

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

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February 2017

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Executive Summary

Last year (August 2016), Medicines New Zealand commissioned a paper showing that in 31 July 2016 there were 92 medicines for 118 therapeutic indications awaiting a Pharmaceutical Schedule listing by the Pharmaceutical Management Agency (PHARMAC) following positive recommendation from the Pharmacology and Therapeutics Advisory Committee (PTAC)¹. Delays to listing of these medicines range between 0.17 years and 10.25 years, and there is one medicine that is known to remain unfunded after more than 12 years December 2015.

That analysis showed an increased from 81 medicines for 109 therapeutic indications in December 2015.

This update shows that, 7 months later (by the end of February 2017) there were 94 medicines for around the same number of therapeutic indications awaiting a Pharmaceutical Schedule listing by PHARMAC following positive recommendation from the PTAC.

While there was a significant budget increase of \$39 million over 2016/17, the financial limitations of a capped medicines budget mean that a range of medicines for patients must remain unfunded.

It is noted there are a number of older treatments, more recently assessed by PTAC, that make up some of the list of unfunded treatments. However, many of the unfunded agents are for the treatment of important diseases in New Zealand including cancer and diabetes.

In the case of the latter (diabetes), there is a strong possibility that PHARMAC do not regard some of these treatments as worthy investments.

In the interests of transparency, we argue that PHARMAC should, in the interests of public transparency, resolve to decline those applications that it does not consider worthy of investment.

Limitations of the Current Study

Given the stated timeframe of investigation ending on 28 February 2017, it is possible that medicines on the waiting list may have been funded after both PHARMAC Board and PTAC meetings after that date. There may also be some medicines for therapeutic indications that have been waiting before 2006.

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 around funding applications, and taking into account PHARMAC's nine decision criteria², 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 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 by PTAC, but are yet to be funded.

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 these were reliably published online) to November 2016. 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's recommendations were reviewed from publicly available minutes (those published on the PHARMAC Website as of February 2017,) 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 February 2017.

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 450 individual therapeutic agents/medicines or indications were considered in the quarterly meetings of PTAC from February 2006 through to February 2016. 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 for the last 7 months.

However, 119 (around 40%) of those positive recommendations were still awaiting a final PHARMAC funding decision on inclusion in the Pharmaceutical Schedule as at February 2017 (See Table 1).

The longest waiting time for a medicine was 10.75 years for telmisartan (although adrenalin auto injector for anaphylaxis which first received a medium priority in November 2005 but remains unfunded in fact has the longest known waiting time of more than 12 years). The second longest waiting period was 10.25 years for fluvestrant for post-menopausal locally advanced or metastatic breast cancer. The shortest waiting time for the most recently recommended products is 0.25 years.

Table 1. The positive recommendations of PTAC since 2006 that have yet to be listed on the New Zealand Pharmaceutical Schedule as of 28 February 2016

Product	Indication	New listing or wider access	Date of Positive Rec	Date of Positive Recommendation	Waiting Period (Years)
	GREATER THAN 5 YEARS WAIT				
Telmisartan	Hypertension	New	May-06	Only if cost-neutral	10.75
Fluvestrant	Locally advanced metastatic breast cancer	New	Nov-06	Low	10.25
Desogestrel	Contraception	New	Aug-07	Low	9.50
Ketotifen fumarate	Occular allergy	New	May-08	Only if cost-neutral	8.75
Oxybutinin patches	Urinary incontinence	New	Jul-08	Low	8.58
Pemetrexed	First line treatment of NCSLC	New	Jul-08	Only if cost-neutral	8.58
Buprenorphine transdermal patch	Moderate to severe pain	New	May-09	Low	7.75
Duloxetine hydrochloride	Treatment of major depressive disorder that is not responsive to other antidepressants	New	Jul-09	Only if cost-neutral	7.58
Sitaglipten	Type 2 diabetes	New	Aug-09	Low	7.50
Bimatoprost and timolol Eye Drops	Glaucoma	New	Feb-09	Only if cost-neutral	7.00
Rosuvastatin	3rd line hypercholesterolemia	New	Feb-09	Medium	7.00
Travoprost and timolol Eye Drops	Glaucoma	New	Feb-09	Only if cost-neutral	7.00
Golimumab	Second-line TNF-inhibitor treatment of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis	New	May-10	Low	6.75
Levofloxacin	Treatment for helicobacter infection	New	May-10	Other	6.75
Metronidazole vaginal gel	Vaginal infections	New	May-10	Only if cost-neutral	6.75
Sildenafil	Fontan patients	Widen access	May-10	High	6.75
Sildenafil	Neonatal/infantile PAH secondary to CLD	Widen access	May-10	Medium	6.75
Quetiapine modified-release tablets	Schizophrenia and other psychoses	New	Jun-10	Low	6.67
Pipobroman	Polycythemia rubra vera and essential thrombocythemia	New	Aug-10	Medium	6.50
Miglustat	Mild to moderate Type 1 Gaucher disease	New	Nov-10	Low	6.25
Nab-paclitaxel	Advanced breast cancer	New	Nov-10	Only if cost-neutral	6.25
Cevimeline	Dry Mouth	New	Aug-11	Low	5.50
Pregabalin	Neuropathic pain	New	Aug-11	Low	5.50

Ustekinumab	Psoriasis	New	Aug-11	Only if cost neutral	5.50
Rituximab	Relapsed/Refractory follicular non-Hodgkin's lymphoma	Widen access	Nov-11	Low	5.25
Saxagliptin	Type II diabetes	New	Nov-11	Low	5.25
	3-5 YEARS WAIT				
Trastuzumab	HER2 positive metastatic gastric cancer	Widen access	Feb-11	Low	5.00
Asenapine	Schizophrenia and Bipolar 1 Disorder	New	Aug-12	Only if cost neutral	4.50
Linagliptin	Type 2 diabetes.	New	Aug-12	Low	4.50
Liraglutide	Type 2 diabetes.	New	Aug-12	Low	4.50
Telaprevir	Genotype 1 chronic hepatitis C	New	Aug-12	High	4.50
TNF Inhibitors	Bechet's Disease	Widen access	Aug-12	Medium	4.50
Melatonin	Psychiatric comorbidities and secondary insomnia associated with dementia	New	Nov-12	Low	4.25
Sildenafil	Cardiac Surgery	Widen access	Nov-12	Hosp only	4.25
Dutasteride	BPH	New	Feb-12	Only if cost-neutral	4.00
Nab-paclitaxel	Metastatic breast cancer	New	Aug-13	Low	3.50
Rotavirus vaccine	Universal childhood vaccine	New	Aug-13	Medium	3.50
Vitamin D	Admin to pregnant women for prophylaxis of rickets in infants at high risk	New	Aug-13	Only if cost neutral	3.50
Vitamin D	Admin to infants at high risk of rickets	New	Aug-13	Only if cost neutral	3.50
Vitamin D	Treatment of infants with rickets	New	Aug-13	Low	3.50
Adalimumab	Weekly dose rescue therapy for Crohn's Disease	Widen Access	Nov-13	Low	3.25
Ciprofloxacin eye drops	Chronic suppurative otitis media	Widen access	Nov-13	High	3.25
Dapagliflozin	Type 2 diabetes	New	Nov-13	Low	3.25
	1-3 YEARS WAIT				
Carbetocin	Uterine atony and excessive bleeding following elective caesarean	New	Feb-13	Only if cost neutral	3.00
Acitretin	Relax SA	Widen Access	May-14	None	2.75
Adrenaline auto injector	Patients that have experienced anaphylactic reaction to venom or food	New	May-14	Medium	2.75

Apixaban	Prophylaxis of venous thromboembolism following major orthopaedic surgery	New	May-14	Only if cost neutral	2.75
Apixaban	Stroke prevention in non-valvular atrial fibrillation	New	May-14	Low	2.75
Gabapentin	Remove SA	Widen Access	May-14	None	2.75
Intracavernosal alprostadil	Erectile dysfunction related to spinal cord injury	New	May-14	Medium	2.75
Isotretinoin	Relax SA	Widen Access	May-14	None	2.75
Lixisenatide	Adults with Type II diabetes	New	May-14	Low	2.75
Midodrine	Relax SA	Widen Access	May-14	None	2.75
Minoxidil	Remove SA	Widen Access	May-14	None	2.75
Phosphodiesterase V inhibitors (PDE5 inhibitors)	Erectile dysfunction related to spinal cord injury	New	May-14	Medium	2.75
Rivaroxaban	Venous thromboembolism	New	May-14	Only if cost neutral	2.75
Rivaroxaban	Secondary prophylaxis of venous thromboembolism	New	May-14	Only if cost neutral	2.75
Rivaroxaban	Stroke prevention in non-valvular atrial fibrillation	New	May-14	Only if cost neutral	2.75
Stribild	HIV-1	New	May-14	Only if cost neutral	2.75
COX-2 inhibitors	Arthritis	New	Aug-14	Only if cost neutral	2.50
Ingenol mebutate 0.015%	Facial and scalp solar keratosis	New	Aug-14	Only if cost neutral	2.50
Melatonin	Secondary insomnia in children and adolescents with neurodevelopmental disorders	New	Aug-14	Low	2.50
Nicotine inhaler and oral spray	Smoking cessation	New	Aug-14	Only if cost neutral	2.50
Nicotine replacement therapy sample packs		New	Aug-14	Only if cost neutral	2.50
Sofosbuvir	Hep C - all	New	Aug-14	Low	2.50
Aminolevulinic acid	Visualisation of glioma	New	Nov-14	High	2.25
Epoprostenol	PAH	New	Nov-14	High	2.25
Rotigotine transdermal patch	Parkinsons' disease	New	Nov-14	Only if cost neutral	2.25
Sub-cutaneous trastuzumab	HER 2positive breast cancer	New	Nov-14	Only if cost neutral	2.25
Melatonin	Secondary insomnia in children and adolescents with neurodevelopmental or psychiatric comorbidities	New	Feb-14	Low	2.00
Nab-Paclitaxel	Previously experienced hypersensitivity	New	Feb-14	Only if cost neutral	2.00

	reactions to paclitaxel or docetaxel				
TNF alpha inhibitors	Inflammatory bowel disease associated arthritis (IBD-A)	Widen Access	Feb-14	Low	2.00
Denosumab	Osteoporosis	New	May-15	Medium	1.75
Indacaterol maleate/glycopyrronium	Chronic obstructive pulmonary disease	New	May-15	Low	1.75
Macitentan	Pulmonary arterial hypertension	New	May-15	Low	1.75
Plerixafor	Stem cell mobilisation - HML	New	May-15	High	1.75
Sofosbuvir with ledipasvir	Hepatitis C - all other sub-populations	New	May-15	Low	1.75
Topical NSAID	Osteoarthritis	New	May-15	Low	1.75
Ustekinumab	Severe chronic plaque psoriasis	New	May-15	Only if cost neutral	1.75
Bendamustine	Chronic Lymphocytic Leukaemia Non Hodgekin's Lymphoma - unable to tolerate fludarabine, cyclophosphamide and rituximab (FCR)	New	Aug-15	Medium	1.50
Bendamustine	Chronic Lymphocytic Leukaemia Non Hodgekin's Lymphoma - first line	New	Aug-15	Low	1.50
Bevacizumab	First line treatment of recurrent, persistent or metastatic cervical cancer	New	Aug-15	Low	1.50
Insulin Pumps	Type I diabetes in Pregnancy	New	Aug-15	Low	1.50
Lidocaine 4% with adrenaline 0.1% and tetracaine 0.5%	Wound repair - children	New	Aug-15	Medium	1.50
Lidocaine 4% with adrenaline 0.1% and tetracaine 0.5%	Wound repair - unrestricted	New	Aug-15	Low	1.50
Pemetrexed	Advanced non-squamous non-small cell lung carcinoma - first line	New	Aug-15	Only if cost neutral	1.50
Pemetrexed	Advanced non-squamous non-small cell lung carcinoma - maintenance	New	Aug-15	Low	1.50
Pemetrexed	Advanced non-squamous non-small cell	New	Aug-15	Only if cost neutral	1.50

	lung carcinoma - second line				
Sodium chloride prefilled syringe	Sterile procedures	New	Aug-15	High	1.50
Subcutaneous tocilizumab	Adult rheumatoid arthritis - last line	New	Aug-15	Low	1.50
Zoster vaccine	65 years and older	New	Aug-15	Medium	1.50
Aripiprazole depot injection	Schizophrenia	New	Nov-15	Only if cost neutral	1.25
Eplerenone	Heart failure patients intolerant to optimal dosing of spironolactone	New	Nov-15	Low	1.25
Ibrutinib	Relapsed or refractory mantle cell lymphoma (MCL) that has progressed within 24 months of allograft or chemotherapy or chemo-immunotherapy	New	Nov-15	Low	1.25
Omalizumab	Chronic spontaneous urticaria	Widen Access	Nov-15	Low	1.25
Tocilizumab	Rheumatoid arthritis	Widen Access	Nov-15	Only if cost neutral	1.25
	LESS THAN 1 YEARS WAIT				
TNF alpha inhibitors	Undifferentiated spondyloarthritis	Widen Access	Feb-15	High	1.00
Methoxyflurane	PSO	Widen Access	Feb-16	Low	1.00
Pomalidomide	Relapsed or refractory multiple myeloma	New	Feb-16	Low	1.00
Varenicline	Smoking cessation - reduce re-treatment interval	Widen Access	Feb-16	Low	1.00
Varenicline	Smoking cessation – 2-week starter and follow-on packs	Widen Access	Feb-16	Only if cost neutral	1.00
Zoster vaccine	People aged 65 with a 2-year catch-up (65-80 years)	New	Feb-16	Low	1.00
Nivolumab	Locally advanced or metastatic non-small cell lung cancer	Widen Access	May-16	Low	0.75
PAH treatments	Dual Therapy for patients with PAH in NYHA/WHO functional class III and IV following	Widen Access	May-16	High	0.75

	3-6 month monotherapy with sildenafil				
PAH treatments	Dual Therapy for patients with PAH in NYHA/WHO functional classes II	Widen Access	May-16	Low	0.75
Selexipag	Pulmonary Arterial Hypertension	New	May-16	Low	0.75
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	0.75
Denosumab	Osteoporosis	New	May-16	Medium	0.75
Sapropterin	Phenylketouria and hyperphenylalaninaemia for women pregnant or planning a pregnancy	New	May-16	High	0.75
Somatropin	Prader-Willi Syndrome under 2 years	Wider	Aug-16	Medium	0.50
Enzalutamide	Treatment of metastatic castration-resistant prostate cancer	New	Aug-16	Only if cost neutral	0.50
Recombinant Factor VIII and IX Fc Fusion Proteins	Haemophilia A and B	New	Aug-16	Only if cost neutral	0.50
Nintedanib	Idiopathic pulmonary fibrosis	New	Aug-16	Only if cost neutral	0.50
Ciclosporin eye ointment	Keratonconjunctivitis sicca and atopic and atopic and vernal keratoconjunctivitis	New	Aug-16	Low	0.50
Adalimumab	Severe hradenitis suppurativa	Wider	Nov-16	Low	0.25
Pembrolizumab	Locally advanced or metastatic, unresectable, PD-L1 positive, non-small cell lung cancer	Wider	Nov-16	Low	0.25
Somatropin	Prader-Willi syndrome - patients under 2 years and adults	Wider	Nov-16	Medium	0.25
Ruxolitinib	Myelofibrosis - high risk and intermediate-2 risk	New	Nov-16	Medium	0.25
Ruxolitinib	Myelofibrosis - intermediate-1 risk	New	Nov-16	Low	0.25

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 although the numbers are small (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 to February 2017

PTAC priority category	Number of recommendations	New Listings	Widened access	Mean waiting time (years)	Range of waiting times
PTAC priority category	Number of medicines	New Listings	Widened access	Mean waiting time (years)	Range of waiting times
High	10	6	4	2.72	0.72-6.75
Medium	16	12	4	2.85	0.25-7.00
Low	50	39	11	3.13	0.25-10.25
Only If Cost Neutral	36	34	2	3.34	0.5-10.75
None/Other	7	1	6	4.17	2.75-6.75

The mean waiting times for all medicines on this list is 3.19 years, although there is a significant range in waiting times (0.25 to 10.75 years). Most interestingly, the majority (77%) 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

Despite the Governments' \$39 million injection into PHARMAC's annual budget this financial year, there has been no reduction in the overall number of pharmaceuticals waiting to be listed on the Pharmaceutical Schedule that have been given a positive recommendation from PTAC.

However, PHARMAC has listed 7 products out of 55 positive PTAC recommendations (13%) made by PTAC since February 2015 compared with 3 out of 75 (4%) of those recommendations made prior to that date. It must therefore be acknowledged that much of the movement in the list of unfunded medicines has come about from listings of products recommended by PTAC within the last two years.

Surely this underlines our August 2016 suggestion that it is time PHARMAC reduced the list of potential investments by completing the decision-making process for those pharmaceuticals on the 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.³ Those numbers were down to between two and four per year by the year 2000⁴. Annual Reviews since 2004 have omitted to publish this information.

The diagram of the Decision Making Process available on PHARMAC’s website (<http://pharmac.govt.nz/2009/09/01/DecisionMakingGraph.pdf>), which has remained largely unchanged since PHARMAC’s inception in 1993, indicates that *all* applications to list pharmaceuticals in the Pharmaceutical Schedule, once reviewed by PTAC, then undergo a process of prioritisation, negotiation with the supplier, consultation and a Board Decision.

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 94 medicines for which NO consultation has been undertaken and NO PHARMAC Board decision has been made. Indeed, since 2003, PHARMAC has consulted on just a few proposals to decline to list pharmaceuticals on the Pharmaceutical Schedule— e.g. acetylcholinesterase inhibitors (2003), trastuzumab (2008), budesonide capsules, memantine (2010) and eculizumab (2013). The rest of the applications received, reviewed and given a positive recommendation by PTAC appear with no current action.

We consider that, in the absence of a publically available list of medicines that PHARMAC considers to be a priority for funding, 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) would provide much greater transparency around PHARMAC’s assessment of the suitability and affordability of these pharmaceuticals for New Zealand than the current situation.

³ “Applications considered and decided” table Page 17, Annual Review, 1996

⁴ Applications declined by the PHARMAC Board” table Page 26, Annual Review, 2003