Funding Medicines in New Zealand: Revision of the Medicines Waiting List to 30 June 2019

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September 2019

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Executive Summary

Medicines New Zealand commissions periodically a report of the number of medicines awaiting Pharmaceutical Schedule listings by the Pharmaceutical Management Agency (PHARMAC) following positive recommendation from the Pharmacology and Therapeutics Advisory Committee (PTAC)[1]. Only 58% of all medicine funding applications submitted to PHARMAC since 2004 have received a positive recommendation from PTAC.

This 2019 update shows that there were 105 applications for new listings, with positive PTAC recommendations, still awaiting funding as at 30 June 2019, compared to 103 in the previous report (to 30 June 2018). There are a further 33 applications with positive recommendations for widened access on the waiting list, compared to 21 in the previous report. This represents a net increase in medicine applications waiting for funding.

Delays to listing medicines ranged from a few months to close to 15 years.

A further time course analysis of the waiting list over the previous years was commissioned. This analysis identifies a medicine waiting list growing at an annual net increase of eight applications per year. Since December 2015 when the first report was published the mean waiting times for PTAC recommended applications has increased from 2.69 to 4.15 years.

Limitations of the Current Study

The report relies on accuracy and completeness of data from publicly available information from PHARMAC's website. Given the stated timeframe of investigation there may have been some medicines for therapeutic indications that have been waiting since before 2004.

[1] 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).

Background

The Pharmacology and Therapeutics Advisory Committee (PTAC) is the primary expert clinical committee that reviews the clinical evidence of funding applications. Taking into account PHARMAC's 12 Factors for Consideration[2] it 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 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 and make a decision that differs from PTAC's recommendation or, in many cases, make no decision at all.

PHARMAC's Board minutes relating to funding decisions are not publicly available in their entirety, making any direct comparison between PTAC's recommendations and PHARMAC Board decisions impossible. 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 June 2018, to calculate how long patients have been waiting for these medicines, and to calculate how long the groups of medicines in each priority category (as allocated by PTAC) have been awaiting funding. This enables an expanded and accurate estimate of the list of medicines that have received a positive recommendation for funding from PTAC, but are yet to be funded.

This report is the fifth of its type and so it also compares the current waiting list of medicines as at 30 June 2019 against the previous four reports. This offers an understanding of trends in medicines funding over time.

[2] 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 the minutes were reliably published online) to February 2019 (the most recently published version of 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 for first positive recommendation
- Intended indication(s)
- 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 30 June 2019) and 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 May 2019.

PTAC recommendations for both new listings and for widened access to medicines were considered. New listing is defined as an application to fund a medicine not currently on the Pharmaceutical Schedule. Widened access is defined as a funding application for a medicine already listed on the Pharmaceutical Schedule but only for a particular population group or indication. The application is a proposal to fund the medicine for a wider population group or for a new indication

Since the last report published in June 2018:

- 10 medicines have moved from the waiting list and have been newly listed on the Pharmaceutical Schedule, or had access widened for 11 indications - Eplerenone, and Denosumab in July 2018, Rivaroxaban in August 2018, Vildagliptin, Omalizumab, Ruxolitinib, Sacubitril with Valsartan, and Secukinumab in October 2018, Sapropterin in November 2018 and Glecaprevir/Pibrentasvir in in February 2019.

- 31 applications for 25 medicines were added to the list from the May 2018, August 2018, November 2018 and February 2019 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[3] through to February 2019. 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, moderate, or low priority or only if cost-neutral). This appears to have remained at a similar level (58%).

However, 138 of those positive recommendations were still awaiting a PHARMAC funding decision for inclusion in the Pharmaceutical Schedule as at 30 June 2019 (See Table 1).

The longest official waiting time for a medicine is almost 15 years for the Adrenalin auto injector for anaphylaxis which received a medium priority in August 2004 but remains unfunded. This application, it should be noted, is in fact a reapplication with the original application preceding electronic publication of PTAC minutes but estimated to be made around the year 2000. The second longest waiting period is 13.18 years for Telmisartan for hypertension. There are now 11 products that have been waiting for more than 10 years for a funding decision. The shortest waiting time for the most recently recommended application is 0.35 years.

[3] 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 2019

Product	Indication	New listing or wider access	Date of Positive Rec	Recommendation	Waiting Period (Years)
	Wait more than 10 years				
Adrenaline auto injector	Patients that have experienced anaphylactic reaction to venom or food	New	Aug -04	Medium	14.92
Telmisartan	Hypertension	New	May-06	Only if cost-neutral	13.18
Fulvestrant	Breast Cancer - Post-menopausal locally advanced or metastatic	New	Nov-06	Low	12.67
Desogestrel	Contraception	New	Aug-07	Low	11.90
Ketotifen fumarate	Ocular allergy	New	May-08	Only if cost-neutral	11.17
Oxybutynin patches	Urinary incontinence	New	Jul-08	Low	11.01
Bimatoprost and timolol Eye Drops	Glaucoma	New	Feb-09	Only if cost-neutral	10.42
Rosuvastatin	Hypercholesterolemia - 3rd line	New	Feb-09	Medium	10.42
Travoprost and timolol Eye Drops	Glaucoma	New	Feb-09	Only if cost-neutral	10.42
Buprenorphine transdermal patch	Pain - Moderate to severe	New	May-09	Low	10.17
Duloxetine hydrochloride	Depression - major depressive disorder that is not responsive to other antidepressants	New	Jul-09	Only if cost-neutral	10.01
	Wait 5 – 10 years				
Sitagliptin	Diabetes - Type 2	New	Aug-09	Low	9.92
Bevacizumab	Metastatic Colorectal Cancer	New	Feb-10	Low	9.42
Golimumab	Second-line TNF-inhibitor treatment of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis	New	May-10	Only if cost-neutral	9.17

Levofloxacin	Helicobacter infection	New	May-10	Other	9.17
Metronidazole vaginal gel	Vaginal infections	New	May-10	Only if cost-neutral	9.17
Quetiapine modified-release tablets	Schizophrenia and other psychoses	New	Jun-10	Low	9.09
Pipobroman	Polycythemia rubra vera and essential thrombocythemia	New	Aug-10	Medium	8.92
Miglustat	Gaucher disease - Type 1 Mild to moderate	New	Nov-10	Low	8.67
Nab-paclitaxel	Breast Cancer - advanced	New	Nov-10	Only if cost-neutral	8.67
Trastuzumab	Gastric cancer - HER2 positive metastatic	Wider	Feb-11	Low	8.42
Cevimeline	Dry Mouth	New	Aug-11	Low	7.92
Ustekinumab	Psoriasis	New	Aug-11	Only if cost-neutral	7.92
Saxagliptin	Diabetes - Type 2	New	Nov-11	Low	7.67
Dutasteride	Benign Prostatic Hyperplasia (BPH)	New	Feb-12	Only if cost-neutral	7.42
Asenapine	Schizophrenia and Bipolar 1 Disorder	New	Aug-12	Only if cost-neutral	6.92
Linagliptin	Diabetes - Type 2	New	Aug-12	Low	6.92
Liraglutide	Diabetes - Type 2	New	Aug-12	Low	6.92
Telaprevir	Hepatitis C - Genotype 1 chronic	New	Aug-12	High	6.92
Melatonin	Psychiatric comorbidities and secondary insomnia associated with dementia	New	Nov-12	Low	6.67
Carbetocin	Uterine atony and excessive bleeding following elective caesarean	New	Feb-13	Only if cost-neutral	6.41
Rilpivirine	HIV	New	Feb-13	Only if cost-neutral	6.41
Nab-paclitaxel	Breast cancer - Metastatic	New	Aug-13	Low	5.92

Rotavirus vaccine	Vaccine - Universal childhood	New	Aug-13	Medium	5.92
Vitamin D	Rickets - pregnant women	New	Aug-13	Only if cost-neutral	5.92
Vitamin D	Rickets - prophylaxis of rickets in infants at high risk	New	Aug-13	Only if cost-neutral	5.92
Vitamin D	Rickets - treatment of rickets in infants	New	Aug-13	Low	5.92
Adalimumab	Crohn's Disease - Weekly dose rescue therapy	Wider	Nov-13	Low	5.67
Dapaglifozin	Diabetes - Type 2	New	Nov-13	Low	5.67
Nab-Paclitaxel	Previously experienced hypersensitivity reactions to paclitaxel or docetaxel	New	Feb-14	Only if cost-neutral	5.41
TNF alpha inhibitors	Inflammatory bowel disease associated arthritis (IBD-A)	Wider	Feb-14	Low	5.41
Apixaban	Venous thromboembolism - Prophylaxis following major orthopaedic surgery	New	May-14	Only if cost-neutral	5.17
Apixaban	Stroke prevention in non-valvular atrial fibrillation	New	May-14	Low	5.17
Phosphodieraterase V inhibitors (PDE5 inhibitors)	Erectile dysfunction related to spinal cord injury	New	May-14	Medium	5.17
Intracavernosal alprostadil	Erectile dysfunction related to spinal cord injury	New	May-14	Medium	5.17
Lixisenatide	Diabetes - Type 2	New	May-14	Low	5.17
Cobicistat/ Elvitegravir/Emtricitabine/Tenofovir	HIV	New	May-14	Only if cost-neutral	5.17
	Wait 3-5 years				
Ingenol mebutate 0.015%	Facial and scalp solar keratosis	New	Aug-14	Only if cost-neutral	4.92

Nicotine inhaler and oral spray	Smoking cessation	New	Aug-14	Only if cost-neutral	4.92
Nicotine replacement therapy sample packs	Smoking cessation	New	Aug-14	Only if cost-neutral	4.92
Aminolevulinic acid	Visualisation of glioma	New	Nov-14	High	4.67
Rotigotine transdermal patch	Parkinson's disease	New	Nov-14	Only if cost-neutral	4.67
Trastuzumab Sub-cutaneous	Breast Cancer - HER 2 positive	New	Nov-14	Only if cost-neutral	4.67
TNF alpha inhibitors	Undifferentiated spondyloarthritis	Wider	Feb-15	High	4.41
Ustekinumab	Severe chronic plaque psoriasis	New	May-15	Only if cost-neutral	4.17
Macitentan	Pulmonary arterial hypertension	New	May-15	Low	4.17
Topical NSAID	Osteoarthritis	New	May-15	Low	4.17
Insulin Pumps	Diabetes Type I in Pregnancy	New	Aug-15	Low	3.92
Bevacizumab	Metastatic cervical cancer - First line treatment of recurrent or persistent	New	Aug-15	Low	3.92
Sodium chloride prefilled syringe	Sterile procedures	New	Aug-15	High	3.92
Lidocaine 4% with adrenlaline 0.1% and tetracaine 0.5%	Wound repair - children	New	Aug-15	Medium	3.92
Lidocaine 4% with adrenlaline 0.1% and tetracaine 0.5%	Wound repair - unrestricted	New	Aug-15	Low	3.92
Ibrutinib	Mantle cell lymphoma (MCL) - Relapsed or refractory that has progressed within 24 months of allograft or chemotherapy or chemo-immunotherapy	New	Nov-15	Low	3.67
Rituximab	Hairy cell leukaemia	Wider	Nov-15	Medium	3.67
Idarucizumab	Dabigatran reversal	New	Nov-15	Medium	3.67

Aripiprazole depot injection	Schizophrenia	New	Nov-15	Only if cost-neutral	3.67
Ipilibumab	Melanoma - Previously treated and unresectable stage IIIc or IV	New	Feb-16	Low	3.41
Pomalidomide	Multiple myeloma - Relapsed or refractory	New	Feb-16	Low	3.41
Velaglucerase alfa	Gaucher disease - first line	New	Feb-16	RFP	3.41
Varenicline	Smoking cessation - reduce re-treatment interval	Wider	Feb-16	Low	3.41
Varenicline	Smoking cessation - 2 week starter and follow-on packs	Wider	Feb-16	Only if cost-neutral	3.41
Nivolumab	Non-small cell lung cancer-Locally advanced or metastatic	Wider	May-16	Low	3.17
Selexipag	Pulmonary Arterial Hypertension	New	May-16	Low	3.17
Taurolidine and citrate solution	Section H - locking of central venous access devices in those at high risk of developing central line-associated bacteraemia	New	May-16	Only if cost-neutral	3.17
	Wait 1-3 years				
Enzalutamide	Prostate cancer - Treatment of metastatic castration-resistant	New	Aug-16	Only if cost-neutral	2.92
Nintedanib	Idiopathic pulmonary fibrosis	New	Aug-16	Only if cost-neutral	2.92
Ciclosporin eye ointment	Keratonconjunctivitis sicca and atopic and vernal keratoconjuncitiviitis	New	Aug-16	Low	2.92
Ivabradine	Computed tomography coronary angiography (CTCA)	New	Aug-16	High	2.92
Adalimumab	Severe hidradenitis suppurativa	wider	Nov-16	Low	2.66
Rituximab	Myasthenia gravis - severe, 3rd line	Wider	Aug-16	High	2.92
Rituximab	Refractory myasthenia gravis	Wider	Aug-16	Low	2.92
Ruxolitinib	Myelofibrosis - intermediate 1	New	Nov-16	Low	2.66

Pembrolizumab	Non-small cell lung cancer - Locally advanced, or metastatic, unresectable, PD-L1 positive	Wider	Nov-16	Low	2.66
Paliperidone palmitate 3-monthly depot injection (Invega Trinza)	Schizophrenia	New	Feb-17	Low	2.41
Levodopa/carbidopa intestinal gel and pump	Parkinson's disease	New	Feb-17	Low	2.41
Topical clindamycin vaginal cream	Bacterial vaginosis	New	Feb-17	Low	2.41
Frusemide 20mg Tab	Paediatric congenital heart disease	Wider	May-17	High	2.17
Lenalidomide	Multiple myeloma - Newly diagnosed pts who are ineligible for stem cell transplant	Wider	Aug-17	Only if cost-neutral	1.92
Adalimumab	Treatment of adults and children with severe or chronic non-infectious intermediate, posterior, and panuveitis who have had a poor response to corticosteroids	Wider	Aug-17	Low	1.92
Atezolizumab	Non-small cell lung cancer (NSCLC) - Second or third-line treatment of adult patients with locally advanced or metastatic after prior chemotherapy	New	Aug-17	Low	1.92
Sofosbuvir/Velpatasvir	Hepatitis C - Chronic	New	Aug-17	Medium	1.92
Peginterferon beta – 1a (rch)	Multiple sclerosis - Relapsing	New	Aug-17	Only if cost-neutral	1.92
Trastuzumab emtansine	Breast cancer - Second-line treatment of patients with HER-2 positive metastatic who have previously received trastuzumab and a taxane, separately or in combination	Wider	Nov-17	Low	1.66
Exenatide	Diabetes - Type 2	New	Nov-17	Low	1.66
Empagliflozin	Diabetes - Type 2 with established high cardiovascular risk	New	Nov-17	High	1.66

Rituximab	Neuromyelitis optica spectrum disorder (NMOSD)	Wider	Nov-17	High	1.66
Dexrazoxane	Cardioprotection in conjunction with anthracycline chemotherapy	New	Feb-18	Low	1.41
Levonorgestrel Intrauterine System	Contraception	New	Feb-18	High	1.41
Levonorgestrel Intrauterine System	Endometriosis	New	Feb-18	High	1.41
Levonorgestrel Intrauterine System	Endometrial hyperplasia without atypia	New	Feb-18	High	1.41
Ocrelizumab	Multiple sclerosis - Relapsing remitting	New	Feb-18	Only if cost-neutral	1.41
Secukinumab	Ankylosing spondylitis 2nd line	New	Feb-18	Medium	1.41
Secukinumab	Psoriatic arthritis 1st line	New	Feb-18	Medium	1.41
Secukinumab	Psoriatic arthritis 2nd line	New	Feb-18	Medium	1.41
Insulin Glargine LA	Type 1 and 2 Diabetes	New	Feb-18	Only if cost-neutral	1.41
Levofloxacin	Helicobacter pylori - 2nd line	Wider	May-18	High	1.16
Budesonide - Oral viscous	Eosinophilic oesophagitis	New	May-18	Medium	1.16
Pembrolizumab	Urothelial carcinoma (UC) - Locally advanced or metastatic for patients after failure of a platinum-containing chemotherapy regimen (2nd line)	Wider	May-18	Low	1.16
Atezolizumab	Locally advanced or metastatic urothelial carcinoma (UC) following progression on platinum-containing chemotherapy (2nd line)	New	May-18	Low	1.16
Liraglutide	Diabetes - Type 2 with established high cardiovascular risk	New	May-18	High	1.16
Adalimumab	Ulcerative Colitis - 2nd line biologic treatment in patients who were non-responders to infliximab	Wider	May-18	Low	1.16

Ustekinumab	Crohn's disease - severe, where a TNF inhibitor has failed	New	May-18	Medium	1.16
Mepolizumab	Eosinophilic Refractory Asthma - Severe	New	May-18	High	1.16
	Wait <1 year				
Sapropterin	Phenylketonuria in those at risk of cognitive impairment	New	Aug-18	Low	0.89
Obinutuzumab	Indolent non-Hodgkin's Lymphoma- relapsed or is refractory to a rituximab regimen, in combination with bendamustine followed by monotherapy	Wider	Aug-18	Low	0.89
Alectinib	Non- small cell lung cancer - Anaplastic lymphoma kinase-(ALK)positive, locally advanced or metastatic	New	Aug-18	Medium	0.89
Tenofovir alafenamide	Hepatitis B - chronic	New	Aug-18	Only if cost-neutral	0.89
Tenofovir alafenamide/emtricitabine	HIV	New	Aug-18	Only if cost-neutral	0.89
Denosumab	Osteoporosis for patients are contraindicated to all bisphosphonate therapy without a trial of a funded antiresorptive agent	Wider	Aug-18	Medium	0.89
Denosumab	Osteoporosis for patients are intolerant to all bisphosphonate therapy without a trial of a funded antiresorptive agent	Wider	Aug-18	Medium	0.89
Denosumab	Treatment of Osteoporosis for patients that have experienced at least one symptomatic new fracture after at least 12 months continuous therapy with zolendronic acid	Wider	Aug-18	Only if cost-neutral	0.89
Abiraterone acetate	Treatment in combination with prednisone and androgen deprivation therapy for high-risk metastatic hormone naïve prostate cancer (mHNPC)	New	Nov-18	Low	0.66

	and newly diagnosed high-risk metastatic hormone-sensitive prostate cancer (mHSPC)				
Calcipotriol with betamethasone foam spray	Psoriasis vulgaris	New	Nov-18	Only if cost-neutral	0.66
Olaparib	Ovarian cancer - Maintenance of platinum-sensitive BRC-mutated relapsed	New	Nov-18	Medium	0.66
Pembrolizumab	Non-small cell lung cancer, metastatic - First line treatment, in combination with chemotherapy for patients with no EGFR or ALK genomic tumour aberrations	Wider	Nov-18	Medium	0.66
Nivolumab	Clear cell renal cell cancer (RCC) - Second line treatment of relapsed following prior angiogenic therapy	Wider	Nov-18	Low	0.66
Denosumab	Hypercalcaemia of malignancy or malignant bone disease in patients with severe renal impairment (creatinine clearance <30mL/min) who are refractory to bisphosphonates	Wider	Nov-18	Low	0.66
Pembrolizumab	Non-small cell lung cancer - Monotherapy for previously untreated advanced PD-1 positive EGFR wildtype	Wider	Feb-19	Medium	0.35
Ivacaftor	Cystic Fibrosis with G551D mutation	New	Feb-19	Low	0.35
Lanreotide acetate	Gastroenteropancreatic neuroendocrine tumours (GEP-NETs) - Treatment of unresectable locally advanced or metastatic WHO Grade 1 or 2, non-functional	Wider	Feb-19	Low	0.35

Sofosbuvir/velpatasvir /voxilaprevir	Hepatitis C - Chronic	New	Feb-19	Medium	0.35
Dapagliflozin	Diabetes - Type 2 with established high cardiovascular risk	New	Feb-19	Medium	0.35
Meningococcal B Vaccine	Vaccine - Childhood prevention of meningitis	New	Feb-19	Medium	0.35
Meningococcal ACWYC Vaccine	Vaccine for prevention of meningitis for adolescents aged 13-19 years in close living situations	Wider	Feb-19	High	0.35
Meningococcal ACWYC Vaccine	Vaccine for prevention of meningitis for adolescents aged 13-19 years (universal) in close living situations	Wider	Feb-19	Low	0.35
Meningococcal ACWYC Vaccine	Vaccine for prevention of meningitis for children aged 1-4 years	Wider	Feb-19	Low	0.35
Alprostadil	Use in penile Doppler exams	New	Feb-19	Only if cost-neutral	0.35
Octreotide LAR	Treatment of unresectable locally advanced or metastatic WHO Grade 1 or 2, non-functional gastroenteropancreatic neuroendocrine tumours (GEP-NETs)	Wider	Feb-19	Low	0.35

The waiting list included new listing applications for all key therapy areas (Table 2). Cancer medicines accounted for one sixth of the new listings awaiting funding (17 new listings). However, the majority of the 105 new listings remaining on the waiting list were for key therapy areas beyond cancer. This includes medicines for cardiovascular conditions (12), diabetes (12), reproductive/urinary conditions (9), musculoskeletal conditions such as arthritis and osteoporosis (8), infectious disease (7), rare disorders including cystic fibrosis, Gaucher's disease and phenylketonuria (6), and mental health (6). Medicines for many other conditions including meningitis, neurological conditions such as multiple sclerosis, Crohn's and colitis, and allergy also remained on the waiting list.

Table 2. Recommended new listings that have yet to be funded on the Pharmaceutical Schedule as of 30 June 2019, by therapy area

Key Therapy Area	**Number of new listing recommendations**	**As a Percentage of all new listing recommendations**
Asthma	1	1.0%
Cancer	17	16.2%
Cardiovascular	12	11.4%
Diabetes	12	11.4%
Infectious disease (e.g. hepatitis, HIV)	7	6.7%
Rare disorders	6	5.7%
Mental health	6	5.7%
Musculoskeletal (e.g. arthritis, osteoporosis)	8	7.6%
Others:	36	34.3%
Allergy	2	1.9%
Dermatological	4	3.8%
Gastrointestinal (e.g. Crohn's and colitis)	4	3.8%
Neurological (e.g. multiple sclerosis, Parkinson's disease)	5	4.8%
Ophthalmic	3	2.9%
Reproductive/urinary	9	8.6%
Smoking cessation	2	1.9%
Surgical/ diagnostic	5	4.8%
Vaccines	2	1.9%

Percentages may not total 100 due to rounding.

The mean waiting time for all applications on the waiting list was 4.15 years. Although there were a significant range in waiting times (from 0.35 to 14.92 years) (Table 3). The majority (77%) of the outstanding recommendations were for new listings. There appears to be a relationship between the priority category of the PTAC recommendation and the mean waiting times although the numbers are small (i.e. mean waiting times for high priority medicines were lower than that for medium and low).

Table 3. Waiting times by priority category to 30 June 2019

PTAC priority category	Total Number of recommendations	New Listings	Widened access	Mean waiting time (years)	Range of waiting times (years)
High	16	10	6	2.46	0.35-6.92
Medium	24	19	5	3.15	0.35-14.92
Low	58	39	19	4.23	0.35-12.67
Only If Cost Neutral	38	35	3	5.25	0.35-13.18
None/Other	2	2	0	6.29	3.41-9.17
TOTAL	138	105	33	4.15	0.35-14.92

Table 4. Changes since last Waiting List update (June 2018)

PTAC priority category	Total Number of recommendations	New Listings	Widened access	Mean waiting time (years)	Range of waiting times (years)
High	No change from 16	Down 1 from 11	Up 1 from 5	Up from 2.03	Up from 0.72-6.75
Medium	Up 4 from 20	Up 1 from 18	Up 3 from 2	Down from 3.59	Up from 0.41-13.92
Low	Up 9 from 49	Up 1 from 38	Up 8 from 11	Up from 4.10	Up from 0.41-11.67
Only If Cost Neutral	Up 3 from 35	Up 2 from 33	Up 1 from 2	Up from 4.89	Up from 0.41-12.17
None/Other	Down 2 from 4	Down 1 from 3	Down 1 from 1	Up from 5.73	Up from 2.41-8.17
TOTAL	Up 13 from 124	Up 2 from 103	Up 12 from 21	Up from 4.03	Up from 0.41-13.92

Since the previous update in June 2018, the overall mean waiting time for all applications had increased (Table 4). The overall mean waiting time had increased to 4.15 years in the last 12 months, up from 4.06 years. The mean waiting times for each priority category increased since the previous update, except for the medium priority waiting time which decreased. This has likely been skewed by the nine new medium priority applications added to the waiting list within the last 12 months.

The total number of applications remaining on the waiting list has also increased, from 124 in June 2018 to 138 in June 2019 despite one fewer high priority recommendation and two fewer 'none/other' recommendations.

Over the time period since the first report in this series was published in 2015, the number of outstanding applications has continued to increase, from 109 in December 2015 to 138 as of 30 June 2019 (Table 5). This is an average net increase of eight unresolved applications per year (Figure 1).

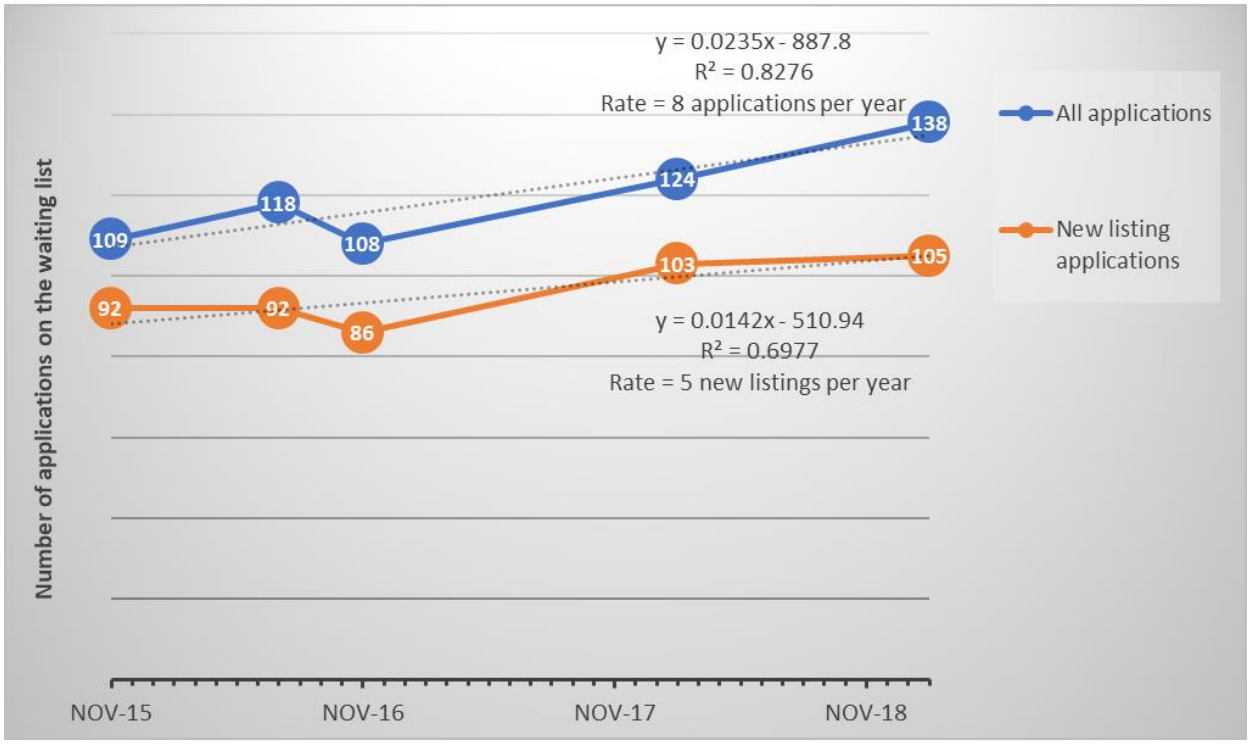
Over the most recent two-year period (Feb 2017 to June 2019), the net rate of increase has been even faster at 13 applications per year.

The rate of increase for new listings remaining on the waiting list had a similar upward trend. The number of outstanding new listing applications has increased from 92 in December 2015 to 105 as of June 2019. This equates to an average net increase of five new listings per year to the waiting list.

Table 5. Changes to the waiting list since first report in December 2015

Publication Date	**Most recent PTAC minutes included**	**Time since first Waiting List**	**Total number of recommendations**	**New listings**	**Widened access**	**Mean waiting time (years)**	**Range of waiting times (years)**
Dec-15	Nov-15	0 years	109	92	17	2.69	0.08-9.08
Aug-16	Jul-16	0.67 years	118	92	26	3.25	0.17-10.25
Feb-17	Nov-16	1 year	108	86	22	3.24	0.25-10.75
Jun-18	Feb-18	2.25 years	124	103	21	4.03	0.41-13.92
Sept-19	Feb-19	3.25 years	138	105	33	4.15	0.35-14.92

Figure 1. Rate of increase in the number of applications with positive PTAC recommendations on the waiting list between 2015-2019



Discussion

In the last 12 months, since June 2018, there has been a net increase in the number of applications on the waiting list awaiting final funding decisions by the PHARMAC Board. The number of applications that had received a positive PTAC recommendation but were still awaiting a final decision increased from 124 to 138 in the last 12 months.

A benefit of the approach taken in this report is that it has included only medicines that have received positive recommendations from PHARMAC's expert clinical committee and should, therefore, have a meaningful positive benefit if funded. PTAC can be expected to have declined any medicines that it considered to not add therapeutic value to the health system.

In the 12-month period, there have been eight applications that PTAC have reviewed and recommended for decline. Since 2006 there have been more than 100 applications (26% of all those reviewed by PTAC) that have been recommended for decline. Many of these negative recommendations also remain open and pending a final decision from the PHARMAC Board.

From a review of PHARMAC's once regular publication the Annual Review, we can see that up until 2003 PHARMAC did at least reconcile if not complete the process for applications each year. Until then PHARMAC published a tabulated list of "Applications Declined by the PHARMAC Board". These tables provided a reconciliation of applications received by PHARMAC, listed and declined and reported the percentage "success" rate. It should be noted that in 1994 and 1995, 20 applications were considered and declined by the PHARMAC Board.[4] Those numbers were down to between two and four per year by the year 2000[5]. In the years since then PHARMAC has rarely declined applications and since 2004 the number of applications with PTAC recommendations left unresolved by the PHARMAC Board has steadily increased.

PHARMAC has started to again work on declining certain types of applications. In April 2019 PHARMAC consulted on moving to decline just eight of the applications as part of its new 'clear, faster, simpler commitment'.[6]

PHARMAC has said it intends to consult on moving to decline more applications in the future.[6] This is limited to 'inactive' applications defined as having either been recommended for decline by PTAC more than two years ago, become irrelevant because another medicine for the same condition has been funded and it would not provide additional benefits, or that there is no longer a company willing to supply the medicine in New Zealand. This means PHARMAC will begin completing decision-making for this group of medicines. Given the applications on the medicines waiting list have been positively recommended by PTAC, they are less likely to fall under the 'inactive' definition. This means the waiting list medicines listed in table 1 of this report would not have their decision-making processes completed through this consultation process and would likely remain unresolved by the PHARMAC Board as is currently the case.

Over the three-year time period since the first edition of this waiting list was commissioned by Medicines New Zealand, there has been a net increase in the number of positively recommended applications still awaiting funding decisions, from 109 to 138 as of June 2019. This is an average net increase of eight applications per year and a net increase of five applications for new listings.

[4] "Applications considered and decided" table Page 17, Annual Review, 1996

[5] "Applications declined by the PHARMAC Board" table Page 26, Annual Review, 2003

[6] PHARMAC, Proposal to decline inactive applications, https://www.pharmac.govt.nz/news/consultation-2019-04-30-inactive-applications/ (accessed 23 August 2019)

Recent announcements by PHARMAC have proposed a number of waiting list medicines to be funded from December 2019[7,8]. Considering the rate of growth of the waiting list over the past three years, it will be interesting to see at the time of next analysis, what effect the announcements have on stemming the year-by-year increase of the waiting list. However, without a broader commitment to specific decision time frames, accountability and reporting measures for outcomes, and increased transparency of decision-making it is likely that the waiting list will continue to exist – if not grow.

There was a very short period in PHARMAC's history around 1999/2000 where they released details of the 10 or so products/application they would focus negotiations with pharmaceutical companies on in the next 12 months - making it clear to the public and the companies whether applications were being "actively considered". Nowadays, this detail is far less transparent with the only gauge of such activity being PHARMAC's activity with patient groups, clinicians and pharmaceutical companies. PHARMAC state that releasing a list of medicines they might fund would reduce their negotiating position. However, there is no apparent evidence that this occurred back when they previously reported their list openly.

It has been in the absence of open decision-making, measurement of outcomes and standard decision timeframes that a medicine waiting list has grown. This, in addition to a reported real-terms shortfall in the annual budget for medicines of $375 million[9], has resulted in more than 100 medicines still awaiting public funding despite a clinical expert committee recommending them.

[7] PHARMAC, Proposal for funding of oncology, multiple sclerosis and respiratory treatments, https://www.pharmac.govt.nz/news/consultation-2019-08-07-various/ (accessed 23 August 2019)

[8] PHARMAC, News. https://www.pharmac.govt.nz/news/consultations (accessed 2 September 2019)

[9] https://nzier.org.nz/publication/community-pharmaceuticals-expenditure-trends-1

Conclusion

The existence of a waiting list of more than 100 medicines recommended for funding by PHARMAC's clinical expert committee is evidence that PHARMAC's processes and funding allocation require a review. With the current low level of transparency and reporting requirements, it still remains unclear whether PHARMAC will progress with funding this full list of positively recommended medicines and if so, when that will occur.

A true medicines waiting list – that is a list of products that have been reviewed by PTAC, assessed by PHARMAC and are intended to be recommended to the PHARMAC Board for funding when funding is available - could be a useful tool in enabling PHARMAC to openly report on performance and provide input to government budget allocation decisions. However, in the absence of a transparent list of medicines that PHARMAC is actively considering for funding, there should at least be a mandate on PHARMAC to complete its decision-making processes (i.e. seek a PHARMAC Board decision) for all medicine applications, whether or not they have been positively or negatively recommended by PTAC, within a specified timeframe from PTAC's recommendation. For those applications recommended by PTAC for decline this process could be completed within a matter of months following publication of PTAC's minutes. For those positively recommended there would clearly be a requirement for PHARMAC to complete its assessment, negotiate on price and potentially bid for additional funding. A period of 18 months to 2 years from the date of the PTAC recommendation would seem a reasonable timeframe to complete this. Adherence to such a process would provide more timely and greater clarity around PHARMAC's assessment of the suitability and affordability of these medicines for the New Zealand health system than what currently occurs.