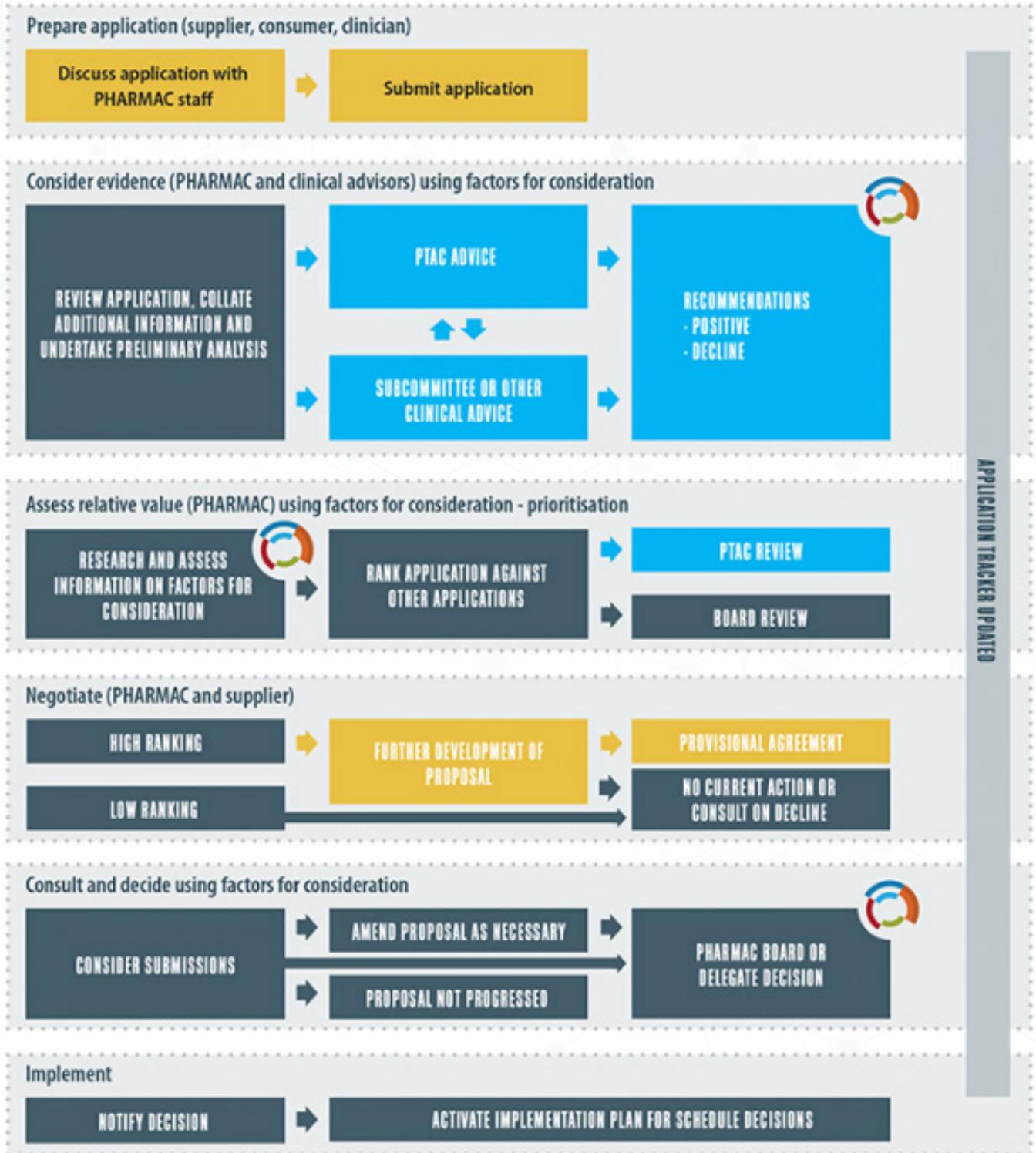
Quality is primarily the role of other organisations, in particular Medsafe.



How medicines are funded: the process

CURRENT PROCESS

FOR CONSIDERING AN APPLICATION FOR FUNDING



Text version of the process diagram

Prepare application (supplier, consumer, clinician)

1. Discuss application with PHARMAC staff
2. Submit application

Consider evidence (PHARMAC and clinical advisors) using factors for consideration

1. Review application, collate additional information and undertake preliminary analysis
2. Either or both:
 - PTAC advice
 - Subcommittee or other clinical advice
3. Recommendations:
 - Positive
 - Decline

Assess relative value (PHARMAC) using factors for consideration – prioritisation

1. Research and assess information on factors for consideration
2. Rank application against other applications
3. Either:
 - PTAC review
 - Board review

Negotiate (PHARMAC and supplier)

High ranking

1. Further development of proposal
2. Either:
 - a. Provisional agreement
 - b. No current action or consult on decline

Low ranking

1. No current action or consult on decline

Consult and decide using factors for consideration

1. Consider submissions
2. Either:
 - Amend proposal as necessary, then PHARMAC Board or delegate decision
 - PHARMAC Board or delegate decision
 - Proposal not progressed

Implement

1. Notify decision
2. Activate implementation plan for Schedule decisions

Last updated: 31 August 2016

PHARMAC: Making funding decisions

In today's world, information about the latest medical treatment travels fast and publicity about the latest 'thing' creates demand. When a new medicine becomes available, it is often presented as doing the job better than older medicines, but it's not always the case. Part of their job is to assess all treatments and fund those that make the most improvement to the health of New Zealanders.

All New Zealanders are, in some way and at some time, affected by the funding decisions we make. To ensure our decisions are as fair and robust as possible they currently use the Factors for Consideration, along with expert clinical advice.

PHARMAC analyses clinical, economic and commercial issues, and seek the views of users and the wider community through consultation. The processes we generally use are outlined in their Operating Policies and Procedures.

The Factors for Consideration

The Factors for Consideration set out the things PHARMAC takes into account when making funding decisions. The Factors became PHARMAC's decision-making framework from 1 July 2016.

The Factors cover four dimensions: need, health benefits, costs and savings, and suitability.

The Factors are used for a range of PHARMAC decisions, but the extent of analysis that is required under each aspect will differ depending on the type of decision that is being made.

The need dimension

We consider the impact of the disease, condition or illness on the person, their family or whānau, wider society, and the broader New Zealand health system.

The health benefit dimension

Health benefit is about the potential health gain from the medicine or medical device being considered.

The costs and savings dimension

We consider the costs and savings to the person and their family, whānau and to wider society. The cost and savings to the health system covers both the pharmaceutical budget and the wider health system.

The suitability dimension

Suitability considers the non-clinical features of the medicine or medical device that might impact on health outcomes.

The Factors for Consideration



Need

To work out what the level of 'need' is we consider the impact of the disease, condition or illness on the person, their family or whānau, wider society, and the broader New Zealand health system.

Health benefit

Health benefit is about the potential health gain from the medicine or medical device being considered.

Suitability

Suitability considers the non-clinical features of the medicine or medical device that might impact on health outcomes.

Costs and savings

We consider the costs and savings to the person and their family, whānau and to wider society. The cost and savings to the health system covers both the pharmaceutical budget and the wider health system.

The Factors are not weighted or applied rigidly, and not every factor is relevant for every funding decision PHARMAC makes.

How does PHARMAC do its assessment?

Work on each funding application falls into three broad assessment areas: clinical, economic and commercial. These areas are interrelated in practice but are described separately below to help clarify the considerations within each area.

Clinical assessment

- What are the existing treatments/alternatives in the area?
- Is this medicine any better than what is available already?
- How do we know it is better?
- How reliable is the clinical trial data? What time period does it cover?
- Is something “proven” or is evidence still emerging?
- Has all available evidence been provided?
- Are there any side effects that need to be considered?
- How big a population will it treat?
- Does access need to be targeted for the medicine to work well?

Our main clinical advice comes from an expert committee of clinicians – the Pharmacology and Therapeutics Advisory Committee (PTAC). In addition, we have a network of 20 subcommittees providing specialised advice on a range of medical areas. Overall, these committees provide us with a resource of over 140 practising clinicians to call upon for advice. Committees also consider the Factors for Consideration when making recommendations.

Economic assessment

Economic assessment looks at the costs and benefits of a proposed course of action. It's based on three fundamental concepts that summarise the issues PHARMAC faces daily:

scarcity - resources will always be insufficient to support all possible activities
choices - due to scarce resources, decisions must be made regarding how best to use them
opportunity cost - by choosing to use resources one way, we forgo other opportunities to use the same resources.

The way PHARMAC assesses pharmaceuticals is described in the Prescription for Pharmacoeconomic Analysis (PFPA), a document that is published on the PHARMAC website. Most funding decisions involve spending more for the additional health gains. We use cost-utility analysis to compare these potential funding options on a more-or-less equal basis, and rank them in order of priority.

Commercial assessment

We all like to get the best deal we can when making a purchase, and as a pharmaceutical funding decision-maker PHARMAC is no different.

We encourage price competition through the use of competitive processes such as tendering for supply (asking for quotes), and reference pricing (applying the same subsidy to all medi-

cines with same or similar effects). PHARMAC does not regulate prices by requiring that pharmaceutical companies supply at a particular price, rather we negotiate subsidies on a 'willing buyer-willing seller' basis.

Consultation

Before we make a funding decision or make a change to our policies, we want to be sure that we have considered all the possible reasons for and against a decision, and any likely implications. One way we do this is to consult with anyone who is interested in the decision or who may be affected by the decision, to get feedback on our proposed approach and hear their views. We welcome all the views we receive, whether from health professionals, the pharmaceutical industry, consumer and patient groups, Government agencies or the general public.

Economic analysis by PHARMAC

The Prescription for Pharmacoeconomic Analysis (PFPA) is a guide for assessing the value for money of pharmaceuticals in New Zealand.

Prescription for Pharmacoeconomic Analysis (PFPA)

The PFPA provides a detailed guide to the methods PHARMAC uses for health economic analysis of health funding. The preferred method is cost-utility analysis, which informs the “health benefits” and “costs and savings” dimensions of the Factors for Consideration, and can generate information helpful for considering Factors in the “need” and “suitability” dimensions.

Assessment of medical devices and vaccines

Version 2.2 of the PFPA reflects our expanding role into vaccines and medical devices. A summary of changes and specific information relating to medical devices and vaccines is in our PFPA Supplement 2: Assessment of Medical Devices and Vaccines.

Cost-Utility Analysis (CUA) Explained

Cost-Utility Analysis (CUA) Explained provides a simple explanation of general CUA concepts. CUA Explained was also updated in August 2015.

The following general CUA concepts are covered:

- a quick overview of CUA
- assessing clinical evidence for inclusion in a CUA
- assessing benefits and costs
- managing risk in CUA
- the economic model
- the cost per quality-adjusted life year (QALY) result of a CUA
- using the cost per QALY information
- and commonly asked questions and answers regarding CUA

Cost Resource Manual

The Cost Resource Manual aims to increase consistency in the costs used in economic analyses provided to PHARMAC as part of pharmaceutical funding applications. It provides information on the key costs that PHARMAC regularly uses in cost-utility analyses and budget impact analyses, so that applicants may, if they wish, use the same cost data in their own economic analyses for PHARMAC.

Technology Assessment Reports

Technology Assessment Reports are detailed analyses of new pharmaceuticals. They are used to determine the cost-effectiveness of pharmaceuticals that we are being asked to fund.

For related guides, go to: <http://www.pharmac.govt.nz/medicines/how-medicines-are-funded/economic-analysis/>

Prioritisation by PHARMAC

PHARMAC uses a prioritisation process to compare and rank funding options. Possible opportunities for new investment will always exceed the budget PHARMAC has available; therefore prioritisation is an intrinsic part of PHARMAC's decision-making process.

The relative ranking of options aims to support PHARMAC's statutory objective "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided".

A funding application or proposal is considered ready for prioritisation when sufficient information is available to permit it to be reviewed against PHARMAC's Factors for Consideration and to inform a comparison with other possible investment decisions. Possible investment decisions include those funded through the Combined Pharmaceutical Budget as well as those relating to hospital pharmaceuticals. This process will likely extend to medical devices in the future.

The pharmaceutical industry in NZ

The pharmaceutical industry in New Zealand takes the active ingredients of drugs (which are imported from overseas) and converts them into a form that can easily be given to a patient. This involves mixing the active ingredient with various other ingredients with appropriate chemical properties, then either compressing the mixture into a tablet, filling a gelatine capsule with it or dissolving it in an appropriate solvent.

Pharmaceutical products used in New Zealand may have been processed in this country or overseas. Many of the large international pharmaceutical companies had in the past their own manufacturing plants in New Zealand but due to the economic reforms that have been enacted over the last 10-12 years the majority of those plants have been closed down. The only ones remaining are those that are principally involved in the manufacture of generic products for sale in the domestic market or for export.

Some important companies engaged in the research, development, manufacture and marketing of prescription medicines.



Good Manufacturing Practice

It is an essential requirement in manufacture of pharmaceuticals that the manufacturer must comply with the New Zealand Code of Good Manufacturing Practice published by the Ministry of Health.

Since inception, considerable efforts have been made in the manufacturing pharmaceutical industry to establish procedures and facilities that decrease the occurrence of any mishap in manufacture and packing that might adversely affect the health of the public.

The New Zealand Code of Good Manufacturing Practice is based on manufacturing principles established internationally, and details the standards that must be maintained by each manufacturer. Compliance with the Code is monitored by annual audit carried out by the Ministry of Health.

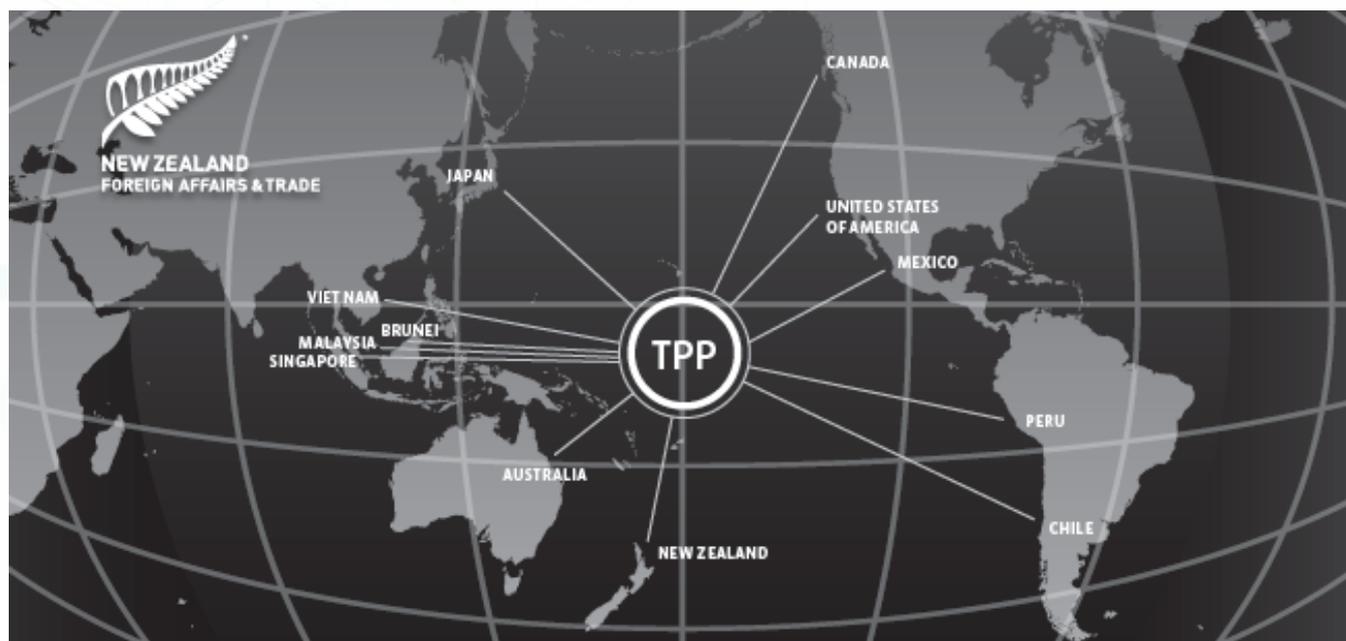
The main points covered by the code are as follows:

- The manufacturing premises must be kept clean and must be designed to allow a product to be made in complete isolation from any other product being made at the same time.
- Equipment must be cleaned before use with all traces of the last product removed.
- The operator is issued with a set of batch records for each separate batch of product to be prepared. The batch records detail the product formula, and the manufacturing steps required to be followed in preparation of that product. The operator enters appropriate information on the batch records during manufacture, such as the identifying numbers of raw materials, the results of in-process checks etc. Once manufacture is complete, these records are retained as they constitute a complete record of the batch and must be readily accessible if required for either audit purposes or investigation of any product complaints.
- Each batch of a product is given a unique identifying number which is written on the batch records and identifies the product throughout manufacture and is then used as the batch number on all labelling of product filled from the batch during packaging.
- Samples of each batch must be kept for the shelf-life of the product plus one year.
- Each raw material and finished product must comply before use or upon packaging with standards that are set down for each product. Such standards may be found in either the British Pharmacopoeia, United States Pharmacopoeia, or the European Pharmacopoeia, or may be standards that are set by the manufacturer and agreed to by appropriate regulatory authorities such as the New Zealand Ministry of Health before the product is allowed for sale. Such standards detail the tests and analytical methods which have to be performed to confirm the identity; determine the concentration of active drug; and ensure the absence of any undesirable contaminants prior to release of the product to market.

Trans-pacific partnership [TPP's] effect on the Pharma industry of NZ

The Trans-Pacific Partnership (TPP) will include provisions that apply to government programmes that subsidise pharmaceuticals and medical devices. The provisions are intended to promote transparency in listing and funding processes.

The outcomes reflect many existing PHARMAC practices that support transparency, but will require PHARMAC to do some new things.



- **TPP will not change the PHARMAC model:** The annex focuses on promoting transparency in the application process and is consistent with many existing PHARMAC policies. In other areas, flexibilities have been included that accommodate current PHARMAC practice. The obligations will not change the PHARMAC model or its ability to fund, prioritise pharmaceuticals for listing for reimbursement, or approve pharmaceutical funding.
- **Dispute settlement does not apply:** while the provisions are legally binding, TPP governments or investors will not be able to bring formal dispute settlement proceedings if they have concerns about another Party's approach to implementation of the annex.
- **Agreed principles:** TPP Parties have agreed the annex does not affect the right of governments to determine health expenditure priorities.
- **Commitment to consider funding applications within a specified period of time:** TPP Parties have agreed to ensure that consideration of all formal applications is completed in a specified timeframe. The timeframe can be determined by each party.
- **A review mechanism:** TPP Parties have agreed to make available a review mechanism that applicants can elect to use if their application for funding is declined.

New Zealand Health Strategy: Future direction

This refreshed New Zealand Health Strategy (the Strategy) sets the framework for the health system to address the pressures and significant demands on its services and on the health budget. As the first refresh of this country's health strategy since 2000, it sets the direction for development during the next 10 years.

*- Hon Dr Jonathan Coleman
Minister of Health
April 2016*



The New Zealand Health Strategy in its government context

Government priorities

Delivering better public services
Responsibly managing the Government's finances
Rebuilding Christchurch
Building a more competitive and productive economy

Cross-government work 2016, eg,

Social Sector Trials
Whanau Ora
Children's Action Plan
Action Plan on Household Crowding to Reduce Rheumatic Fever
Prime Minister's Youth Mental Health Project
New Zealand Disability Strategy



New Zealand Health Strategy

Population and other health strategies, eg,

He Korowai Oranga – Māori Health Strategy
'Ala Mo'ui – Pathways to Pacific Health and Wellbeing
Health of Older People Strategy
Primary Health Care Strategy
Rising to the Challenge: Mental Health and Addiction Service Development Plan
Living Well with Diabetes: A Plan for People at High Risk or Living with Diabetes

‘Given New Zealand’s ageing population... it is critical that the health system includes in its planning specific actions to manage this demographic change.’

- Non-governmental organisation

NZ faces challenges

New Zealanders are living longer, and every year, more of us are aged over 65 years. This is good for individuals and their families. But it does mean social and health services will have to adapt, and it challenges the health system to find ways of providing services that are still affordable.

Keeping an older person healthy and independent can involve more health and social services than are needed for younger people. Older people are also more likely to have a disability and to have more than one health condition. We want a health system that supports people to live longer but also to spend more of that life in good health.

An independent review of New Zealand’s health funding system¹⁵ noted three ways in which funding arrangements sometimes prevent resources from being used to achieve the best possible outcomes.

- Present arrangements may not clearly show the results that we get from health spending, making it hard to prioritise funding or take into account long-term, cross-sectoral benefits from investment.

- When demand changes, service mix and design may not change quickly enough to deal with it. Often our funding and contracting arrangements encourage health services to keep doing things as they have always done them, instead of allowing them to work differently.

- Some funding arrangements contribute to disparities between groups in their access to services, and sometimes they widen the gap in unmet need.

Refreshed guiding principles for the system

1. Acknowledging the special relationship between Māori and the Crown under the Treaty of Waitangi

2. The best health and wellbeing possible for all New Zealanders throughout their lives

3. An improvement in health status of those currently disadvantaged

4. Collaborative health promotion, rehabilitation and disease and injury prevention by all sectors

5. Timely and equitable access for all New Zealanders to a comprehensive range of health and disability services, regardless of ability to pay

6. A high-performing system in which people have confidence

7. Active partnership with people and communities at all levels

8. Thinking beyond narrow definitions of health and collaborating with others to achieve wellbeing.

Five strategic themes

Building on our guiding principles, this strategy has five themes to guide us. These provide a focus for change.



1. People-powered:

- making New Zealanders ‘health smart’; that is, they can get and understand the information they need to manage their care
- enabling individuals to make choices about the care or support they receive
- understanding people’s needs and preferences and partnering with them to design services to meet these
- communicating well and supporting people’s navigation of the system, including through the use of accessible technology such as mobile phones and the internet.

2. Closer to home:

- providing care closer to where people live, learn, work and play, especially for managing long-term conditions
- integrating health services and making better connections with wider public services
- promoting wellness and preventing long-term conditions through both population-based and targeted initiatives

- investing in health and wellbeing early in life and focusing on children, young people, families and whānau.

3. Value and high performance:

- delivering better outcomes relating to people’s experience of care, health status and best-value use of resources
- striving for equitable health outcomes for all New Zealand population groups
- measuring performance well and using information openly to drive learning and decision-making that will lead to better performance
- building a culture of performance and quality improvement that values the different contributions the public and health workforce can make to improving services and systems
- having an integrated operating model that makes responsibilities clear across the system
- using investment approaches to address complex health and social issues.

Five strategic themes

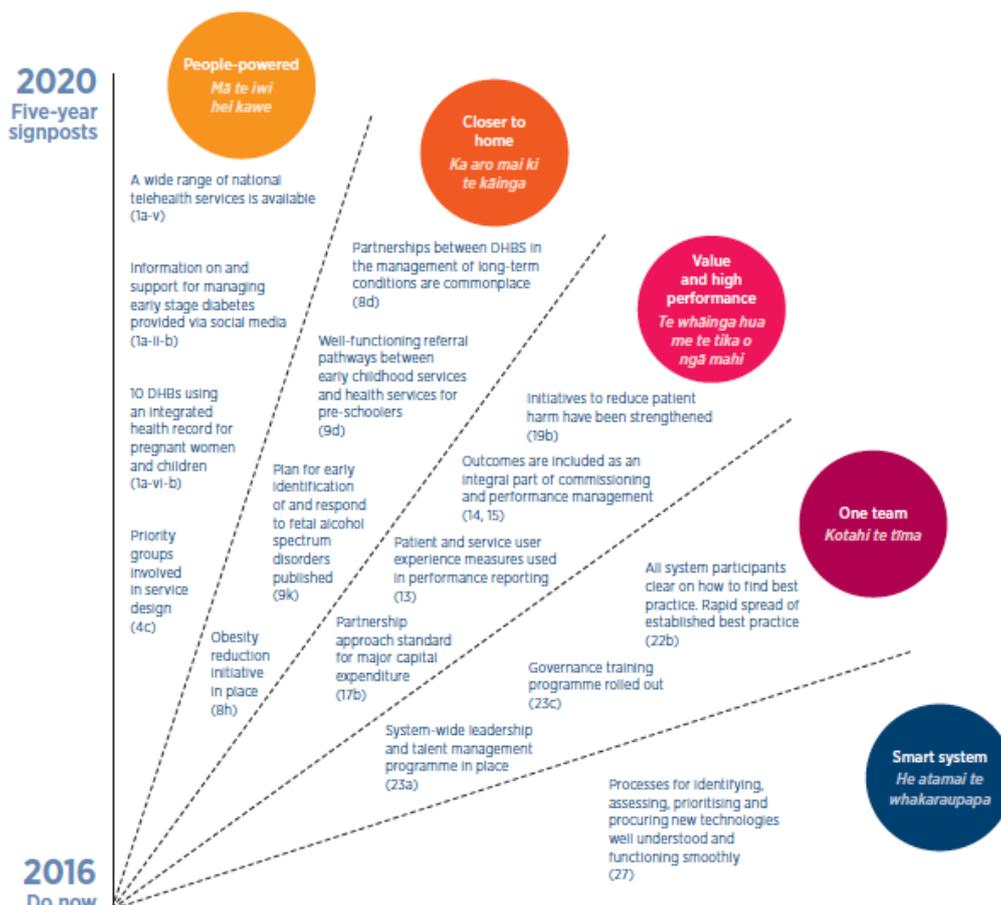
4. One team:

- operating as a team in a high-trust system that works together with the person and their family and whānau at the centre of care
- using our health and disability workforce in the most effective and most flexible way
- developing leadership, talent and workforce skills throughout the system
- strengthening the roles of people, families, whānau and communities as carers
- the Ministry of Health leading the system effectively
- collaborating with researchers.

5. Smart system:

- discovering, developing and sharing effective innovations across the system
- taking advantage of opportunities offered by new and emerging technologies
- having data and smart information systems that improve evidence-based decisions, management reporting and clinical audit
- having reliable, accurate information that is available at the point of care
- providing individual online health records that people are able to access and contribute to
- using standardised technology that allows us to make changes easily and efficiently.

Possible results from implementing the Roadmap of Actions over time



Important Links & Sources

Ministry of Health

Postal address:
Ministry of Health
PO Box 5013, Wellington 6140
Phone: (04) 496 2000

Website: <http://www.health.govt.nz/>

District Health Boards:

<http://www.adhb.health.nz/> [Auckland]
<http://www.northlanddhb.org.nz/> [Northland]
<http://www.cdhb.health.nz/> [Canterbury]

Medicines New Zealand

Level 8, 86-90 Lambton Quay
PO Box 10-447
Wellington
New Zealand
P: 04 499 4277
F: 04 499 4276
info@medicinesnz.co.nz
www.medicinesnz.co.nz

Medicines New Zealand is the industry association representing companies engaged in the research, development, manufacture and marketing of prescription medicines.

Membership of Medicines New Zealand is voluntary.

PHARMAC

Level 9 Simpl House
40 Mercer Street , Wellington Central
Wellington 6011
P: +64 4 460 4990
<http://www.pharmac.govt.nz/>

PHARMAC is the New Zealand government agency that decides which pharmaceuticals to publicly fund in New Zealand.

The New Zealand Institute of Chemistry (NZIC): <http://nzic.org.nz/>

Represents some 1000 members involved in the profession of chemistry. Members participate in the study, practice, teaching, promotion and management of chemistry.

The New Zealand Medical Association (NZMA): <https://www.nzma.org.nz/>

NZ's foremost pan-professional medical organisation in New Zealand representing the collective interests of all doctors. Our members come from all disciplines within the medical profession, and include specialists, general practitioners, doctors-in-training and medical students.

Pharmaceutical Society of New Zealand: <http://www.psnz.org.nz/>

PSNZ is a professional, membership based association representing 3,400 pharmacists and technicians.

Pharmacy Today is the leading pharmacy publication in New Zealand: <http://www.pharmacy-today.co.nz/>

Sources

<http://nzic.org.nz/ChemProcesses/biotech/12F.pdf>

<https://www.health.govt.nz/system/files/documents/publications/new-zealand-health-strategy-futuredirection-2016-apr16.pdf>

<http://www.pharmac.govt.nz/about/your-guide-to-pharmac/>

<http://www.pharmac.govt.nz/medicines/>

https://tpp.mfat.govt.nz/assets/docs/TPP_factsheet_Pharmaceutical-and-Medical-Device-Purchasing-Reimbursement.pdf

https://www.psnz.org.nz/Folder?Action=View%20File&Folder_id=86&File=10_yea_plan.pdf

<https://www.health.govt.nz/system/files/documents/publications/new-zealand-health-strategy-futuredirection-2016-apr16.pdf>

<http://www.health.govt.nz/publication/new-zealand-health-strategy-2016>



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