Chapter 11
Pharmaceutical Pricing in New Zealand

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Abstract All New Zealand residents are covered by a national public health system, and approximately 80 % of all health expenditure is publically financed. A well-regulated system of privately owned pharmacies supplies outpatient pharmaceuticals, while inpatient pharmaceuticals are provided in secondary care facilities. New Zealand does not use pharmaceutical price controls, leaving prices to be determined by negotiation. However, the public health system has a very effective monopsony purchaser, the Pharmaceutical Management Agency of New Zealand (PHARMAC). PHARMAC negotiates the prices of inpatient, outpatient and cancer pharmaceuticals, vaccines and medical devices, and manages a capped national budget for outpatient and cancer pharmaceuticals. PHARMAC also sets (separate) national positive formularies of publically funded outpatient and inpatient pharmaceuticals, and administers access schemes for pharmaceuticals that are not on these formularies. PHARMAC uses a variety of mechanisms to obtain favourable prices, including competitive tendering, sole supply contracts, reference pricing, bundling deals, risk sharing agreements and promoting use of generics. Health technology assessment is used extensively in decision making and price negotiations. As a result, New Zealanders have universal and nationally consistent pharmaceutical coverage, with lower patient pharmaceutical co-payments than many comparable countries.

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11.1 Introduction

This chapter discusses pharmaceutical pricing in New Zealand. The chapter focuses on the universal public health system and the public health system's monopsony pharmaceutical purchaser, the Pharmaceutical Management Agency of New Zealand (PHARMAC).

The structure of the New Zealand health system is briefly described, including financing and service provision. This is followed by an overview of the pharmacy system, including controls on ownership, contractual relationship with the public health system and pharmacy charges to consumers. The remit of Medsafe, the national drug regulatory authority, is also briefly described. The majority of the chapter describes PHARMAC's role within the public health system, its impact on the prices of publically funded medicines, and effects on public health. PHARMAC differs from many other pharmaceutical pricing agencies by integrating formulary setting, budget management, price negotiation and health technology assessment within the same agency. The chapter likewise considers these aspects of New Zealand's pharmaceutical pricing together. The pricing of pharmaceuticals that are not publically funded (and hence outside PHARMAC's remit) is also briefly discussed.

11.2 The New Zealand Health System

All New Zealand residents are covered by a national public health system. New Zealand's per capita health expenditure in 2011 was $3,182 United States Dollar Purchasing Power Parity (USD PPP). This was slightly below the OECD average of $3,322 USD PPP. New Zealand's per capita pharmaceutical expenditure was $284 USD PPP, the fifth lowest in the OECD, and well below the OECD average of $483 USD PPP (The Organisation for Economic Co-operation and Development 2013).

Approximately 80 % of all New Zealand's health expenditure is publically funded (The Commonwealth Fund 2010; The Organisation for Economic Co-operation and Development 2013). The public funding sources are central Government tax revenue (85 %), levies on employers including compulsory accident insurance contributions (7 %), and local Government (8 %) (The Commonwealth Fund 2010). The remaining 20 % of health expenditure largely consists of out-of-pocket patient contributions (co-payments). Private health insurance only accounts for 5 % of all health expenditure (The Organisation for Economic Co-operation and Development 2013).

The central Government tax revenue allocated to health is known as 'Vote Health'. Approximately 19 % of Vote Health is spent on national health programmes, including screening, maternity care and child health services (The New Zealand Ministry of Health 2013a). Over 75 % of Vote Health is allocated to

regional organisations known as District Health Boards (DHBs), which are responsible for public health services for the people of their respective regions (The Commonwealth Fund 2010; The New Zealand Ministry of Health 2013a).

Each DHB has a funding arm (responsible for planning, funding and purchasing health services) and a provider arm (responsible for administering and staffing public health facilities) (The Commonwealth Fund 2010). The provider arms of DHBs provide roughly half of New Zealand's health services by value (The Commonwealth Fund 2010). This mainly consists of secondary and tertiary care, and includes pharmaceuticals for inpatient treatment within public hospitals (The Commonwealth Fund 2010).

DHBs also contract health services from private providers. These are mainly primary care providers such as general practitioners, but can also include elective surgical and other secondary care services (The Commonwealth Fund 2010). Most general practices belong to networks called Primary Health Organisations (PHOs), which are funded by DHBs to provide care for their enrolled populations (The Commonwealth Fund 2010). Patients who are enrolled in a PHO pay lower general practice and outpatient prescription co-payments, and 95 % of New Zealanders are enrolled in a PHO (The Commonwealth Fund 2010; The New Zealand Ministry of Health 2014a).

DHBs are responsible for funding outpatient pharmaceuticals, cancer treatments and vaccines for their eligible populations. PHARMAC is responsible for managing this spending on behalf of the DHBs, and ensuring that it remains within a set national budget each year (The Commonwealth Fund 2010; The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2012a). PHARMAC's role is described in more detail in Sect. 11.5 of this chapter. It should be noted that DHB funding for prescription dispensing and other pharmacist services (which is described in Sect. 11.3) is distinct from the funding of pharmaceuticals.

The public health system also covers outpatient, inpatient, maternity and pre-natal care, national screening and immunisation programmes, and other public health services in addition to pharmaceuticals (The New Zealand Ministry of Health 2011b). These are largely publically funded (as described above), although patient co-payments are required for some services (The Commonwealth Fund 2010).

The public health system also covers some dental services, including preventive services for children, emergency care for both children and adults, and basic dental care for low-income adults in some areas (The New Zealand Ministry of Health 2011c). Treatment for injuries resulting from accidents is usually provided by the public health system, but is funded by the Accident Compensation Corporation (ACC), a publically funded no-fault accident compensation scheme that covers all New Zealanders (The New Zealand Ministry of Health 2011a). ACC also funds the treatment costs of injuries resulting from medical treatment, gradual work processes and violent crimes (The Accident Compensation Corporation 2013).

11.3 The New Zealand Pharmacy System

New Zealand pharmacies are an integral part of the New Zealand public health system. There are over 900 pharmacies in New Zealand, which dispense over 50 million prescriptions per year, as well as providing primary health care and facilitating the provision of medicines to thousands of New Zealanders (Pharmaceutical Society of New Zealand 2014). For this reason, the New Zealand pharmacy system is tightly controlled by robust laws and regulations to protect health and disability consumers.

The Medicines Act 1981 sets out strict laws regulating the ownership and operation of pharmacies in New Zealand. Each pharmacy must hold a license, which authorises the establishment of the pharmacy and the provision of pharmacy practice in that pharmacy (Medicines Act 1981). Licenses are issued and controlled by the Licensing Authority at the Ministry of Health (The New Zealand Ministry of Health 2010). Pharmacies that hold a valid license are able to operate a pharmacy if a New Zealand registered pharmacist is present to supervise the pharmacy.

Pharmacies may be owned by individuals, as a partnership or by a company (Medicines Act 1981). Most pharmacies in New Zealand are owned by companies. However, the majority share capital of the company must be held by a New Zealand registered pharmacist or a group of pharmacists. Companies are prohibited from operating or holding majority interest in more than five pharmacies at any one time. Similarly to companies, individuals either alone or in partnership may only operate a pharmacy if the majority interest is held by a pharmacist and held in no more than five pharmacies. There are also restrictions on authorised prescribers holding interests in a pharmacy. No authorised prescriber shall hold an interest in a pharmacy unless permission is given by the licensing authority (Medicines Act 1981). This prevents the delivery of health care being influenced by financial or commercial interests.

Pharmacies have contractual relationships with DHBs to provide specific services to certain patients, such as long term condition services, warfarin monitoring and methadone dispensing (New service model for community pharmacy 2012; New Zealand District Health Boards 2007). Pharmacies receive payments for providing these services in addition to funding for community pharmaceuticals (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2012b).

In July 2012 the Pharmacy Service model shifted from paying pharmacies based on each dispensing transaction to providing a patient-centered service (New service model for community pharmacy 2012). Pharmacies now receive a core service fee per patient, per pharmacy, per day and then a handling fee for each medicine dispensed (Central Region's Technology Advisory Services 2014). This is paid from the DHB budget via the Ministry of Health's centralised payment service (Pharmaceutical Management Agency of New Zealand (PHARMAC) 2014). This model has been developed to combat growth in pharmacy dispensing costs, which was considered unsustainable by the New Zealand Government (New service model for community pharmacy 2012).

Pharmaceutical products which are listed on the Pharmaceutical Schedule (a nationwide positive formulary of publically funded pharmaceuticals, administered by PHARMAC) will be reimbursed by DHBs. The medicine price listed in the Pharmaceutical Schedule indicates the amount of subsidy paid to community pharmacies for each medicine (before mark-ups and tax) (Wilson et al. 2014). This payment is made from the combined pharmaceutical budget (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2014b, c). Patients also make a co-payment for funded medicines, which is usually $5 New Zealand Dollars (NZD) per item. This co-payment is paid directly to the community pharmacy and is then subtracted from the pharmacy's invoice to the DHB (i.e. patients pay $5 NZD per item towards their medicines). If the manufacturer's medicine price exceeds the subsidy price, patients will then have to pay a manufacturers fee on top of the usual co-payment fee to receive the medicine (Wilson et al. 2014). This is considered a partially subsidised medicine, and the cost to the patient will vary between pharmacies based on the size of the mark-up the dispensing pharmacy charges (this will be discussed further in Sect. 11.6).

PHARMAC's aim is to publically fund a high volume of medicines across a wide range of therapeutic classes from the available pharmaceutical budget (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2014b, c). The strategies PHARMAC uses to achieve these goals are discussed in detail in Sect. 11.5 of this chapter.

11.4 Drug Regulatory Authority (Medsafe)

The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) is the authority responsible for regulating all medicines in New Zealand (The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) 2013). Medsafe is responsible for ensuring the safety, efficacy and quality of medicines through pre-marketing evaluation and post-marketing monitoring (The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) 2013).

Medsafe is widely perceived to be an efficient and impartial regulator by key informants familiar with the New Zealand pharmaceutical system. Medsafe is perceived to have a cordial and professional relationship with the pharmaceutical industry that allowed the two to work together effectively, without compromising Medsafe's objectivity (Ragupathy 2013). This opinion was shared by a wide range of informants that included health professionals, pharmaceutical industry representatives, public servants, and elected representatives (Ragupathy 2013). Medsafe is currently harmonising its regulatory activities with the Australian Therapeutic Goods Administration (TGA). The eventual goal is the creation of a joint regulatory agency, the Australia New Zealand Therapeutic Products Agency (ANZTPA), which will regulate medicines in both countries (The Australia New Zealand Therapeutic Products Agency 2014).

Medsafe and PHARMAC each carry out their own evaluations of a given pharmaceutical, and make decisions independently of each other. This means that medicines approved by Medsafe will not necessarily be publically funded. Conversely, PHARMAC can on rare occasions fund medicines that have not been approved by Medsafe, or fund medicines for uses other than those approved by Medsafe (Best Practice Advocacy Centre New Zealand 2013).

11.5 Managing Pharmaceutical Spending in the Public Health System (PHARMAC)

11.5.1 PHARMAC's Role in the Public Health System

PHARMAC is responsible for negotiating the prices of pharmaceuticals used in the public health system, but its role goes much further. PHARMAC's statutory objective is "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*" (emphasis added) (The New Zealand Parliament 2000).

PHARMAC administers the Pharmaceutical Schedule, a nationwide positive formulary that lists which outpatient and cancer treatments are publically funded, along with special access schemes for some pharmaceuticals that are not on the Pharmaceutical Schedule. PHARMAC also decides the listing (or de-listing) of pharmaceuticals on the Pharmaceutical Schedule, along with variations on the conditions of listing. Neither the Government nor the Judiciary can order or block the listing of any pharmaceutical (Ragupathy 2013; Ragupathy et al. 2012a; Aaltonen et al. 2010; Raftery 2008; Cumming et al. 2010; Morgan et al. 2006).

PHARMAC also manages national pharmaceutical budgets for outpatient pharmaceuticals, and cancer treatments. PHARMAC conducts its own health technology assessments (see Sect. 11.5.3). Budgetary constraints and health technology assessments are incorporated into listing (or de-delisting) decisions and price negotiations (Ragupathy 2013; Ragupathy et al. 2012a; Aaltonen et al. 2010; Raftery 2008; Cumming et al. 2010; Morgan et al. 2006).

Another function of PHARMAC is to manage the funding of pharmaceuticals for patients in exceptional circumstances (i.e. situations not adequately provided for by the Pharmaceutical Schedule) (Pharmaceutical Management Agency (PHARMAC) 2013; Pharmaceutical Management Agency (PHARMAC) 2014a). This is a requirement of PHARMAC set out in the New Zealand Public Health and Disability Act 2000, and funding is from the combined pharmaceutical budget or individual DHB budgets (Pharmaceutical Management Agency (PHARMAC) 2013). The Named Patient Pharmaceutical Assessment (NPPA) is the framework PHARMAC uses to assess applications for subsidising pharmaceuticals in exceptional circumstances. NPPA is not used to provide access to *every* medicine not

listed on the Pharmaceutical Schedule, but instead where the patient has unusual clinical circumstances, or if PHARMAC is considering or is likely to consider to fund the pharmaceutical in the future (Pharmaceutical Management Agency (PHARMAC) 2013).

PHARMAC's role is also expanding in ways that are likely to increase its ability to negotiate favourable prices. PHARMAC has been involved in managing inpatient pharmaceutical expenditure within DHBs since the launch of the National Hospital Pharmaceutical Strategy in 2002. The National Hospital Pharmaceutical Strategy included negotiating nationally consistent supply contracts (which reduced inpatient pharmaceutical prices by up to 90 %), along with providing health technology assessments to guide DHBs in their inpatient pharmaceutical formulary listing decisions, and promoting the quality use of medicines. However, each DHB retained final control over its own inpatient pharmaceutical formulary decisions, and managed its own budget for inpatient pharmaceuticals (Tordoff 2007). This led to concerns about variability in access based on where a patient lived, sometimes called 'post-code prescribing' (Ragupathy 2013; Ragupathy et al. 2012b).

In July 2013, all DHBs began using the Hospital Medicines List (HML), a nationally consistent inpatient prescribing formulary managed by PHARMAC. The HML replaced all DHB pharmaceutical formularies, and lists the pharmaceuticals that may be prescribed for inpatients, and the conditions under which these may be prescribed. If a pharmaceutical is not on the HML, it cannot be prescribed except through a Named Patient Pharmaceutical Assessment (NPPA) application, though there is some flexibility for urgent situations (Pharmaceutical Management Agency of New Zealand 2014a).

DHBs currently still manage individual budgets for inpatient pharmaceuticals, but PHARMAC will eventually undertake this role, just as it does for outpatient pharmaceuticals. Where a pharmaceutical is funded for both inpatient and outpatient use, PHARMAC aims to align the conditions under which it may be used in both instances (Pharmaceutical Management Agency (PHARMAC)). It has been argued that aligning the management of inpatient and outpatient pharmaceuticals under one agency makes New Zealand unique in the world (Dew and Davis 2014).

PHARMAC's scope is also moving beyond traditional pharmaceuticals. Since July 2012, PHARMAC has also been responsible for the purchase and management of vaccines, including those on the national childhood immunisation schedule. PHARMAC negotiates vaccine prices with manufacturers and makes listing decisions, as well as deciding changes to eligibility (The New Zealand Ministry of Health 2013b). PHARMAC has also begun taking over the purchasing and management of medical devices from individual DHBs, and is expected to be managing most medical devices by mid-2015 (Pharmaceutical Management Agency (PHARMAC) 2014b).

The concentration of so many powers and health technologies under one agency arguably place PHARMAC in very select company among pharmaceutical pricing agencies, if not actually making PHARMAC *sui generis*. PHARMAC even has the authority to fund pharmaceuticals or treatment protocols that have not been approved by New Zealand's drug regulatory agency (Best Practice Advocacy

Centre New Zealand 2013). Certainly none of the pharmaceutical pricing bodies in Australia, Canada, Finland, the United Kingdom, nor the United States combine nationwide jurisdiction with such broad powers (Ragupathy 2013; Ragupathy et al. 2012a; Aaltonen et al. 2010; Morgan et al. 2006). This gives PHARMAC much stronger levers for controlling pharmaceutical expenditure than many other agencies (Ragupathy et al. 2012a; Aaltonen et al. 2010; Raftery 2008; Cumming et al. 2010).

11.5.2 PHARMAC's Price Negotiation Strategy

In order to fund a large number of medicines, PHARMAC, use a number of techniques to operate within the fixed medicines budget. A central strategy for PHARMAC is promoting competition among pharmaceutical companies in order to keep prices low. Other commercial purchasing strategies include price negotiations, tendering for generic or sole supply contracts, and reference pricing for medicines with similar therapeutic effects (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2014b, c; Woodfield 2001).

PHARMAC also use price rebates for subsidised medicines and cross-product agreements (bundling) to keep prices low (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2014b, c; Morgan et al. 2007; Woodfield 2001). Pharmaceutical companies and PHARMAC may negotiate a price for a medicine, and DHBs will purchase the medicines at the stated price. However, after an agreed period of time the DHB will receive a rebate back from the pharmaceutical company, with the deal remaining confidential (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2014b, c; Management Sciences for Health 2012). A rebate may also be received for expenditure caps; when sales of a subsidised product exceed an agreed limit, the manufacturer will cover all or some of the costs to supply the medicine above the set expenditure cap (Morgan et al. 2007).

In the case of cross-product (bundling) agreements, PHARMAC may only agree to subsidise a new medicine in return for price reduction on one or more medicines already listed on the Pharmaceutical Schedule, produced by the same manufacturer (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2014b, c; Morgan et al. 2007). The listed price in the Pharmaceutical Schedule for the new medicine will be the manufacturer's international price, not including the overall discount obtained by PHARMAC for subsidising a bundle of medicines (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2014b, c; Morgan et al. 2007; Woodfield 2001).

Rebates, expenditure caps and cross-product agreements are all techniques which result in the Pharmaceutical Schedule listing a medicine price which is higher than the true price paid by DHBs (Wilson et al. 2014; The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2014b, c). PHARMAC will agree with the manufacturer on the listed price and continue to protect details about

the true price paid for the pharmaceutical. This method avoids other buyers (including those in other countries) from knowing what discount PHARMAC negotiated, and thereby requesting equivalent pricing discounts from pharmaceutical companies. These procurement techniques produce a lack of transparency, as the official medicine prices in the Pharmaceutical Schedule are often higher than the actual transactional price. However, these techniques are essential for PHARMAC to contain pharmaceutical expenditure in New Zealand and encourage access to a wide range of subsidised medicines.

11.5.3 PHARMAC's Health Technology Assessment

PHARMAC takes nine decision criteria into account when deciding whether a pharmaceutical will be publically funded, and at what price (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2006). These are:

1. The health needs of all eligible people within New Zealand
2. The particular health needs of Māori and Pacific People
3. The availability and suitability of existing medicines, therapeutic medical devices and related products and related things
4. The clinical benefits and risks of pharmaceuticals
5. The cost effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services
6. The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule
7. The direct cost to health service users
8. The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere
9. Such other criteria as PHARMAC thinks fit. PHARMAC will carry out appropriate consultation when it intends to take any such "other criteria" into account (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2006)

It is worth noting that PHARMAC is carrying out consultation on these decision criteria at the time of writing (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2014a). Individual criteria may therefore be subject to change. However, PHARMAC's statutory obligation to remain within its capped budget means that health technology assessment (broadly speaking, criteria 3–6) is likely to remain a key part of PHARMAC's strategy.

PHARMAC takes clinical advice from its Pharmacology and Therapeutics Advisory Committee (PTAC). PTAC consists of senior medical practitioners who are highly experienced in their respective fields, and has specialist subcommittees with particular experience in a given field, such as oncology. PTAC members are expected to critically appraise each pharmaceutical's harms and benefits, and the strength of the evidence for these. (Well-designed randomised controlled trials and

meta-analyses are the preferred sources of evidence, and the internal validity of the trials as well as their applicability to New Zealand clinical practice are considered). PTAC may recommend that the pharmaceutical be funded with a high, medium or low priority or that it be declined (Grocott et al. 2013). PTAC uses the same nine decision criteria in making its recommendation, but this recommendation is not the final PHARMAC decision (Grocott et al. 2013; Morgan et al. 2006).

PHARMAC also conducts economic evaluation of the pharmaceutical, along with price negotiations. PHARMAC's preferred method of economic evaluation is cost-utility analysis (CUA). This method of economic analysis produces a common outcome measure across all pharmaceutical treatments, namely the cost per Quality Adjusted Life Year (QALY) gained. PHARMAC takes a health system perspective in its economic analyses, which means that all public health system costs (not just pharmaceutical costs) are included in its analyses, along with potential savings (Grocott et al. 2013). Non health system costs (such as foregone tax revenue or increased social welfare spending from a patient's inability to work) are not included (Grocott et al. 2013).

As PHARMAC operates with a capped budget, and cost utility is only one of the decision criteria, PHARMAC does not use a 'cost utility threshold' (a cost per QALY level below which a pharmaceutical is likely to be funded). Between 1999 and 2007, the cost utility of new PHARMAC funding decisions varied from *savings* of NZ $40,000 per QALY to spending of over NZ $200,000 per QALY (Metcalf et al. 2012). Furthermore, New Zealand funded five of the ten pharmaceuticals that the United Kingdom's National Institute for Health and Care Excellence (NICE) had found to have the highest cost per QALY between 1996 and 2005 (Raftery 2008). Having a high cost per QALY doesn't therefore in itself preclude a pharmaceutical from being funded. However, there is widespread agreement among key informants that pharmaceuticals are assessed much more stringently for economic benefit than other New Zealand health investments, including non-pharmaceutical health technologies (Ragupathy et al. 2012b; Babar and Francis 2014).

11.6 Drug Pricing in New Zealand

11.6.1 Pharmaceutical Price Control

Unlike other OECD countries, in New Zealand there is no government price regulation for pharmaceuticals which are not listed on the Pharmaceutical Schedule (Organisation for Economic Co-operation and Development 2010; Kilpatrick et al. 2014). This means that manufacturers are able to set pharmaceutical prices at market entry without any restrictions such as profit controls, volume limitations or international reference pricing (United States Department of Commerce: International Trade Administration 2004).

If a medicine is publically funded, PHARMAC negotiates the price with the manufacturer, and the taxpayer subsidises all or part of the price for the patient. If a medicine is non-funded (i.e. not listed on the Pharmaceutical Schedule), the consumer must pay the full price out-of-pocket to receive the medicine.

The MIMS (Monthly Index of Medical Specialties) New Ethicals—a widely used prescribing reference—lists manufacturer prices for commonly prescribed medicines available in New Zealand (MIMS New Ethicals 2014). A wholesale mark-up is added to the manufacturer's price, which determines the pharmacy purchase price. The pharmacy is then able to add a mark-up to the medicine price which can be at any level (Burden of Disease Epidemiology and Equity and Cost-Effectiveness Programme (BODE)). A recommended mark-up in New Zealand is a multiplier of 1.86, but this is intended as a guide only. In reality community pharmacies may have mark-ups lower or higher than this (MIMS New Ethicals 2014). The total cost to the patient for non-funded medicines includes all three pricing components with no government control, and therefore varies for different medicines purchased at individual community pharmacies within New Zealand.

Recent evidence suggests the lack of government control on New Zealand medicine prices may lead to higher prices for non-funded medicines. In a 2013 study exploring medicine price differences between New Zealand and Europe, New Zealand consistently had high medicine prices compared to sixteen European countries for medicines not listed on the Pharmaceutical Schedule (i.e. medicines not funded in New Zealand) (Kilpatrick et al. 2014). The differences in medicine prices seen in the study are likely attributable to varying Government price controls and reimbursement policies between the countries investigated. The true impact of these findings is not fully known and further research is needed to determine the effect high non-funded medicine prices have on New Zealanders' access to medicine.

In 2012–2013 about 30 % of the New Zealand population had private health insurance (Health Funds Association of New Zealand 2013). Private health insurance can cover the cost of some pharmaceuticals and prescription charges for consumers with comprehensive care policies (Health Funds Association of New Zealand 2013). Private insurers are also able to negotiate medicine prices with pharmaceutical companies, which is especially significant for highly specialised, high cost pharmaceuticals not funded in New Zealand (Lakdawalla and Yin 2013; McCormack et al. 2009). The true cover provided by insurance companies is kept confidential and therefore it is not fully known to what extent non-funded medicines will be paid for by insurance companies. New Zealanders may also be unwilling to obtain private insurance for pharmaceuticals (2012c). Despite this, comprehensive care policies *may* allow some patients with private insurance access to funding for a wider range of pharmaceuticals.

Access to and affordability of medicines that are not publically funded may be a productive area for future research. Such research could include determining the effect high non-funded medicine prices have on New Zealand patients, the effectiveness of private insurance as means of accessing non-funded medicines, and the

benefits and pitfalls of policy options such as pharmaceutical price controls for non-funded medicines.

However, as the vast majority of pharmaceutical spending in New Zealand is public spending (The Organisation for Economic Co-operation and Development 2013), the remainder of this chapter will focus on publically funded pharmaceuticals.

11.6.2 PHARMAC's Impact on the Price of Publically Funded Medicines

Medicine prices in New Zealand have significantly fallen since the introduction of PHARMAC in 1993 (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2014b, c). Figure 11.1 shows the impact PHARMAC has had on drug expenditure over time. The shaded area between the two lines represents the total savings since 2002. Cumulative savings attributed to PHARMAC from 2000 to 2010 was $4.37 billion (NZD) (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2013). These results are directly related to the purchasing techniques PHARMAC uses, which have been discussed above.

An example of the dramatic price reductions achieved by PHARMAC can be assessed using fluoxetine, a selective serotonin reuptake inhibitor. In 1993 fluoxetine 20 mg capsules cost $1.93 NZD/capsule, but referencing pricing with paroxetine brought the price down to $1.58 (The Pharmaceutical Management Agency of New Zealand PHARMAC and Evans 2008). There was a significant price reduction

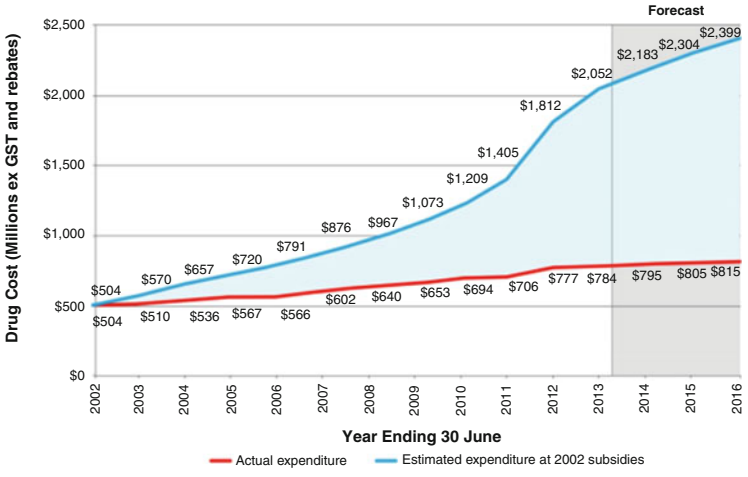

Fig. 11.1 Impact of PHARMAC on drug expenditure over time; actual and predicted expenditure from 2002 to 2016. Drug cost is expressed in millions of New Zealand Dollars excluding GST and rebates (Pharmaceutical Management Agency (PHARMAC) 2013)

on paroxetine which took the price of fluoxetine to $1.12 due to reference pricing. Following this, the introduction of generics in 2000 produced a price of $0.45. Subsequent price reductions, reference pricing and sole supply led to a price of $0.05 in 2004 which is a cumulative reduction of 97 %. In 2012 the price had reduced further to $0.032/capsule (The Pharmaceutical Management Agency of New Zealand (PHARMAC) and Evans 2008). This example shows some of the key techniques used by PHARMAC to achieve significant price reductions over time. Despite this, the lack of transparency for medicine prices published in the Pharmaceutical Schedule makes it impossible to determine the exact medicine price changes over time in New Zealand.

Many OECD countries have policies in place to support the use of generic medicines (Derek et al. 2002). When a patent expires, generic medicines will emerge with lower medicine prices than the originator. New Zealand also has policies in place to support the uptake of generic medicines, and to create competition between different generic manufacturers through tendering (The Pharmaceutical Management Agency of New Zealand (PHARMAC) 2014b, c). In 2013 almost half of all medicines purchased (by volume) were through multi product tendering, which represents 20 % of the combined pharmaceutical budget (The Pharmaceutical Management Agency of New Zealand (PHARMAC)). The large number of medicines available in generic brands produces a significant price saving, which can be reinvested to subsidise other new medicines on the Pharmaceutical Schedule.

11.7 The Impact of Pricing on Public Health (Access and Affordability of Medicines)

The impact of PHARMAC's cost-containment strategies on the health of New Zealanders has been a source of considerable controversy (Ragupathy 2013). At the broadest level, the debate focuses on the impact funding or not funding particular medicines has on New Zealanders' health outcomes, both in absolute terms and relative to comparable countries (Castalia Strategic Advisors 2005; Business and Economic Research Limited (BERL) 2005; Easton 2005). However, linking differences in access to medicines to health outcomes is difficult, due to multiple confounding factors such as differences in demographics, environmental and lifestyle factors, access to screening, and waiting times for treatment (Ragupathy 2013).

There has also (until recently) been a dearth of systematic, peer-reviewed comparisons of New Zealanders' overall access to publically funded medicines relative to comparable countries (Ragupathy 2013). Past controversies have therefore focused on smaller parts of the access picture. These included particular PHARMAC techniques such as sole supply tendering or funding switches for HMG CoA Reductase Inhibitors (statins) (Begg et al. 2003; MacKay 2005),

funding for sub-types of medicines such high cost and highly specialised medicines (McCormack et al. 2009), or the funding of medicines for particular indications, such trastuzumab for early stage HER2 positive breast cancer (Isaacs et al. 2007). These controversies had to be considered in light of the fact PHARMAC had considerably expanded the number of publically funded medicines while restraining the growth in pharmaceutical expenditure (Cumming et al. 2010).

In recent years, published studies have compared New Zealand's access to publically funded medicines with publically funded health systems in Finland, Australia, the United Kingdom and the United States (Ragupathy et al. 2012a; Aaltonen et al. 2010; Wonder and Milne 2011). Taken together, these studies do much to clarify the impact of PHARMAC's strategies on public access to medicines.

PHARMAC funded fewer medicines than Finland's public health system in 2007, 471 unique entities compared to 495 (Aaltonen et al. 2010). PHARMAC also funded fewer entities (503) than the Australian Pharmaceutical Benefit's Scheme (567), the United Kingdom's National Health Service (1016) and the United States Department of Veterans Affairs National Formulary (505) in 2007 (Ragupathy et al. 2012a). The above study also compared access to innovative entities that provided important health gains. PHARMAC subsidised 19 of the 65 innovative entities in 2007, compared with 30 by the Pharmaceutical Benefits Scheme (and a further four by the Life Saving Drugs Program, which operates alongside the Pharmaceutical Benefits Scheme in Australia), 58 by the National Health Service, and 20 by the Department of Veterans Affairs National Formulary (Ragupathy et al. 2012a).

A separate comparison of Australia and New Zealand found that PHARMAC only subsidised 59 (43 %) of the 136 new prescription medicines subsidised by the Pharmaceutical Benefits Scheme between 2000 and 2009 (conversely, only four medicines were subsidised by PHARMAC but not the Pharmaceutical Benefits Scheme). The 59 medicines were on average subsidised later by PHARMAC than by the Pharmaceutical Benefits Scheme (mean difference 32.7 months, $p < 0.0001$) (Wonder and Milne 2011).

Though it has been shown that PHARMAC subsidises fewer medicines than its comparators, however its impact on public health and health outcomes is not fully known (Babar and Vitry 2014). Also, while evaluating the impact of PHARMAC on New Zealanders' health, many other factors should be taken into account. These include universality and equity of coverage, the restrictions placed on how subsidised medicines may be prescribed, and patient cost sharing (Ragupathy 2013; Raftery 2008). It is worth noting that unlike the situation in the United States, where publicly funded systems such as Department of Veterans Affairs National Formulary or Medicare only cover selected subsets of the population, PHARMAC covers all New Zealand residents. Similarly, unlike the United Kingdom, where variable decisions by local funding bodies can lead to 'post-code prescribing', PHARMAC's coverage is nationally consistent (Ragupathy 2013).

Over 86 % of the entities subsidised by PHARMAC in 2007 were fully subsidised, which meant most patients only paid a fixed $3 NZD co-payment for

up to 3 months' supply (this co-payment has since been increased to $5 NZD) (Aaltonen et al. 2010). Furthermore, 69 % of entities were fully subsidised without any restrictions on how they could be prescribed. PHARMAC's strategy appears to be providing fully subsidised options across almost all therapeutic areas, including options for symptom relief such as analgesics and antacids (Aaltonen et al. 2010). The co-payments and yearly maximum payments for PHARMAC subsidised medicines are lower than other comparable systems (Ragupathy et al. 2012a; Aaltonen et al. 2010). Co-payments in New Zealand for funded medicines are currently $5 NZD per item, up to a maximum of 20 co-payments per family per year. Once this threshold is met (i.e. once a patient or family spend $100 NZD per year on medicines), patients no longer need to pay the co-payment to receive their medicines (The New Zealand Ministry of Health 2014b). Less than 3 % of New Zealanders spent more than $1,000 USD on out of pocket payments for prescription medicines, compared with 5 % in Australia and 13.2 % in the United States (Morgan and Kennedy 2010). The 10 % of New Zealanders who reported not filling prescriptions or skipping doses in a year because of cost was lower than in Australia (13.4 %) and the United States (23.1 %).

The impact of PHARMAC's strategies on New Zealanders' public health could therefore be seen as a trade-off. A degree of therapeutic choice (including access to new and innovative medicines, and medicines for rare conditions) is traded for equity of access to the medicines that are subsidised, and maximising the affordability of medicines to both patient and taxpayer. Whether the right balance has been struck between these competing priorities is likely to remain a source of debate.

11.8 Country Summary: New Zealand

New Zealand does not rely on legal controls of manufacturers' selling prices, profits or mark-ups to ensure affordable pharmaceutical prices. Rather, the price is determined by the relative negotiating power of the seller and the buyer. Individuals who privately purchase non-funded pharmaceuticals may therefore pay higher prices than in many other countries.

However, the New Zealand pharmaceutical market is dominated by its public health system, and therefore by PHARMAC. PHARMAC's monopsony on publically funded pharmaceuticals and its statutory independence in decision-making give it a very strong bargaining position. PHARMAC leverages these advantages effectively in order to maximise its capped budget, and uses a variety of techniques such as competitive tendering, reference pricing, generic substitution and bundling agreements. Health technology assessment also plays a key role in funding decisions. This has allowed PHARMAC to drastically restrain the growth of New Zealand's pharmaceutical expenditure while expanding access to medicines.

Given PHARMAC's central role in determining New Zealanders' access to pharmaceuticals, controversies about its decisions and processes are inevitable. Despite this, PHARMAC has benefited from a broad political consensus, and this stability has allowed it to focus on negotiating favourable prices. Its role has expanded considerably, and now encompasses outpatient and inpatient pharmaceuticals, cancer treatments, vaccines, and medical devices. PHARMAC is therefore likely to be a feature of the New Zealand health system for many years to come.

Glossary

ACC Accident Compensation Corporation
ANZTPA Australia New Zealand Therapeutic Products Agency
DHB District Health Board
HML Hospital Medicines List
Medsafe New Zealand Medicines and Medical Devices Safety Authority
NICE National Institute for Health and Care Excellence (United Kingdom)
NPPA Named Patient Pharmaceutical Assessment
OECD Organisation for Economic Co-operation and Development
PHARMAC Pharmaceutical Management Agency of New Zealand
PHO Primary Health Organisation
PTAC Pharmacology and Therapeutics Advisory Committee
QALY Quality Adjusted Life Year
TGA Therapeutic Goods Administration (Australia)

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