

# Funding Medicines in New Zealand: Revision of the Medicines Waiting List

**Author: Cristine Della Barca**



February 2016

# Funding Medicines in New Zealand: Revision of the Medicines Waiting List

## Executive Summary

In 2015 a paper was published which showed evidence of a waiting list of 29 medicines that had a positive recommendation from the Pharmacology and Therapeutics Advisory Committee (PTAC)<sup>1</sup> but were yet to be funded by the Pharmaceutical Management Authority (PHARMAC)<sup>2</sup>.

The current study undertook an analysis that has further investigated the list of PTAC recommendations from January 2006 to December 2015. The list of recommendations has been compared with the New Zealand Pharmaceutical Schedule as at December 2015 to generate an expanded and updated list of medicines that have yet to be funded.

This revision shows that there are 81 medicines for 109 therapeutic indications awaiting listing on the Pharmaceutical Schedule after receiving positive PTAC recommendations. Delays to listing of these medicines range between 0.08 years and 9.58 years, and there is one medicine that is known to remain unfunded after more than 12 years.

This analysis illustrates that a significant number of medicines are yet to be funded by PHARMAC. It would appear that financial limitations, due to a capped medicines budget, may mean that a range of medicines for patients with a variety of significant diseases in New Zealand, including cancer and diabetes, remain unfunded and clinicians and patients are left with reduced therapeutic options. In this regard, it is felt that in the interest of public good and transparency PHARMAC should itself publish a list of medicines waiting listing on the Pharmaceutical Schedule including length of time on that list and their PTAC priority status.

### *Limitations of the Current Study*

*Given the stated timeframe of investigation ending in December 2015, it is possible that medicines on the waiting list may have been funded after both PHARMAC Board and PTAC meetings in 2016. There may also be some medicines for therapeutic indications that have been waiting before 2006.*

---

<sup>1</sup> In New Zealand, the Pharmaceutical Management Agency (PHARMAC) decides which medicines will receive public funding, following advice from the Pharmacology and Therapeutics Advisory Committee (PTAC).

<sup>2</sup> Reference: Barber, J, Sheehy, K. (2015). Uptake of new medicines in New Zealand: evidence of a waiting list. NZ Med J. 128: 1412 (6492)

## Background

In 2015 a paper was published in the New Zealand Medical Journal which showed evidence of a waiting list of 29 medicines that have had a positive recommendation from the Pharmacology and Therapeutics Advisory Committee (PTAC)<sup>3</sup> but are yet to be funded by PHARMAC (Barber and Sheehy, 2015). The study's authors acknowledged that the list did not include all PTAC recommendations.

The current study and analysis has therefore revisited the PTAC minutes for medicines that had a positive recommendation to be funded for the first time and also for widening access to medicines already funded. The period of the analysis has been updated to include recommendations for vaccines, and PTAC recommendations to December 2015, thereby providing a more complete and updated analysis.

## PHARMAC Process

The Pharmacology and Therapeutics Advisory Committee (PTAC) is the primary expert clinical committee that reviews the clinical evidence around funding applications, and taking into account PHARMAC's nine decision criteria<sup>4</sup>, makes recommendations to PHARMAC on which medicines to fund, and with what priority.

PHARMAC requires applicants to provide a health technology assessment (usually Cost Effectiveness Analyses) in their applications for funding; it also frequently performs a preliminary Health Assessment Reports (HAR) comparing the medicines in an application with a funded alternative (Grocott, 2009). Both the applicant and PHARMAC health technology assessment are provided to PTAC to inform their decisions.

PTAC's recommendation and a final HAR are then reviewed by PHARMAC staff, and an internal priority list of medicines is generated from which potential investment options are then chosen. This priority list is not published. PHARMAC then hold commercial negotiations with the applicant and if an agreeable provisional outcome is reached this is submitted to the PHARMAC Board for a final investment decision. Despite the expert status of PTAC, PHARMAC is not bound to accept its advice or follow its recommendations, and PHARMAC may attach a different listing priority to a medicine, or make a decision that differs from PTAC's recommendation. PHARMAC's Board minutes relating to funding decisions are not publicly available, so no direct comparison between the PTAC recommendation and PHARMAC Board decisions can be made.

---

<sup>3</sup> In New Zealand, the Pharmaceutical Management Agency (PHARMAC) decides which medicines will receive public funding, following advice from the Pharmacology and Therapeutics Advisory Committee (PTAC).

<sup>4</sup> PHARMAC's nine decision criteria are to be replaced by 12 Factors for Consideration in mid-2016.

Not all products that have been recommended for funding by PTAC, however, appear to progress through to a decision by the PHARMAC Board; and the Board's minutes are not publicly available.

Previously published views hold that the PHARMAC list of medicines awaiting funding is effectively a waiting list for medicines in New Zealand (Barber & Sheehy, 2015).

The intent of the current study and analysis was to further revise and update the list of PTAC recommendations for new listings and recommendations for widened access to medicines that are already listed, and to calculate how long patients have been waiting for the medicines, the corresponding categories of priority as allocated by PTAC, and to calculate how long the groups of medicines in each priority category have been awaiting funding. This enables an expanded and accurate estimate of the list of medicines that have received a positive recommendation for funding by PTAC, but are yet to be funded.

## Method

Minutes from quarterly PTAC meetings were assessed from February 2006 (the first year that these were reliably published online) to November 2015. Generation of a tabulated list of therapeutic agents, including vaccines (the latter of which came under PHARMAC responsibility from 2013 onwards) was then undertaken using the following metrics:

- PTAC meeting date for first positive recommendation
- Intended indication/indications
- PTAC first recommendation (decline, list, referral to subcommittee etc.) and priority status (positive recommendations only and any changes in priority status).

PTAC recommendations were reviewed from publicly available minutes (those published on the PHARMAC website as of December 2015) and these were compared with the list of medicines (including vaccines) funded by PHARMAC as published in its Pharmaceutical Schedule (including more recently, the Hospital Medicines List (HML)) – again as at December 2015.

We have included PTAC recommendations for widened access to medicines that already have a listing on the Pharmaceutical Schedule (i.e. to fund medicines with less restrictive special authority criteria, for wider population coverage or new indications).

## Results

Minutes for over 375 individual therapeutic agents/medicines or indications were considered in the quarterly meetings of PTAC from February 2006 through to November 2015. Of those, 245 (65%) were given a positive recommendation from PTAC (to list on the HML or Pharmaceutical Schedule with a positive priority (high, medium, moderate, or low) or only if cost-neutral).

However, 109 (29%) of those positive recommendations were still awaiting a final PHARMAC funding decision on inclusion in the Pharmaceutical Schedule as at December 2015 (See Table 1).

The longest waiting time for a medicine was 9.6 years for Telmisartan (although adrenalin auto injector for anaphylaxis, which first received a medium priority in November 2005 but remains

unfunded, has the longest known waiting time of more than 12 years). The second longest waiting period was 9.1 years for Fluvestrant, for post-menopausal locally advanced or metastatic breast cancer. The shortest waiting time is 0.08 years for Pembrolizumab for melanoma, which was recently added to the list in November 2015.

**Table 1. The positive recommendations of PTAC since 2006 that have yet to be listed on the New Zealand Pharmaceutical Schedule as of December 2015**

Pharmaceutical Agent	Therapeutic indication in PTAC minutes	New listing or wider access	Date of Positive Rec	Priority	Waiting period (years)
<b>GREATER THAN 5 YEARS WAIT</b>					
Telmisartan	Hypertension	List	May-06	Only if cost-neutral	9.58
Fluvestrant	Locally advanced metastatic breast cancer	List	Nov-06	Low	9.08
Fulvestrant	Post-menopausal locally advanced or metastatic breast cancer	List	Nov-06	Low	9.08
Desogestrel	Contraception	List	Aug-07 <sup>5</sup>	Low	8.33
Ketotifen fumarate	Ocular allergy	List	May-08	Only if cost-neutral	7.58
Oxybutinin patches	Urinary incontinence	List	Jul-08	Low	7.42
Pemetrexed	First line treatment of NCSLC	List	Jul-08	Only if cost-neutral	7.42
Bimatoprost and timolol eye drops	Glaucoma	List	Feb-09	Only if cost-neutral	6.83
Rosuvastatin	3rd line hypercholesterolemia	List	Feb-09	Medium	6.83
Travoprost and timolol eye drops	Glaucoma	List	Feb-09	Only if cost-neutral	6.83
Buprenorphine transdermal patch	Moderate to severe pain	List	May-09	Low	6.58
Duloxetine hydrochloride	Treatment of major depressive disorder that is not responsive to other antidepressants	List	Jul-09	Only if cost-neutral	6.42
Bevacizumab	Metastatic Colorectal Cancer	List	Feb-10	Low	5.83
Golimumab	Second-line TNF-inhibitor treatment of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis	List	May-10	Low	5.58
Levofloxacin	Treatment for helicobacter infection	List	May-10	Other	5.58
Metronidazole vaginal gel	Vaginal infections	List	May-10	Only if cost-neutral	5.58

<sup>5</sup> Originally recommended with a “high” priority in May 2000, before the start date for this analysis.

Sildenafil	Fontan patients	Widen access	May-10	High	5.58
Sildenafil	Neonatal/infantile PAH secondary to CLD	Widen access	May-10	Medium	5.58
Quetiapine modified-release tablets	Schizophrenia and other psychoses	List	Jun-10	Low	5.50
Pipobroman	Polycythemia rubra vera and essential thrombocythemia	List	Aug-10	Medium	5.42
Deferiprone	Iron Overload secondary to acquired anaemia	Widen access	Nov-10	Medium	5.08
Miglustat	Mild to moderate Type 1 Gaucher disease	List	Nov-10	Low	5.08
Nab-paclitaxel	Advanced breast cancer	List	Nov-10	Only if cost-neutral	5.08
<b>3-5 YEARS WAIT</b>					
Trastuzumab	HER2 positive metastatic gastric cancer	Widen access	Feb-11	Low	4.83
Cevimeline	Dry mouth	List	Aug-11	Low	4.33
Pregabalin	Neuropathic pain	List	Aug-11	Low	4.33
Rituximab	Relapsed/Refractory follicular non-Hodgkins lymphoma	Widen access	Aug-11	Low	4.33
Ustekinumab	Psoriasis	List	Aug-11	Only if cost neutral	4.33
Saxagliptin	Type 2 diabetes	List	Nov-11	Low	4.08
Dutasteride	BPH	List	Feb-12	Only if cost-neutral	3.83
Asenapine	Schizophrenia and bipolar 1 disorder	List	Aug-12	Only if cost neutral	3.33
Linagliptin	Type 2 diabetes	List	Aug-12	Low	3.33
Liraglutide	Type 2 diabetes	List	Aug-12	Low	3.33
Telaprevir	Genotype 1 chronic hepatitis C	List	Aug-12	High	3.33
TNF Inhibitors	Behçet's Disease	Widen access	Aug-12	Medium	3.33
Sitagliptin	Type 2 diabetes	List	Aug-12	Low	3.33
Melatonin	Psychiatric comorbidities and secondary insomnia associated with dementia	List	Nov-12	Low	3.08
Sildenafil	Cardiac surgery	Widen access	Nov-12	Hosp only	3.08
<b>1-3 YEARS WAIT</b>					
Rilpivirine	HIV	New	Feb-13	Only if cost neutral	2.83
Carbetocin	Uterine atony and excessive bleeding following elective caesarean	New	Feb-13	Only if cost neutral	2.83
Nab-paclitaxel	Metastatic breast cancer	New	Aug-13	Low	2.33
Vitamin D	Admin to pregnant women for	New	Aug-13	Only if cost neutral	2.33

	prophylaxis of rickets in infants at high risk				
Vitamin D	Admin to infants at high risk of rickets	New	Aug-13	Only if cost neutral	2.33
Vitamin D	Treatment of infants with rickets	New	Aug-13	Low	2.33
Rotavirus vaccine	Universal childhood vaccine	New	Aug-13	Medium	2.33
Ciprofloxacin eye drops	Chronic suppurative otitis media	Widen access	Nov-13	High	2.08
Adalimumab	Weekly dose rescue therapy for Crohn's Disease	Widen Access	Nov-13	Low	2.08
Dapaglifozin	Type 2 diabetes	New	Nov-13	Low	2.08
Melatonin	Secondary insomnia in children and adolescents with neurodevelopmental or psychiatric comorbidities	New	Feb-14	Low	1.92
Nab-Paclitaxel	Previously experienced hypersensitivity reactions to paclitaxel or docetaxel	New	Feb-14	Only if cost neutral	1.92
Pertuzumab	First line patients with HER-2-positive metastatic breast cancer in combo with trastuzumab and docetaxel	New	Feb-14	Low	1.92
TNF alpha inhibitors	Inflammatory bowel disease associated arthritis (IBD-A)	Widen Access	Feb-14	Low	1.92
Rivaroxaban	Venous thromboembolism	New	May-14	Only if cost neutral	1.58
Rivaroxaban	Secondary prophylaxis of venous thromboembolism	New	May-14	Only if cost neutral	1.58
Rivaroxaban	Stroke prevention in non-valvular atrial fibrillation	New	May-14	Only if cost neutral	1.58
Apixaban	Prophylaxis of venous thromboembolism following major orthopaedic surgery	New	May-14	Only if cost neutral	1.58
Apixaban	Stroke prevention in non-valvular atrial fibrillation	New	May-14	Low	1.58
Adrenaline auto injector	Patients that have experienced anaphylactic reaction to venom or food	New*	May-14	Medium	1.58
Phosphodiesterase V inhibitors (PDE5 inhibitors)	Erectile dysfunction related to spinal cord injury	New	May-14	Medium	1.58

Intracavernosal alprostadil	Erectile dysfunction related to spinal cord injury	New	May-14	Medium	1.58
Midodrine	Relax SA	Widen Access	May-14	None	1.58
Minoxidil	Remove SA	Widen Access	May-14	None	1.58
Gabapentin	Remove SA	Widen Access	May-14	None	1.58
Isotretinoin	Relax SA	Widen Access	May-14	None	1.58
Acitretin	Relax SA	Widen Access	May-14	None	1.58
Lixisenatide	Adults with Type 2 diabetes	New	May-14	Low	1.58
Stribild	HIV-1	New	May-14	Only if cost neutral	1.58
Sofosbuvir	Hep C - non Geno 1 on liver transplant list	New	Aug-14	High	1.33
Sofosbuvir	Hep C - all	New	Aug-14	Low	1.33
Ingenol mebutate 0.015%	Facial and scalp solar keratosis	New	Aug-14	Only if cost neutral	1.33
Nicotine inhaler and oral spray	Smoking cessation	New	Aug-14	Only if cost neutral	1.33
Nicotine replacement therapy	Sample packs	New	Aug-14	Only if cost neutral	1.33
Melatonin	Secondary insomnia in children and adolescents with neurodevelopmental disorders	New	Aug-14	Low	1.33
Aminolevulinic acid	Visualisation of glioma	New	Nov-14	High	1.08
Rotigotine transdermal patch	Parkinsons disease	New	Nov-14	Only if cost neutral	1.08
Sub-cutaneous trastuzumab	HER 2 positive breast cancer	New	Nov-14	Only if cost neutral	1.08
Epoprostenol	PAH	New	Nov-14	High	1.08
COX-2 inhibitors	Arthritis	New	Aug-14	Only if cost neutral	1.33
<b>LESS THAN 1 YEARS WAIT</b>					
Obinutuzumab	First line treatment of Chronic Lymphocytic Leukaemia	New	Feb-15	Medium	0.92
Aflibercept	Neovascular (wet) aged-related macular degeneration	New	Feb-15	RFP	0.92
TNF alpha inhibitors	Undifferentiated spondyloarthritis	Widen Access	Feb-15	High	0.92
Sofosbuvir with ledipasvir	Hepatitis C - HCV pts with decompensated cirrhosis (all geno)	New	May-15	High	0.58
Sofosbuvir with ledipasvir	Hepatitis C - HCV pts pre/post liver transplant (all geno)	New	May-15	High	0.58
Sofosbuvir with ledipasvir	Hepatitis C - HCV pts with essential mixed cryoglobulinaemia	New	May-15	High	0.58



Sofosbuvir with ledipasvir	Hepatitis C - all other sub-populations	New	May-15	Low	0.58
Ustekinumab	Severe chronic plaque psoriasis	New	May-15	Only if cost neutral	0.58
Pertuzumab	Metastatic HER2 positive breast cancer	New	May-15	Low	0.58
Plerixafor	Stem cell mobilisation - HML	New	May-15	High	0.58
Indacaterol maleate/glycopyrronium	Chronic obstructive pulmonary disease	New	May-15	Low	0.58
Macitentan	Pulmonary arterial hypertension	New	May-15	Low	0.58
Denosumab	Osteoporosis	New	May-15	Medium	0.58
Topical NSAID	Osteoarthritis	New	May-15	Low	0.58
Insulin Pumps	Type I diabetes in Pregnancy	New	Aug-15	Low	0.33
Bendamustine	Chronic Lymphocytic Leukaemia Non-Hodgkin's Lymphoma - unable to tolerate fludarabine, cyclophosphamide and rituximab (FCR)	New	Aug-15	Medium	0.33
Bendamustine	Chronic Lymphocytic Leukaemia Non-Hodgkin's Lymphoma - first line	New	Aug-15	Low	0.33
Pemetrexed	Advanced non-squamous non-small cell lung carcinoma - first line	New	Aug-15	Only if cost neutral	0.33
Pemetrexed	Advanced non-squamous non-small cell lung carcinoma - maintenance	New	Aug-15	Low	0.33
Pemetrexed	Advanced non-squamous non-small cell lung carcinoma - second line	New	Aug-15	Only if cost neutral	0.33
Bevacizumab	First line treatment of recurrent, persistent or metastatic cervical cancer	New	Aug-15	Low	0.33
Tolcilizumab	Polyarticular juvenile idiopathic arthritis	New	Aug-15	Medium	0.33
Subcutaneous tocilizumab	Adult rheumatoid arthritis - last line	New	Aug-15	Low	0.33
Rituximab	Resistant nephrotic syndrome	Widen Access	Aug-15	Medium	0.33
Paritaprevir/ritonavir, ombitasvir, dasabuvir +/- ribavirin	Chronic Hepatitis C genotype 1	New	Aug-15	Low	0.33
Zoster vaccine	65 years and older	New	Aug-15	Medium	0.33
Lidocaine 4% with adrenaline 0.1% and tetracaine 0.5%	Wound repair - children	New	Aug-15	Medium	0.33

Lidocaine 4% with adrenaline 0.1% and tetracaine 0.5%	Wound repair - unrestricted	New	Aug-15	Low	0.33
Sodium chloride prefilled syringe	Sterile procedures	New	Aug-15	High	0.33
Pembrolizumab	Metastatic or unresectable melanoma stage III or IV	New	Nov-15	Low	0.08

From a summary of the PTAC priority categories (Table 2), there appears to be a reasonable level of correlation between the priority of the PTAC recommendation and the length of waiting times ( i.e. mean waiting time for high priority medicines seems to be lower than that for medium and low.)

Table 2. Waiting times by priority category

<b>PTAC priority category</b>	<b>Number of recommendations</b>	<b>New Listings</b>	<b>Widened access</b>	<b>Mean waiting time (years)</b>	<b>Range of waiting times</b>
High	12	9	3	1.94	0.33-5.58
Medium	17	13	4	2.32	0.33-6.83
Low	42	38	4	3.01	0.33-9.08
Only If Cost Neutral	30	30	0	2.93	0.33-9.58
None/Other	8	2	6	1.70	0.92-3.08
<b>TOTAL</b>	<b>109</b>	<b>92</b>	<b>17</b>	<b>2.69</b>	<b>0.08-9.08</b>

The mean waiting times for all medicines on this list is 2.69 years, although there is a significant range in waiting times (0.08 to 9.08 years). Most interestingly, the majority (84%) of the outstanding recommendations appear to be for new listings i.e. recommendations for a range of new medicines rather than widened access to existing funded medicines.

## Discussion

Waiting lists for health treatments within a resource constrained environment are relatively common both locally and internationally, and are arguably a means of identifying bottlenecks in the system.

We have tried to quantify the waiting list in terms of size and waiting times.

Our report is not specifically aimed at achieving listing of the therapeutic agents identified. Rather, the intent is to illuminate that there is a New Zealand medicines waiting list and discuss the need for transparent reporting of such a waiting list in the future.

Our work aims to identify a measurable and reproducible waiting list specific to New Zealand, which will need to be updated regularly in order to get an overall perspective on the issues of access to cost-effective medicines within the healthcare sector.

For some of the diseases that the medicines on the waiting list treat, there may already be funded medicines that are considered similar in efficacy, but we believe that for a medicine to be recommended by PTAC as any priority other than “if cost neutral”, PTAC would have considered that there is additional benefit to be gained from providing access to the medicine.

The criteria for a listing priority is elusive, and the public would benefit from understanding the criteria that is applied particularly as the priorities do not appear to predict the speed with which agents are listed. This may, in part at least, be due to PHARMAC’s right to reprioritise PTAC’s recommendations. The public would also benefit from understanding how listing priorities can change.

## Concluding remarks

A pharmaceutical waiting list in New Zealand is evident, the extent of which we believe needs to be communicated to New Zealand clinicians and the public. The study found that there are 109 recommendations (92 unlisted new medicines and 17 listed medicines for which wider access is recommended), affecting 81 medicines with positive recommendations from PTAC that are awaiting funding. Waiting times identified ranged from 0.083 to 9.58 years and there were only small differences in mean waiting times between the groups of medicines by PTAC priority.

We support the opinion previously published by Barber and Sheehy (2015) that a waiting list can be a useful tool in PHARMAC openly reporting on performance and providing input to government budget allocation decisions (analogous to a District Health Board (DHB) waiting list for various health interventions).

We consider that if New Zealand is truly to provide the best health outcomes that are reasonably achievable from pharmaceutical treatment, there should be a more open disclosure and debate about what investment options are available to PHARMAC.

This report, as well as the previously published paper by Barber and Sheehy (2015) will therefore provide more evidence to allow for a balanced and rational debate about the appropriate level of medicines access for New Zealand patients. It would seem that rather than the country focusing on fiscal pressure or containment measures around medicines as noted by other authors (Moodie et al, 2011; Ragupathy et al, 2012; Milne & Wonder, 2001; Taylor & Wonder, 2015) – a broader debate needs to be held on the role of cost-effective medicines and their role as part of the suite of practical and suitable solutions for New Zealand patients and the New Zealand healthcare system.

## References

1. Barber, J, Sheehy, K. (2015). Uptake of new medicines in New Zealand: evidence of a waiting list. *NZ Med J.* 128: 1412 (6492)
2. Braae R, McNee W, Moore D.(1999) Managing pharmaceutical expenditure while increasing access. The Pharmaceutical Management Agency (PHARMAC) experience. *Pharmacoeconomics.* 16(6):649–660
3. Cumming J, Mays N, Daube J (2010). How New Zealand has contained expenditure on drugs. *BMJ.*18; 340
4. Grocott R. (2009) Applying Programme Budgeting Marginal Analysis in the health sector: 12 years of experience. *Expert Rev Pharmacoecon Outcomes Res.* 9(2):181-187.
5. Milne R, Wonder M. (2011) Response to PHARMAC on access to new medicines in New Zealand compared to Australia. *N Z Med J.* 124(1347).
6. Moodie P, Metcalf S, Poynton M. (2011) Do pharmaceutical score cards give us the answers we seek? *N Z Med J.* 25; 124(1346).
7. Ragupathy R, Aaltonen K, Tordoff J, **et al.** (2012) A 3-dimensional view of access to licensed and subsidized medicines under single-payer systems in the US, the UK, Australia and New Zealand, *Pharmacoeconomics.* 30(11)1051–65.
8. Taylor C, and Wonder, M. (2015) Exploring the implications of a fixed budget for new medicines: a study of reimbursement of new medicines in Australia and New Zealand. *Australian Health Review.*