

11. Market Access in New Zealand

Zafer Çalışkan¹

¹ Department of Economics, Hacettepe University, Ankara, Turkey

11.1 Background

New Zealand or *Aotearoa* (in Māori: land of the long white cloud) is situated in the South Pacific Ocean, south-east of Australia (Figure 1). The three main islands (North Island, South Island and Stewart Island) cover an area of 264,537 km². In 2016 the population was estimated at 4,790,371. The majority of the people are of European heritage; other ethnic groups are Maori, Pacific Islander, and Asian. New Zealand has three official languages: Te Reo Māori, English and New Zealand Sign Language.



Figure 1. New Zealand Administrative Division

In recent years the economic growth has been faster in New Zealand than in most other OECD (Organization for Economic Co-operation and Development) countries. In 2016 the Gross Domestic Product (GDP) was worth 174.8 billion US dollars Purchasing Power Parity (PPP), while the GDP per capita was last recorded at 37,108 US dollars (PPP). According to the report “Health at a Glance 2015” from the OECD, New Zealand spends about 3,590 US dollars (PPP) on healthcare annually. In addition, OECD reports that in 2015 New Zealand’s per capita pharmaceutical expenditure was 284 US dollars PPP. In recent years, thanks to high and sustainable economic growth rates, New Zealand’s expenditure on health was equivalent to 9.4% of the GDP, well above the OECD average of 9% of the GDP. In comparison with other OECD countries, New Zealand spends less on pharmaceuticals in terms of percentage of total expenditure on health.

Despite the high per capita healthcare expenditure, over the last decade the share of government spending, as a quota of the total spending on health, remained relatively constant (at around 80%), although well above the average for OECD countries (73%). In New Zealand, about 20% of the total health spending is privately funded, mainly through out-of-pocket payments, while the private health insurance market is relatively small.

People living in the countries with the highest health spending also tend to have better health outcomes; since New Zealand has one of the highest living standards among OECD countries, the higher spending is accompanied by better health outcomes. Since the early 1980s, New Zealand accomplished remarkable improvements in terms of health status, and recent OECD Health Statistics indicate that major health indicators – such as infant mortality rate, life expectancy and maternal mortality – have improved considerably. New Zealand’s life expectancy figures are similar to those for most western European nations.

During the last decades, the population experienced a shift from high mortality/high fertility to low mortality/low fertility. According to the OECD Health Statistics, life expectancy in 2015 was 81.7 years overall, with a low gap between the genders, since life expectancy at birth was 79.9 and 83.4 years for men and women, respectively, both above the average for OECD countries. With regard to the health standards of the population, the average health expectancy for females increased from 68.1 years in 1990 to 71.8 in 2015; for males, it increased from 64.3 years to 69.9. Between 2006 and 2016, the percentage of New Zealanders aged 65 years and over increased from around 12% to around 15%; therefore, New Zealand is one of the four leading countries, with more than 85% of people reporting to be in good health, like Canada, the United States, and Australia.

Although in the past four decades there have been improvements in the health status, the changing demographic structure influenced the epidemiological transition, with a shift from communicable to non-communicable diseases, and to the conditions associated with an aging population (heart disease, diabetes and mental health conditions), and issues such as obesity, that lead to long-term health problems. A large proportion of the health loss New Zealanders experience comes from long-term conditions, such as cancer and diabetes. According to the most recent mortality data (2016) all cancers, ischemic heart disease, cerebrovascular disease and diabetes mellitus seem to be the major cause of death.

11.2 The Healthcare System

New Zealand Public Health and Disability Act 2000 (the NZPHD Act) stated that the ultimate objectives of the health care system are to provide equal, accessible and high-quality health care services to the whole population. New Zealand has been one of the countries with universal health coverage to finance and deliver healthcare to all its citizens, where healthcare is mostly covered by the public structures, with support from private and also non-governmental organizations. The Ministry of Health (the Ministry) is the main agency responsible for the provision of healthcare services; it has a range of roles in the system, in addition to being the key advisor and support to the Minister, and it funds a series of national services, including disability support and public health services.

Historically, the development of health care services in New Zealand was initiated by the New Zealand Social Security Act 1938. According to this setting, New Zealand set up a predominantly tax-funded healthcare system that made most services freely available at the point of delivery, with a mix of public and private provision which marked the introduction of the universal right to tax-financed and comprehensive healthcare.

The New Zealand health and disability system's statutory framework is made up of over 20 pieces of legislation, among which the most significant are:

- Health Act 1956;
- New Zealand Public Health and Disability Act 2000 (the NZPHD Act);
- Crown Entities Act 2004.

The Health Act 1956 sets out the roles and responsibilities of key participants to safeguard public health (the Minister of Health, the Director of Public Health, and the designated public health officers). It contains provisions for environmental health, infectious diseases, health emergencies, and the National Cervical Screening Programme.

The NZPHD Act i) establishes the structure underlying the public sector funding and the organization of health and disability services; ii) establishes the District Health Boards; iii) sets out the duties and roles of key participants (the Minister of Health, the Ministerial committees, and the health sector organizations); and iii) sets the strategic direction and goals for the New Zealand health system.

Many of the organizations that provide health services in New Zealand are Crown Entities. The Crown Entities Act provides the statutory framework for the establishment, governance, and operation of the Crown entities, and clarifies accountability relationships and report requirements between the Crown entities, their board members, the responsible Ministers, and the House of Representatives.

The New Zealand healthcare system underwent some changes after the Social Security Act 1938. A number of developments also occurred in terms of social security from the 1940s to the 1990s. In 1993 a new model called 'purchaser/provider' market-oriented system was introduced. With the 1993 Health and Disability Services Act, four Regional Health Authorities were established, and each was allocated a budget to purchase, from both public and private providers, health and disability services for its own regional populations; many disability services were previously the responsibility of the social welfare

sector. The provider arms of the previously 14 Area Health Boards were converted into 23 Crown Health Enterprises, which had to function as commercial entities, run hospital, community, and public health services; and return a surplus to be reinvested in health.

The current system was implemented through the NZPHD Act 2000, which created 20 District Health Boards (DHBs) and was a fundamental step in the transition to a population-based health system. The DHBs cover geographically defined populations and may either deliver services themselves or fund other providers to do it. They are crown entities (statutory corporations) and must report to the Minister of Health for setting strategic direction, appointing the chief executive, and their own performance.

The Ministry of Health is primarily responsible for ensuring the efficiency of the health and disability system that in New Zealand is mainly funded by general taxation into central government (Vote Health). Box 1 outlines the main responsibilities of the Ministry of Health.

Other policy-making bodies include The Ministry of Social Development, the Ministry of Māori Development, the Ministry of Pacific Island Affairs, the Office for Disability Issues and the Accident Compensation Corporation. There are also twenty DHBs, which operate on local level and are responsible for providing and funding healthcare in their areas and are monitored by the National Health Board, within the Ministry of Health.

The Ministry's role in the funding of health services remained relatively stable over the last three decade. The health reforms occurred in the 1980s and the 1990s were not of the same magnitude as the changes occurred during the middle of the 20th century. Over the past 30 years, the percentage of total current funding from public sources gradually decreased from 88% to the 77-83% range, which has persisted since 1992. Of this public funding source, the Government's direct health funding through the Ministry is the largest contributor to the total health and disability funding (approximately 72.5% in 2009/2010 compared with 69.6% in 1999/2000).

The New Zealand health system's funding comes mainly from Vote Health, which in 2016/2017 amounted to just over \$16.142 billion. Other significant funding sources include the Accident Compensation Corporation (ACC), other government agencies, local

Box 1. Responsibilities of the Ministry of Health [NZ Health System. Ministry of Health website]

- Providing policy advice on improving health outcomes, reducing inequalities, and increasing participation.
- Implementing, administering, and enforcing relevant legislation and regulations.
- Monitoring the performance of DHBs and other Crown entities in the health sector.
- Acting as the Minister's agent
- Providing health information and processing payments.
- Facilitating the collaboration and coordination within and across sectors.
- Planning and maintaining the service frameworks nationwide.
- Planning and funding public health services, disability support services and other service areas that are retained centrally.

governments, and private sources (private health insurance premiums and a small contribution from non-profit organizations) and out-of-pocket payments. The Ministry of Health allocates more than three-quarters of the public funds to manages DHBs through Vote Health. DHBs use this funding to plan, purchase and provide health services, including public hospitals and the majority of public health services, within their areas.

11.3 Pathways of Market Access (Regulation, Pricing, and Reimbursement)

The demand for pharmaceuticals and medical devices in New Zealand is growing, along with the government expenditure in this sector; on the other hand, the supply side of the New Zealand pharmaceutical market has been defined an oligopolistic structure. Since the local manufacturing base is small and production is insufficient, many pharmaceuticals are imported from European, Australian and North American manufacturers. There are three agencies that are responsible for pharmaceutical regulation, pricing and reimbursement in New Zealand: the New Zealand Medicines and Medical Devices Safety Authority (Medsafe), the Pharmaceutical Management Agency (PHARMAC) and the Pharmacology and Therapeutics Advisory Committee (PTAC). PHARMAC decides which medicines receive public funding, following advice from PTAC (Figure 2).

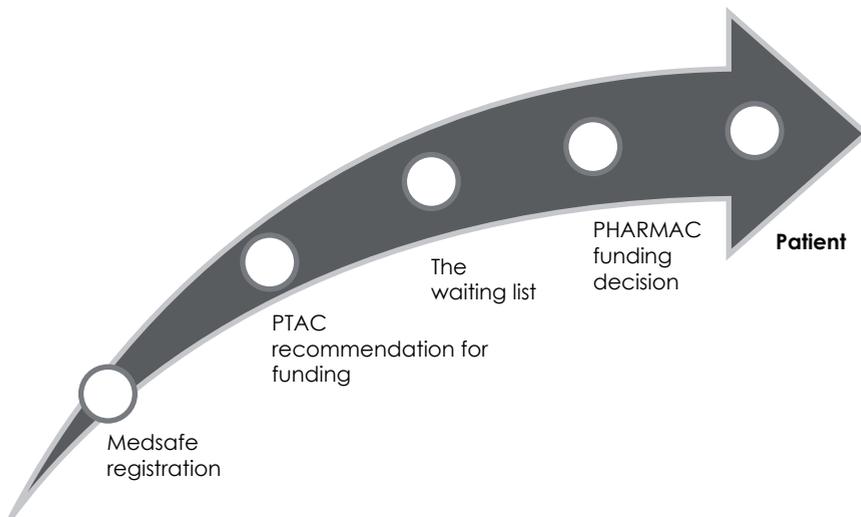


Figure 2. The funding process of prescription medicines in New Zealand

Medsafe = New Zealand Medicines and Medical Devices Safety Authority;
 PHARMAC = Pharmaceutical Management Agency; PTAC = Pharmacology and Therapeutics Advisory Committee

Market Authorization

Medsafe is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand. Medsafe determines which medicines and medical devices can be marketed and sold in New Zealand, and regulates the products used for therapeutic purposes, including medicines, related products, medical devices and controlled drugs used as medicines. Medsafe is responsible for ensuring the safety, efficacy and quality of medicines through pre-marketing approval, that must be obtained for new and changed medicines, and post-marketing surveillance. New medicines cannot be marketed in New Zealand without the consent of the Minister of Health, while medicines to which changes have been made cannot be marketed without the consent of the Director-General of Health. Post-marketing surveillance monitors the safety of medicines and medical devices in use. Products shown to be unsafe are removed from use, and prescribers are advised about the new safety information.

Coverage, Pricing and Reimbursement

PHARMAC is a single purchasing entity that manages the determination and purchase of pharmaceuticals on behalf of the DHBs, following their registration by Medsafe. PHARMAC has a predetermined fixed budget and, in order to provide the medicines considered necessary, employs therapeutic and economic analyses to guide its decisions. PHARMAC develops and maintains the New Zealand Pharmaceutical Schedule (the

Box 2. PHARMAC's activity 2015/2016 [PHARMAC Annual Report 2015/16]

Combined Pharmaceutical Budget

- **\$ 800 million:** DHBs' combined pharmaceutical expenditure (on budget)
- **44.4 million:** number of funded prescription items filled (3% increase)
- **3.5 million:** number of New Zealanders receiving funded medicines
- **\$ 79 million:** amount of savings achieved
- **15:** number of medicines funded
- **6:** number of medicines with access widened
- **38,478:** estimated number of additional patients benefiting from decisions

Hospital Medicines

- **\$ 6.69 million:** full-year savings for DHB hospitals from hospital medicines decisions
- **\$ 1.178 million:** cost of new investments in hospital medicines
- **\$ 25.37 million:** savings for Vote Health over five years after the costs of the new investments
- **13:** number of new hospital medicines funded

Hospital Devices

- **2,084:** additional line items in the Pharmaceuticals Schedule under national contracts
- **\$ 9.15 million:** net saving over five years from contracts during the year
- **\$ 22.35 million:** savings over five years from all contracting to date

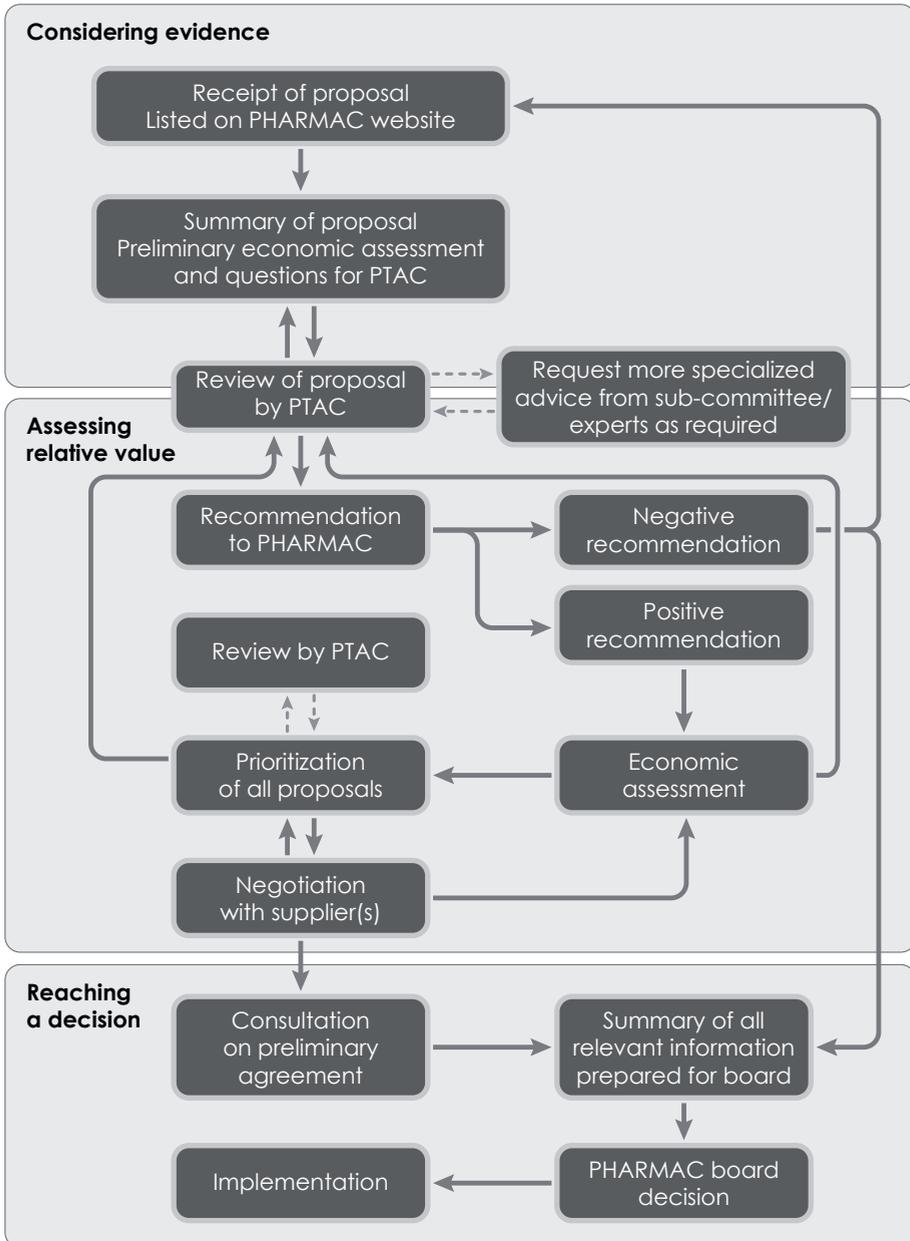


Figure 3. The Pharmaceutical Schedule (the Schedule) decision-making process. Modified from [PHARMAC Annual Report 2014-2015]
 PHARMAC = Pharmaceutical Management Agency; PTAC = Pharmacology and Therapeutics Advisory Committee

Schedule), in which all funding decisions are listed. If a clinically effective product is offered at a price that reflects comparative value-for-money in the New Zealand context, it is listed on the Pharmaceutical Schedule.

In 2016, approximately 2000 prescription medicines and therapeutic products that can be prescribed by a medical doctor, dentist, registered midwife, designated nurse practitioner or optometrist, are listed in the Schedule. It is partly or fully subsidized from a national pharmaceutical budget. The Schedule is published three times a year and updated monthly on the PHARMAC website. PHARMAC negotiates the prices of inpatient and outpatient medicines, vaccines, and medical devices, and manages a capped national budget for outpatient and cancer medicines (Box 2). The mechanism used by PHARMAC to obtain lower prices include competitive tendering, sole supply contracts, reference pricing, bundling deals, risk-sharing agreements and the promotion of the use of generics.

PHARMAC generally undertakes or reviews two forms of economic analysis: a cost-utility analysis (CUA) and a budget-impact analysis (BIA). Therefore, if PHARMAC believes that clinical advice on the application is required, the first step in the assessment process will be a review of the Application by the PTAC or one of the specialized sub-committees (Figure 3).

PHARMAC is currently a Crown Entity and, while its corporate status has changed over the years, it has always remained accountable to the public (by way of the District Health Boards and/or the Minister of Health). In order to meet the budgetary goals, PHARMAC employs a variety of formulary-based expenditure management tools on behalf of the District Health Boards. In this way, the price is established by negotiation (a process which parallels standard commercial negotiations) and savings are derived from the stimulation of the competition, by listing new product and by reviewing the terms and conditions of products already listed in the Schedule.

According to the OECD Report on Competition and Regulation Issues in the Pharmaceutical Industry, there are also some key strategies for the efficient definition of subsidies and prices:

- **Reference pricing** is the primary way by which PHARMAC stimulates price competition. Reference pricing establishes a common subsidy for drugs that have the same or similar therapeutic effect.
- **Market caps** establish limits for the expenditure on a particular drug. These limited maximum annual contracts require PHARMAC to pay a fixed annual maximum amount to a supplier, regardless of the amount prescribed, dispensed or consumed.
- A **tendering** process is used to enhance the level of price competition in the generic markets. This involves selecting one off-patent drug to be the sole brand listed in the Schedule. This technique enables generic suppliers to achieve a greater market share and overcomes the tendency of physicians to prescribe by brand name.
- **Targeting**. There are restrictions on the access to a subsidy for a limited amount of drugs in the Schedule. The purposes of these restrictions are: targeting the subsidy for the drug to those patients for whom it will provide the best value (mainly for the more expensive drugs); taking into account the specific features of the drug (e.g. the

Box 3. Nine criteria for funding decision [PHARMAC website]

1. Health needs of all the eligible population.
2. Particular health needs of Maori and Pacific peoples.
3. Availability and sustainability of existing medicines, therapeutic medical devices, and related products.
4. Clinical benefits and risks.
5. Cost-effectiveness of meeting the health needs by funding the drug rather than using other publicly funded health and disability support services.
6. Budget impact of any changes to the schedule.
7. Direct cost to health service users.
8. Government's priorities for health funding.
9. Any other criteria PHARMAC might consider fit (after appropriate consultation).

need to be prescribed by a specialist); helping manage the expenditure; and providing a bargaining tool for the pharmaceutical companies.

In the decision process, the committee also takes into account nine decision criteria (Box 3).

PTAC is PHARMAC's primary clinical advisory committee. It recommends to PHARMAC which medicines to fund, and with what priority.

PTAC and its sub-committees perform a critical review of the application, leading to a confidential statement of the value of a product, in terms of recommendation for funding at a given level of priority (i.e., high, medium, low, or cost neutral), deferment pending further information, or decline. The interested parties, including consumers, are excluded from any direct involvement at this stage.

11.4 Mapping and Structure of Decision Makers

As shown in Figure 4, the healthcare organization in New Zealand is characterized by a mix of public and private ownership, and the Ministry of Health has a range of roles in the system. In terms of financing, most services are universal and the government funding derives from general taxes. This funding contributes to almost 80% of the total healthcare expenditure.

In addition to the Minister of Health, the system includes PHARMAC, DHBs, Primary Health Organizations (PHOs), Public Health Units (PHUs), private non-governmental providers, Māori and Pacific providers and independent general practitioners (GPs). There are also many consumer bodies and Non-Governmental Organizations (NGOs) that provide services and advocate the interests of the various groups, as well as formal advocacy and inquiry boards, committees and entities. The role of the private sector is more organized in terms of supply than financing. Private insurance companies represent a very small segment of the total healthcare expenditure.

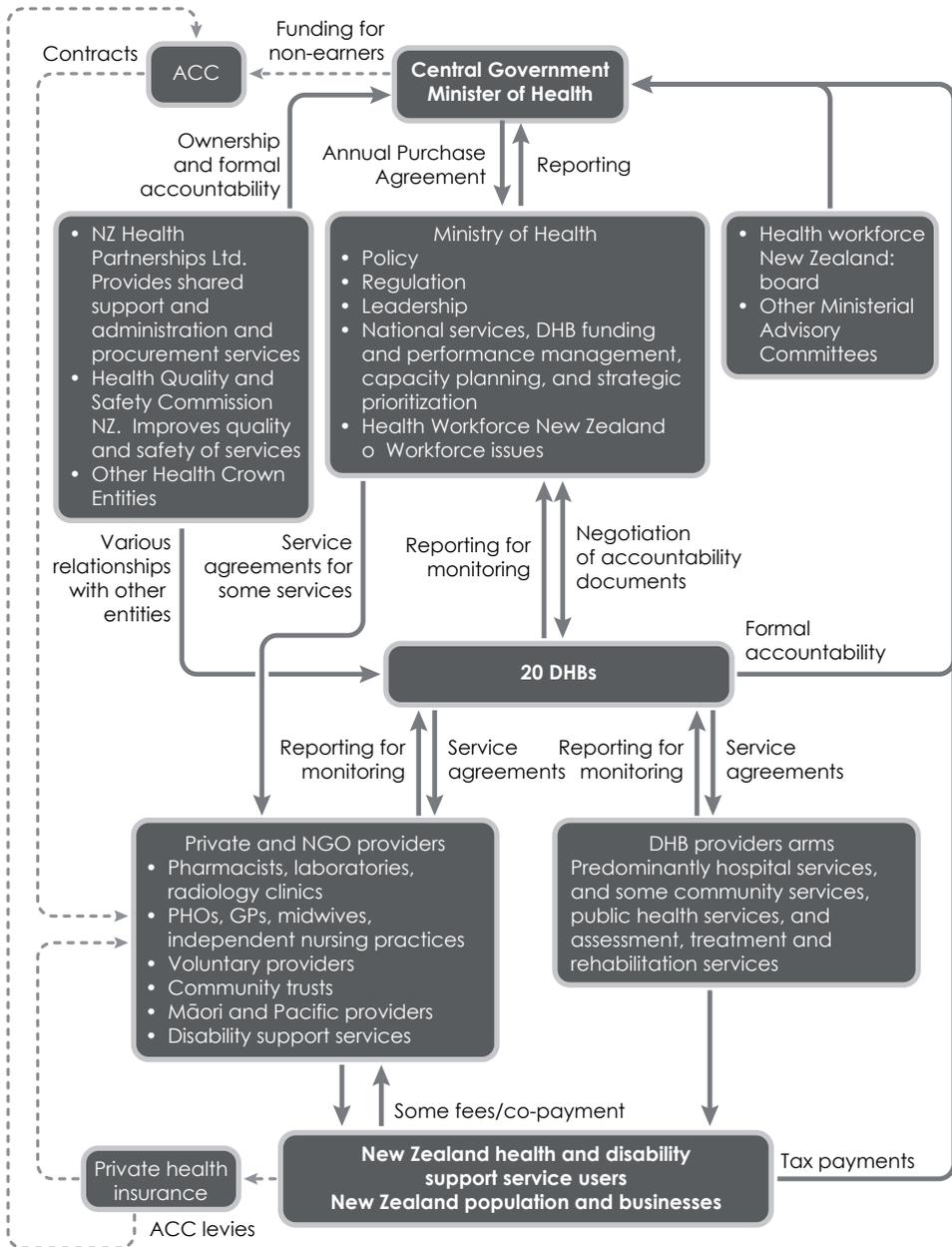


Figure 4. Structure of the health and disability sector of New Zealand. Modified from [NZ Health System. Ministry of Health website]

ACC = Accident Compensation Corporation; DHB = District Health Boards GP = General Practitioner; NGO = Non-Governmental Organization; PHO = Primary Health Organization

The Pharmaceutical Management Agency (PHARMAC)

As previously reported, PHARMAC is a cornerstone agency for the management of pharmaceuticals in the New Zealand healthcare system. PHARMAC was established in June 1993 with the objective of ensuring the best health outcomes from drug treatment, within the amount of the available funding. PHARMAC is governed by a government-appointed but independent board, which refers to the Minister of Health; it acts on behalf of New Zealand's 20 geographically based DHBs, and plans, purchases, and provides health services. PHARMAC plays a crucial role in ensuring the efficiency and effectiveness in New Zealand tendering and negotiations with the pharmaceutical companies, to ensure the best deals.

Over the years, PHARMAC's role has been expanded, and now it ensures the optimal use of medicines, negotiates prices and supply terms for some hospital medicines, manages the basket of essential cancer drugs, and manages special schemes that supply drug funding for people with rare conditions, in addition to manage the community drug budget.

PTAC's members (including senior health practitioners, with expertise in critical appraisal and broad experience and knowledge of pharmaceuticals and their therapeutic uses) are appointed by the Director-General of Health, in consultation with the PHARMAC Board. There are also several PTAC sub-committees, made up of experts in specialist clinical fields such as cardiology and oncology.

District Health Boards (DHBs)

DHBs are responsible for planning and purchasing the full range of services for their respective local populations, including primary and disability support services and hospital care (mainly in public hospitals). Private hospitals provide mainly elective procedures, occasionally under contract with the public system. Government-owned hospitals provide accident and emergency, inpatient, outpatient, and community care for free. Primary health care services such as general practitioner, pharmacy, and diagnostic services are delivered through privately owned, small independent businesses, funded by government fee-for-service subsidies. Patients must pay for GP service except for maternity care, and GP services for children <13. The DHBs allocate resources to improve, promote, and protect the health of the population within their district, and to promote the independence of people with disabilities. DHBs are expected to cooperate with the adjoining districts in delivering services, particularly where there are cross-border issues, and where specialist services draw patients from a larger region, rather than a single district.

Primary Health Organizations (PHOs)

Primary Health Organizations (PHOs) were designed to coordinate ongoing patient care, plan population healthcare needs and reduce the financial and other primary care access barriers, especially for the most disadvantaged. Created between 2002 and 2006, and based

on WHO Alma Ata principles of 'comprehensive primary care', PHOs are no-profit, multidisciplinary organizations serving the registered population. PHO funding is capitation-based by DHBs although many continue to reimburse GPs on a fee-for-service basis. A PHO provides services either directly by employing staff, or through its provider members. Additional PHO funding is available for developing Care Plus programs for the management of chronic disease patients, for 'services to improve access', and for the promotion of health.

11.5 Challenges and Catalysts for Market Access

In essence, New Zealand provides accessible, affordable and universal health care through tax funding. As for the cost of pharmaceuticals, it can be argued that the New Zealand reimbursement system aims to achieve the lowest possible prices. However, as stated by Morgan et al. (2010), PHARMAC's approach to expenditure management is considered aggressive by some, and critics have questioned whether this approach requires a trade-off between expenditure management and patient access to drugs.

Challenges

New Zealand reimbursement model has controlled the rising cost of pharmaceuticals, using containment measures as a budget cap and tender procedure. On the other hand, the impact of these strategies has been very controversial, due to the lower number of new drugs available in New Zealand, compared to other countries. For example, in the period 2000-2009, the New Zealand patient population had access to less than half of the new medicines that were reimbursed in Australia. Furthermore, in New Zealand, the new drugs registration occurred on average 9.0 months later and listing occurred 32.7 months later, giving a 23.7-month difference in the interval between registration and listing. Sixteen of the new medicines listed in both countries (27%) were registered first in New Zealand, but only three of these (ursodeoxycholic acid, dorzolamide and ezetimibe) were listed first in New Zealand. The main reason is that PHARMAC is too focused on cost-containment rather than improving health outcomes.

Another example, reported by Metcalfe et al., is the funding of medicines for particular indications, such as trastuzumab for early-stage HER2+ breast cancer. In 2006 PHARMAC decided against funding a 12-month trastuzumab (Herceptin) program for women with the HER2+ form of breast cancer, which would have an estimated cost of \$ 25-30 million/year. Instead, as reported by Cumming et al. (2010), it funded a 9-week course, at an estimated cost of \$ 5 million, with a further \$ 3.2 million to participate in an international trial of a short versus long course of concurrent treatment. Finally in 2008, the National Party-led government allowed the funding of the 12-month course of trastuzumab for HER2+ breast cancer, bypassing PHARMAC.

In recent years, a separate comparison of New Zealand and 17 other countries showed that New Zealand's drug prices were in the lowest quartile in five cases, and ranked low-

est in four cases (abacavir, escitalopram generic version, mycophenolatemofetil originator, and pioglitazone generic), whereas they were in the highest quartile in seven cases, and ranked highest in one case (prasugrel). The six other medicines in the highest quartile were darunavir ethanolate, indinavir, insulin lispro, sunitinib, and venlafaxine (being the originator and the generic).

Catalyzers

The New Zealand pharmaceutical market is dominated by its public health system, so the public funding system may be attractive for the pharmaceutical industry. On the other hand, with a relatively small population, and a weak purchasing power, a single purchasing organization is considered the best option to protect the healthcare interests of New Zealand consumers. Here, a variety of techniques such as competitive tendering, reference pricing, generic substitution and bundling agreements are key objectives.

Good Examples from Successful Market Access Strategies

In Box 5 are reported the major investments of PHARMAC in 2016.

Box 5. Major investments in 2016 [PHARMAC Annual Report 2015-16]

- **Six new respiratory treatments:** five new treatments were funded for people with Chronic Obstructive Pulmonary Disease, one new once-daily treatment for asthma, and access was widened for two others. These changes cover \$ 61 million in gross expenditure, provide savings of approximately \$ 27 million over five years, and will benefit over 23,000 New Zealanders.
- **Valaciclovir:** access was widened to this treatment for infections caused by the herpes virus. Nearly 34,000 more people will now be able to access this funded treatment.
- **New treatments for multiple sclerosis:** dimethyl fumarate and teriflunomide were funded, bringing the number of funded MS treatments to seven.
- **New medicines for rare disorders:** during the year, PHARMAC managed its pilot initiative for the funding of medicines for rare disorders. Four medicines for the treatment of rare disorders were funded, with an estimated \$ 8.2 million of gross expenditure in the first full year:
 - Icatibant is used to treat severe attacks of hereditary angioedema and can be administered at home, which benefits the person and their whānau, and DHBs.
 - Siltuximab is a treatment for HIV-negative, HHV-8 negative multicentric Castleman's disease.
 - Galsulfase is a treatment for people with the rare enzyme deficiency condition Maroteaux-Lamy Syndrome (mucopolysaccharidosis VI). It is usually diagnosed in children and can cause damage to bones, joints, eyes, heart valves and the nervous system.
 - Bedaquiline is used to treat extensively drug-resistant tuberculosis, a rare form caused by bacteria resistant to some usual tuberculosis treatments.

Promoting Generics

New Zealand has one of the highest proportions of generic medicines by volume (third out of 26 OECD countries). PHARMAC encourages the development of generics, calling for competitive tenders for the exclusive supply right, for a limited period, after the patent expires. According to the PHARMAC Annual Report, in 2014/15, the combined pharmaceutical expenditure was \$ 795 million. Nevertheless, the estimated spending without the savings achieved since 2004, would have been almost \$ 2 billion.

11.6 Look-out for Near Future

New Zealanders have a very good coverage of their healthcare needs, through public health services. In the past, there were some barriers, such as high co-payments to access healthcare services and pharmaceuticals. Today, cost is no longer a barrier, but the access to new medicines is ongoing in some countries, although the reimbursement and price of pharmaceuticals are assessed and decided on the national level in New Zealand and the major concern is the waiting list for innovative pharmaceuticals.

Since the introduction of the use of generic drugs instead of their originators is an effective way to rationalize healthcare, generic pharmaceutical industry will be an important part of the drug policy in New Zealand in the near future.

Overall, New Zealanders appear satisfied with their healthcare system, with the hope that any changes will bring more equity and sustainability.

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