

# Funding Medicines in New Zealand: Revision of the Medicines Waiting List to 30 June 2018

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

## Executive Summary

Medicines New Zealand commissions a report periodically of the number of medicines awaiting Pharmaceutical Schedule listing by the Pharmaceutical Management Agency (PHARMAC) following positive recommendation from the Pharmacology and Therapeutics Advisory Committee (PTAC)<sup>1</sup>.

This update shows that there were over 100 medicines awaiting funding for 124 indications as at 30 June 2018 compared to 86 medicines for 108 indications in the previous report.<sup>2</sup>

Delays to listing these medicines range from a few months to more than 13 years.

### *Limitations of the Current Study*

*Given the stated time frame of investigation there may have been some medicines for therapeutic indications that have been waiting before 2004.*

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<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> The data in the report (for period to 31 December 2016) has been corrected to adjust for cancellation of registration status, missed listings elsewhere in the Pharmaceutical Schedule (Section H), unpublished or missed recommendations since identified, and errors. Numbers reported in February 2017 were 92 medicines for 119 indications but have since been found to be 86 medicines for 108 indications.

## Background

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>3</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 Report (HAR) comparing the medicines in an application with a funded alternative. Both the application and PHARMAC's HAR 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. It appears that PHARMAC then holds commercial negotiations with some applicants and, if an agreeable provisional contractual outcome can be reached, this is consulted and ultimately 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, make a decision that differs from PTAC's recommendation or, in many cases, make no decision at all.

While PHARMAC's Board minutes relating to funding decisions are not publicly available, making any direct comparison between PTAC's recommendations and PHARMAC Board decisions impossible, as not all products that have been recommended for funding by PTAC are the subject of a full decision-making process by the PHARMAC Board. Evidence of this can be found by cross checking published PTAC recommendations against Pharmaceutical Schedule listings, and also by referring to the "Application Tracker" on PHARMAC's website which lists a number of applications as "ranked" or "under assessment".

The intent of this report and analysis is to update the list of PTAC recommendations for new listings and recommendations for widened access to medicines that are already listed, from that published in February 2017, to calculate how long patients have been waiting for these medicines, and to calculate how long the medicines in each priority category (as allocated by PTAC) have been awaiting funding. This enables an expanded and accurate estimate of the number of medicines that have received a positive recommendation for funding by PTAC, but are yet to be funded.

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<sup>3</sup> PHARMAC's nine decision criteria were replaced by 12 Factors for Consideration in mid-2016.

## Method

Minutes from quarterly PTAC meetings were assessed from February 2006 (the first year that these were reliably published online) to February 2018 (the most recently published version on PTAC minutes). 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 of first positive recommendation
- Intended indication/indications
- PTAC's most recent recommendation (decline, list, referral to subcommittee etc.) and priority status (positive recommendations only and any changes in priority status).

PTAC's recommendations were reviewed from publicly available minutes (those published on the PHARMAC Website as of June 2018,) and these were compared with the list of medicines (including vaccines) funded by PHARMAC as published in its Web Application Tracker, and the Pharmaceutical Schedule (including more recently, the Hospital Medicines List (HML)) – as at June 2018.

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).

It is noted that in compiling this analysis some errors/adjustments in the base data were made for products recommended for listing but overlooked from inclusion in the original list, and other errors such as duplicates, listings in Section H not Section B of the Pharmaceutical Schedule, missed listings and lapsing of Medsafe registration in NZ.

Since the last report in December 2016:

- Eight (8) medicines from the original list have been newly listed or had access widened - aminolevulinic acid for visualisation of glioma listed in Section H on 1 June 2017, as well as somatropin, rituximab and tocilizumab for which access was widened in January 2017, melatonin 1 July 2017, pemetrexed 1 Nov 17, PAH treatments February 2018, and aflibercept 1 June 2018.
- Thirty-eight (38) medicines were added to the list from the February 2017, May 2017, August 2017, November 2017 and February 2018 PTAC minutes.
- Application dates and indications have been updated to reflect changes apparently made to the application tracker.

## Results

Minutes for over 500 individual therapeutic agents/medicines or indications were considered in the quarterly meetings of PTAC from February 2006<sup>4</sup> through to February 2018. In previous updates, we have reported that around 60% of applications were given a positive recommendation from PTAC (to list on the HML or Pharmaceutical Schedule with a positive priority (usually a high, medium or low priority) or only if cost-neutral). This appears to have remained at a similar level.

However, 124 of those positive recommendations were still awaiting a final PHARMAC funding decision on inclusion in the Pharmaceutical Schedule as at 30 June 2018 (See Table 1).

The longest waiting time for a medicine was 13.92 years for adrenaline auto-injector for anaphylaxis received a medium priority in August 2004 but remains unfunded. The second longest waiting period was 12.17 years for telmisartan for hypertension. Fulvestrant for post-menopausal locally advanced or metastatic breast cancer, desogestrel for contraception, ketotifen fumarate for ocular allergy and oxybutynin patches for incontinence have also been waiting for more than ten years. The shortest waiting time for the most recently recommended products is 0.41 years.

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<sup>4</sup> PHARMAC recently add to its Application Tracker dates for EpiPen going back to 2004.

**Table 1.** The positive recommendations of PTAC since 2006 that have yet to be listed on the New Zealand Pharmaceutical Schedule as of 30 June 2018

Product	Indication	New listing or wider access	Recommendation	Date of Positive Rec	Waiting Period (Years)
	<b>Wait more than 10 years</b>				
Adrenaline auto-injector	Patients that have experienced anaphylactic reaction to venom or food	New	Medium	1-Aug-04	13.92
Telmisartan	Hypertension	New	Only if cost-neutral	1-May-06	12.17
Fulvestrant	Post-menopausal locally advanced or metastatic breast cancer	New	Low	1-Nov-06	11.67
Desogestrel	Contraception	New	Low	9-Aug-07	10.90
Ketotifen fumarate	Ocular allergy	New	Only if cost-neutral	1-May-08	10.17
Oxybutynin patches	Urinary incontinence	New	Low	1-Jul-08	10.00
	<b>Wait 5 – 10 years</b>				
Bimatoprost and timolol Eye Drops	Glaucoma	New	Only if cost-neutral	1-Feb-09	9.41
Rosuvastatin	3rd line hypercholesterolemia	New	Medium	1-Feb-09	9.41
Travoprost and timolol Eye Drops	Glaucoma	New	Only if cost-neutral	1-Feb-09	9.41
Buprenorphine transdermal patch	Moderate to severe pain	New	Low	1-May-09	9.17
Duloxetine hydrochloride	Treatment of major depressive disorder that is not responsive to other antidepressants	New	Only if cost-neutral	1-Jul-09	9.00
Sitagliptin	Type 2 diabetes	New	Low	1-Aug-09	8.92
Bevacizumab	Metastatic Colorectal Cancer	New	Low	1-Feb-10	8.41
Golimumab	Second-line TNF-inhibitor treatment of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis	New	Only if cost-neutral	1-May-10	8.17
Levofloxacin	Treatment for helicobacter infection	New	Other	1-May-10	8.17
Metronidazole vaginal gel	Vaginal infections	New	Only if cost-neutral	1-May-10	8.17
Brimonidine (Alphagan P)	Glaucoma	New	None given	1-May-10	8.17
Quetiapine modified-release tablets	Schizophrenia and other psychoses	New	Low	1-Jun-10	8.08

Pipobroman	Polycythemia rubra vera and essential thrombocythemia	New	Medium	1-Aug-10	7.92
Miglustat	Mild to moderate Type 1 Gaucher disease	New	Low	1-Nov-10	7.67
Nab-paclitaxel	Advanced breast cancer	New	Only if cost-neutral	1-Nov-10	7.67
Trastuzumab	HER2 positive metastatic gastric cancer	Widen access	Low	1-Feb-11	7.41
Cevimeline	Dry Mouth	New	Low	1-Aug-11	6.92
Ustekinumab	Psoriasis	New	Only if cost-neutral	1-Aug-11	6.92
Saxagliptin	Type II diabetes	New	Low	1-Nov-11	6.67
Dutasteride	BPH	New	Only if cost-neutral	1-Feb-12	6.41
Asenapine	Schizophrenia and Bipolar 1 Disorder	New	Only if cost-neutral	1-Aug-12	5.92
Linagliptin	Type 2 diabetes.	New	Low	1-Aug-12	5.92
Liraglutide	Type 2 diabetes.	New	Low	1-Aug-12	5.92
Telaprevir	Genotype 1 chronic hepatitis C	New	High	1-Aug-12	5.92
Melatonin	Psychiatric comorbidities and secondary insomnia associated with dementia	New	Low	1-Nov-12	5.66
Carbetocin	Uterine atony and excessive bleeding following elective caesarean	New	Only if cost-neutral	1-Feb-13	5.41
Rilpivirine	HIV	New	Only if cost-neutral	1-Feb-13	5.41
Renal Multivitamin	Patients with chronic kidney disease	New	Medium	1-Feb-13	5.41
	<b>Wait 3-5 years</b>				
Nab-paclitaxel	Metastatic breast cancer	New	Low	1-Aug-13	4.92
Rotavirus vaccine	Universal childhood vaccine	New	Medium	1-Aug-13	4.92
Vitamin D	Admin to pregnant women for prophylaxis of rickets in infants at high risk	New	Only if cost-neutral	1-Aug-13	4.92
Vitamin D	Admin to infants at high risk of rickets	New	Only if cost-neutral	1-Aug-13	4.92
Vitamin D	Treatment of infants with rickets	New	Low	1-Aug-13	4.92
Adalimumab	Weekly dose rescue therapy for Crohn's Disease	Widen access	Low	1-Nov-13	4.66
Ciprofloxacin eye drops	Chronic suppurative otitis media	Widen access	High	1-Nov-13	4.66
Dapagliflozin	Type 2 diabetes	New	Low	1-Nov-13	4.66

Nab-Paclitaxel	Previously experienced hypersensitivity reactions to paclitaxel or docetaxel	New	Only if cost-neutral	1-Feb-14	4.41
TNF alpha inhibitors	Inflammatory bowel disease associated arthritis (IBD-A)	Widen access	Low	1-Feb-14	4.41
Isotretinoin	Relax SA	Widen access	None given	1-May-14	4.17
Rivaroxaban	Secondary prophylaxis of venous thromboembolism	New	Only if cost-neutral	1-May-14	4.17
Rivaroxaban	Stroke prevention in non-valvular atrial fibrillation	New	Only if cost-neutral	1-May-14	4.17
Apixaban	Prophylaxis of venous thromboembolism following major orthopaedic surgery	New	Only if cost-neutral	1-May-14	4.17
Apixaban	Stroke prevention in non-valvular atrial fibrillation	New	Low	1-May-14	4.17
Phosphodiesterase V inhibitors (PDE5) inhibitors	Erectile dysfunction related to spinal cord injury	New	Medium	1-May-14	4.17
Intracavernosal alprostadil	Erectile dysfunction related to spinal cord injury	New	Medium	1-May-14	4.17
Lixisenatide	Adults with Type II diabetes	New	Low	1-May-14	4.17
Cobicistat/ Elvitegravir/Emtricitabine/Tenofovir	HIV-1	New	Only if cost-neutral	1-May-14	4.17
Ingenol mebutate	Facial and scalp solar keratosis	New	Only if cost-neutral	1-Aug-14	3.92
Nicotine inhaler and oral spray	Smoking cessation	New	Only if cost-neutral	1-Aug-14	3.92
Nicotine replacement therapy sample packs		New	Only if cost-neutral	1-Aug-14	3.92
Aminolevulinic acid	Visualization of glioma	New	High	1-Nov-14	3.66
Rotigotine transdermal patch	Parkinson's disease	New	Only if cost-neutral	1-Nov-14	3.66
Trastuzumab Subcutaneous	HER2 positive breast cancer	New	Only if cost-neutral	1-Nov-14	3.66
TNF alpha inhibitors	Undifferentiated spondyloarthritis	Widen access	High	1-Feb-15	3.41
Ustekinumab	Severe chronic plaque psoriasis	New	Only if cost-neutral	1-May-15	3.17
Macitentan	Pulmonary arterial hypertension	New	Low	1-May-15	3.17
Denosumab	Osteoporosis	New	Medium	1-May-15	3.17
Topical NSAID	Osteoarthritis	New	Low	1-May-15	3.17
	Wait 1-3 years				
Insulin Pumps	Type I diabetes in	New	Low	1-Aug-15	2.92



	Pregnancy				
Bevacizumab	First line treatment of recurrent, persistent or metastatic cervical cancer	New	Low	1-Aug-15	2.92
Tocilizumab Subcutaneous	Adult rheumatoid arthritis - last line	New	Low	1-Aug-15	2.92
Lidocaine 4% with adrenaline 0.1% and tetracaine 0.5%	Wound repair - children	New	Medium	1-Aug-15	2.92
Lidocaine 4% with adrenaline 0.1% and tetracaine 0.5%	Wound repair - unrestricted	New	Low	1-Aug-15	2.92
Sodium chloride prefilled syringe	Sterile procedures	New	High	1-Aug-15	2.92
Ibrutinib	Relapsed or refractory mantle cell lymphoma (MCL) that has progressed within 24 months of allograft or chemotherapy or chemo-immunotherapy	New	Low	1-Nov-15	2.66
Rituximab	Hairy cell leukaemia	Widen access	Medium	1-Nov-15	2.66
Idarucizumab	Dabigatran reversal	New	Medium	1-Nov-15	2.66
Omalizumab	Chronic spontaneous urticaria	Widen access	Low	1-Nov-15	2.66
Eplerenone	Heart failure patients intolerant to optimal dosing of spironolactone	New	Low	1-Nov-15	2.66
Aripiprazole depot injection	Schizophrenia	New	Only if cost-neutral	1-Nov-15	2.66
Dornase Alfa	Cystic fibrosis under 6 years	Widen access	Medium	1-Feb-16	2.41
Ipilimumab	Previously treated and unresectable stage IIIc or IV melanoma	New	Low	1-Feb-16	2.41
Pomalidomide	Relapsed or refractory multiple myeloma	New	Low	1-Feb-16	2.41
Velaglucerase alfa	Gaucher disease - first line	New	RFP	1-Feb-16	2.41
Varenicline	Smoking cessation - reduce re-treatment interval	Widen access	Low	1-Feb-16	2.41
Varenicline	Smoking cessation - 2 week starter and follow-on packs	Widen access	Only if cost-neutral	1-Feb-16	2.41
Nivolumab	Locally advanced or metastatic non-small cell lung cancer	Widen access	Low	1-May-16	2.16
Selexipag	Pulmonary Arterial Hypertension	New	Low	1-May-16	2.16

Taurolidine and citrate solution	Section H - locking of central venous access devices in those at high risk of developing central line-associated bacteraemia	New	Only if cost-neutral	1-May-16	2.16
Denosumab	Osteoporosis	New	Medium	1-May-16	2.16
Sapropterin	Phenylketonuria and hyperphenylalaninemia for women pregnant or planning a pregnancy	New	High	1-May-16	2.16
Enzalutamide	Treatment of metastatic castration-resistant prostate cancer	New	Only if cost-neutral	1-Aug-16	1.91
Rituximab	Severe myasthenia gravis - 3rd line	Widen access	High	1-Aug-16	1.91
Rituximab	Refractory myasthenia gravis	Widen access	Low	1-Aug-16	1.91
Nintedanib	Idiopathic pulmonary fibrosis	New	Only if cost-neutral	1-Aug-16	1.91
Ciclosporin eye ointment	Keratoconjunctivitis sicca and atopic and vernal keratoconjunctivitis	New	Low	1-Aug-16	1.91
Methylnaltrexone subcutaneous injection	Treatment of opioid-induced constipation in patients receiving palliative care	New	High	1-Aug-16	1.91
Ivabradine	Computed tomography coronary angiography (CTCA)	New	High	1-Aug-16	1.91
Adalimumab	Severe hidradenitis suppurativa	Widen access	Low	1-Nov-16	1.66
Pembrolizumab	Locally advanced, or metastatic, unresectable, PD-L1 positive, non-small cell lung cancer	Widen access	Low	1-Nov-16	1.66
Ruxolitinib	Myelofibrosis - high risk and intermediate 2	New	Medium	1-Nov-16	1.66
Ruxolitinib	Myelofibrosis - intermediate 1	New	Low	1-Nov-16	1.66
Sacubitril with valsartan	Heart failure (NYHA III + IV) with reduced ejection fraction <35%	New	Low	1-Feb-17	1.41
Paliperidone palmitate 3-monthly depot injection (Invega Trinza)	Schizophrenia	New	Low	1-Feb-17	1.41
Levodopa/carbidopa intestinal gel and pump	Parkinson's disease	New	Low	1-Feb-17	1.41
Topical clindamycin	Bacterial vaginosis	New	Low	1-Feb-17	1.41

vaginal cream					
Furosemide	Paediatric congenital heart disease	Widen access	High	1-May-17	1.16
Secukinumab	Subcutaneous injections for severe chronic plaque psoriasis	New	Medium	1-May-17	1.16
Lenalidomide	Newly diagnosed multiple myeloma who are ineligible for stem cell transplant	Widen access	Only if cost-neutral	1-Aug-17	0.91
Adalimumab	Treatment of adults and children with severe or chronic non-infectious intermediate, posterior, and panuveitis who have had a poor response to corticosteroids	Widen access	Low	1-Aug-17	0.91
Atezolizumab	Second or third-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy	New	Low	1-Aug-17	0.91
Glecaprevir/Pibrentasvir	Chronic hepatitis C in adults	New	Medium	1-Aug-17	0.91
Sofosbuvir/Velpatasvir	Chronic Hepatitis C	New	Medium	1-Aug-17	0.91
Peginterferon beta – 1a (rch)	Relapsing forms of multiple sclerosis	New	Only if cost-neutral	1-Aug-17	0.91
Trastuzumab emtansine	Second-line treatment of patients with HER2 positive metastatic breast cancer who have previously received trastuzumab and a taxane, separately or in combination	Widen access	Low	1-Nov-17	0.66
Exenatide	Treatment of patients with type 2 diabetes mellitus	New	Low	1-Nov-17	0.66
Empagliflozin	Treatment of patients with type 2 diabetes with established high cardiovascular risk	New	High	1-Nov-17	0.66
Rituximab	Treatment of neuromyelitis optica spectrum disorder (NMOSD)	Widen access	High	1-Nov-17	0.66

Insulin Glargine LA	Type 1 and 2 Diabetes	New	Only if cost-neutral	1-Feb-18	0.41
Dexrazoxane	Cardioprotection in conjunction with anthracycline chemotherapy	New	Low	1-Feb-18	0.41
Levonorgestrel Intrauterine System	Contraception	New	High	1-Feb-18	0.41
Levonorgestrel Intrauterine System	Endometriosis	New	High	1-Feb-18	0.41
Levonorgestrel Intrauterine System	Endometrial hyperplasia without atypia	New	High	1-Feb-18	0.41
Levonorgestrel Intrauterine System	Treatment of heavy menstrual bleeding	New	High	1-Feb-18	0.41
Ocrelizumab	Relapsing remitting multiple sclerosis	New	Only if cost-neutral	1-Feb-18	0.41
Secukinumab	Ankylosing spondylitis 2nd line	New	Medium	1-Feb-18	0.41
Secukinumab	Psoriatic arthritis 1st line	New	Medium	1-Feb-18	0.41
Secukinumab	Psoriatic arthritis 2nd line	New	Medium	1-Feb-18	0.41

From a summary of the PTAC priority categories (Table 2), there appears to be some correlation between the priority of the PTAC recommendation and the mean length of waiting times only although the numbers are small (i.e. mean waiting time for high priority medicines appear lower than that for medium and low.)

**Table 2.** Waiting times by priority category to 30 June 2018

<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>
<b>High</b>	16	11	5	2.04	0.41-5.92
<b>Medium</b>	20	18	2	3.59	0.41-13.92
<b>Low</b>	49	38	11	4.10	0.41-11.67
<b>Only If Cost Neutral</b>	35	33	2	4.89	0.41-12.17
<b>None/Other</b>	4	3	1	5.73	2.41-8.17
<b>TOTAL</b>	124	103	21	4.03	0.41-13.92

**Table 3.** Changes since last update published February 2017 (for period ending December 2016)

<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	Up 6 from 10	Up 5 from 6	Up 1 from 4	Down from 2.72	Down from 0.72-6.75
Medium	No change from 16	Up 6 from 12	Down 2 from 4	Up from 2.85	Up from 0.25-7.00
Low	Down 1 from 50	Down 1 from 39	No change from 11	Up from 3.13	Up from 0.25-10.25
Only If Cost Neutral	Down 1 from 36	Down 1 from 34	No change from 2	Up from 3.34	Up from 0.5-10.75
None/Other	Down 3 from 7	Up 2 from 1	Down 5 from 6	Up from 4.17	Up from 2.75-6.75
TOTAL	Up 5 from 119	Up 11 from 92	Down 6 from 27	Up from 3.19	Up from 0.25- 10.75

The mean waiting times for all medicines on this list is 4.03 years, although there is a significant range in waiting times (0.41 to 13.92 years). Most interestingly, the majority (83%) of the outstanding recommendations appear to be for new listings (i.e. recommendations for new medicines rather than widened access to existing funded medicines).

We also note that while it appears that the mean waiting time for high priority medicines has decreased since the last update (Table 3), this is only a result of a skewing of the mean time due to 6 new recommendations being made from 1 November 2017 to 1 Feb 2018. These 6 recent recommendations have brought the mean down, but does not in our view, reflect that the decision-making process has become faster. In fact, the overall mean waiting time for all medicines on the list has increased since the last update, from 3.19 year to 4.03 years.

## 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 developed evidence that a medicines waiting list does exist in New Zealand and tried to quantify it in terms of size and waiting times.

It is noted that around 30% of products on the waiting listing (Table 1) are in fact available in New Zealand as generic medicines (but not yet publicly funded). So alternative and cheaper product options are in fact available to be funded in the public system - assuming decisions are made in a timely manner. In other words the justification that there is a cost-capped medicines budget does not in our view, fully justify the reason that a good number of the waiting list medicines cannot be funded publicly and removed from the list once and for all.

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

PHARMAC is the only body within the New Zealand health sector that is legislated to work within the constraints of a fixed budget, set annually by the Minister of Health from within the overall Health Budget ("Vote Health"). PHARMAC's success in generating savings is frequently stated by many stakeholders; although the actual size of these savings; any trade-offs in terms of delayed access; or the health consequences of them have not been adequately measured in a peer reviewed manner. Where PHARMAC quotes estimates of long term savings in its Annual Reports there is no methodology provided and no external review of how this has been generated.

Our work aims to identify a measurable and reproducible waiting list specific to New Zealand. Any such waiting list would change frequently, and require regular updating to be meaningful to policy considerations.

We recognise that medicines that receive a specific priority may have this priority changed over time. However analyses of the priority classification as regards the waiting list indicates that in short, the classification as high, medium or low priority seems to have no major impact on length of stay on the waiting list or reflect any correlation with faster decision-making, given that the longest wait time for a high priority recommendation is almost 6 years and the longest overall wait time on the list is almost 14 years, which is for a medicine with a medium priority.

A benefit of our approach is that by relying on the expert clinical committee PTAC's positive recommendations for listing, we have included only medicines that may be deemed to have a meaningful positive benefit from being funded. The PTAC process can be expected to have declined any medicines that it considered to not add therapeutic value to the health system.

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.

In overall terms since the first compilation of the Waiting List report in 2015 until this most recent analysis, we have noted both the increase of medicines waiting to be funded for new indications now at 103 and the increase in mean waiting time from 2.7 years to 4.03 years. This is despite new four-year of investment being programmed into PHARMAC budget in 2016 with an additional investment of \$60 million being made in the 2017 Budget. In other words, there has been no significant reduction in the overall number of pharmaceuticals waiting to be listed on the Pharmaceutical Schedule that have been given a positive recommendation from PTAC.

It will be interesting to determine with the supposed record level for PHARMAC's combined pharmaceutical budget in 2018/19 financial year will alter the trends seen over the past four years. In other words, a reduction in the number of medicines and the waiting time reduces via transferring the medicines from the Waiting List onto the Pharmaceutical Schedule

The previous paragraph reinforces our previous suggestion that it is time PHARMAC reduced the list of potential investments by completing the decision-making process for those pharmaceuticals on the waiting list that it has no intention of funding. Some of those recommendations date back 10 years or more. Almost half of them have been on the list for 3 years or more.

Over time PHARMAC appears to have changed its original policy and practice of processing all applications to a decision by the PHARMAC Board.

Until 2003 PHARMAC published a list of "Applications Declined by the PHARMAC Board". These tables also provided a reconciliation of applications received, listed and declined and reported the percentage "success" rate. It should be noted that in 1994 and 1995, twenty (20) applications were considered and declined by the PHARMAC Board.<sup>5</sup> Those numbers were down to between two and four per year by the year 2000<sup>6</sup>. Annual Reviews since 2004 have omitted to publish this information.

The diagram of the Decision Making Process available on PHARMAC's website <https://www.pharmac.govt.nz/medicines/how-medicines-are-funded/> which has been around in one form or another since PHARMAC's inception in 1993, used to indicate that *all* applications to list medicines in the Pharmaceutical Schedule, once reviewed by PTAC, then underwent a process of prioritisation, negotiation with the supplier, consultation and a Board Decision. The diagram now suggests that those of "low ranking" are either not actioned or consulted on for decline. However, it is not clear which of PTAC's priority rankings (high, medium-high, medium, low and only if cost-neutral) constitutes a "high ranking". Certainly, of the medicines that have been listed since 2006, less than 25% have been given a "high" priority by PTAC and very few have been consulted on and taken to the PHARMAC Board to be declined.

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<sup>5</sup> "Applications considered and decided" table Page 17, Annual Review, 1996

<sup>6</sup> Applications declined by the PHARMAC Board" table Page 26, Annual Review, 2003

The diagram is framed with a caveat that *“The process set out in this diagram is intended to be indicative of the process that may follow where a supplier or other applicant wishes a pharmaceutical to be funded on the Pharmaceutical Schedule. PHARMAC may, at its discretion, adopt a different process or variations of the process. For example, decisions on whether or not it is appropriate to undertake consultation, are made on a case-by-case basis.”*

However, we now have over 100 medicines for which no consultation has been undertaken and no PHARMAC Board decision has been made.

### **Conclusion:**

We believe that a waiting list can be a useful tool in PHARMAC openly reporting on performance and providing input to government budget allocation decisions. For the sake of transparency it would be sensible for PHARMAC to publish a regularly updated list of pharmaceuticals awaiting listing on the Pharmaceutical Schedule, their PTAC priority status and the length of time they have been waiting (analogous to a DHB waiting list for various health interventions).

However, currently this waiting list tool is absent from PHARMAC’s asset base. A suitable solution therefore, may be having a process where there is consultation on declining an application i.e. where evidence is considered to be lacking, costs are too great/unjustifiable, or commercial negotiations have ceased or failed. This would provide much greater transparency than the current situation as regards PHARMAC’s assessment of the suitability and affordability of these pharmaceuticals for both New Zealand patients and health system.