Consultation

PHARMAC
TE PĀTAKA WHAIORANGA

Modifying funded access to mifepristone and misoprostol

EMBARGOED until 9am 20 April 2020

What we're proposing

We are seeking feedback on a proposal to change funded access arrangements to two medicines currently listed on the Pharmaceutical Schedule that are used for medical abortion – mifepristone and misoprostol, noting that misoprostol is unregistered for this indication.

Facilitating funded access in the community to these medicines would support the changes enacted by Parliament in the Abortion Legislation Act 2020.

This consultation process seeks feedback relating to PHARMAC's proposal to make mifepristone available in a community setting and make an amendment to the listing of misoprostol. Submitters should note that the consultation does not cover the changes to the Abortion legislation, or where and how procedures can take place; these matters fall outside PHARMAC's scope of responsibility

Consultation closes at **5 pm on Friday, 29 May** and feedback can be emailed to consult@pharmac govt nz

What would the effect be?

Modifying funded access to mifepristone and misoprostol means that these pharmaceuticals would be available for use by qualified health practitioners who may provide medical abortion services in community or primary care settings.

Health practitioners authorised to provide abortion services could order mifepristone and misoprostol on a Practitioner's Supply Order (PSO), meaning that they would have these pharmaceuticals on hand. This means that patients would not have to take a prescription to a pharmacy to get the medicines dispensed.

Who we think will be interested

- Heath Practitioners authorised to provide medical abortion services (includes doctors, midwives, nurse practitioners)
- Pharmaceutical suppliers
- District Health Boards
- Pharmacists

About this proposal

On 24 March 2020 the Abortion Legislation Act 2020 came into force. This amends the law to better align the regulation of abortion services with other health services.

The previous legislative framework that applied to abortion in New Zealand was set out in the Crimes Act 1961 and the Contraception, Sterilisation, and Abortion Act 1977.

The previous legislative framework allowed an abortion to be performed under certain conditions by specified types of medical practitioners in institutions licensed for this purpose. The Abortion Legislation Act 2020 allows qualified health practitioners to provide abortion services in places other than hospitals and licensed clinics, such as in community and primary care settings

PHARMAC already funds the two medicines that are currently used for medical abortion misoprostol and mifepristone through the Pharmaceutical Schedule as follows:

- Misoprostol is listed in Section B (community) and Section H (hospital) of the Pharmaceutical Schedule, and it has no funding restrictions. Misoprostol is a registered prescription medicine, and its registered indications are set out in the Medsafe datasheet.
- Mifepristone is only listed in Section H (hospital) of the Pharmaceutical Schedule and therefore only currently funded when used in DHB hospitals. Mifepristone is a registered prescription medicine, and its registered indications are set out in the Medsafe datasheet.

Why we're proposing this

The Abortion Legislation Act 2020 permits abortion services to be provided in a range of community settings. However, the relevant pharmaceuticals are not currently funded in such a way as to enable this to occur on a publicly funded basis.

In order to support these legislative changes, and to ensure consistent access to these pharmaceuticals across the country, an amendment to the Pharmaceutical Schedule is proposed.

Details about our proposal

The listing of misoprostol in Section B of the Pharmaceutical Schedule would be amended by enabling it to be supplied on a Practitioners' Supply Order (PSO), to a limit of one pack (120 tablets) at a time

Mifepristone would be listed in Section B of the Pharmaceutical Schedule from 1 July 2020 as follows (price and subsidy are ex manufacturer, and exclusive of GST):

Chemical	Formulation	Brand	Pack size	Price and subsidy
Mifepristone	Tab 200 mg	Mifegyne	3	$180

Mifepristone would be subject to the following subsidy restrictions:

a) Up to 15 available on a PSO
b) Only on a PSO

PSOs are a mechanism for provision of funded community pharmaceuticals to ensure they are available for emergency use, teaching and demonstration purposes and for provision to certain patient groups where an individual prescription is not practicable PSOs are most commonly used for this purpose in general practice.

Provision of misoprostol and mifepristone on PSO would mean that patients would not need to present a prescription to a pharmacy and would instead be given these treatments directly by the abortion services provider.

To provide feedback

Send us an email: consult@pharmac govt nz by **5 pm on Friday, 29 May 2020**

All feedback received before the closing date will be considered by PHARMAC prior to making a decision on this proposal

This consultation process is limited to feedback relating to PHARMAC's proposal to make mifepristone available in a community setting and amendment to the listing of misoprostol. Submitters should note that the consultation does not cover the changes to the Abortion legislation, or where and how procedures can take place; these fall outside PHARMAC's scope of responsibility.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld PHARMAC will give due consideration to any such request.

From: Rachel Read
Sent: Monday, 30 March 2020 5:15 pm
To: [redacted]
Cc: Lizzy Cohen [redacted]
Subject: No Surprises - Mifepristone

Hi [redacted]

This is a 'no surprises' update for Minister Clarke and Minister Genter

Abortion legislation implementation issues – mifepristone

The new Abortion Legislation Act 2020, recently enacted, will change the models of care for how and where abortions can be performed.

PHARMAC staff have been engaging with the Ministry of Health on implementation issues relating to the legislation, which will now allow for early medical abortion to be performed in a primary care setting.

One of the required medicines, mifepristone, is currently only funded in the hospital setting and a change to the Pharmaceutical Schedule would be required for mifepristone to be funded in community settings.

We are currently working through this issue and expect to publicly consult on a proposed schedule change in the next few weeks. PHARMAC is legally required to consult on matters that relate to the management of pharmaceutical expenditure.

We will provide a further update at the time of consultation.

If you require further information please let me know

regards Rachel

Rachel Read| Policy Manager, Engagement and Implementation
PHARMAC | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington [redacted] | P: +64 4 460 4990 | [redacted]
www.pharmac.govt.nz [redacted]

PHARMAC
TE PĀTAKA WHAIORANGA

Level 9, 40 Mercer Street, Wellington
PO Box 10254, Wellington 6143, New Zealand
P: +64 4 460 4990 | F: +64 4 460 4995
www.pharmac.govt.nz

11 May 2020

[redacted]
Cancer Control Agency
Via email: [redacted]

Dear [redacted]

Thank you for your email (23 April 2020) including the proposal coordinated by the Southern Cancer Network for a range of alternative cancer treatments for potential public funding.

We appreciate the effort that you and the collaborators on this proposal have undertaken to consider the unique challenges for cancer care during the COVID-19 pandemic, and to come up with suggestions aimed at reducing hospitalisations, reducing chair time for outpatient chemotherapy, and providing alternatives in the event that hospital chemotherapy workforce capacity is compromised by the COVID-19 pandemic.

PHARMAC acknowledges that the COVID-19 pandemic has had a considerable impact on the health sector, including cancer care.

PHARMAC's key priorities over the COVID-19 pandemic response have been to support the health sector respond to the pandemic, and to ensure ongoing stock and supply of pharmaceuticals.

Supporting the health sector

The main way we have tried to support the health sector to respond is by easing restrictions on already funded medicines, to reduce hospital visits and risk of highly vulnerable patients catching COVID-19. Many of these changes have been made to cancer medicines (a full list can be found here).

The aim of these changes is to help ensure patients can still receive the medicine they need while:

- reducing clinic contact time (such as enabling telehealth approaches);
- supporting isolation principles as much as possible; and
- freeing up resources across clinical staffing, infusion centres, laboratories and pharmacy.

These are temporary measures to help lessen the impact on patients and health services when accessing existing funded treatments. We intend to change the criteria back once health services have stabilised to a point where it becomes practical, and we're pleased to see that this may occur sooner than was originally thought.

We have also encouraged health care practitioners and suppliers to make suggestions to us for other funding changes that might support the aims described above. These suggestions were not sought with the intention to bypass our existing processes, rather, it has allowed us to quickly identify possible rapid ways in which we could support the wider health sector to balance demand on services and ensure continuity of care for new and existing patients.

A full list of the suggestions that we have received to date can be found here. Upon receiving any suggestions, PHARMAC has carefully considered each and decided what can be rapidly addressed and what cannot.

Southern Cancer Network's proposal

The Southern Cancer Network has proposed that PHARMAC should fund the following treatments:

1. Subcutaneous trastuzumab instead of IV trastuzumab
2. Subcutaneous rituximab instead of IV rituximab
3. Oral paclitaxel instead of IV paclitaxel
4. Use of lenalidomide +/- ixazomib based treatment for myeloma first line instead of SC bortezomib
5. Improve access to ibrutinib for CLL patients e.g. instead of FCR / obinutuzumab + chlorambucil / rituximab + bendamustine and in Mantle Cell Lymphoma
6. Improved access to eltrombopag treatment of ITP (second line before rituximab)
7. Access to leuprorelin (Lucrin) instead of goserelin (Zoladex) for prostate cancer
8. Enzalutamide for metastatic castrate-resistant prostate cancer instead of abiraterone

Prior to receiving your letter, PHARMAC had already been asked to consider funding for five of these treatments. Our published responses can be found here.

PHARMAC staff have reviewed each of these requests carefully in the context of our short term COVID-19 response activities, giving consideration to a number of factors including:

- the relative need of affected patients in the context of the current pandemic;
- the additional cost of the proposals to the Combined Pharmaceutical Budget;
- the commercial complexity of progressing a Schedule listing, particularly in a temporary format, including securing contractual arrangements for pricing and supply and the impact on existing commercial arrangements for other products.
- the implementation support needed for clinicians and patients for the introduction and withdrawal of funded access to these treatments;

- whether the request is already being considered through PHARMAC's usual processes and, if so, whether there is a sufficient change in circumstances due to the current pandemic to warrant separate assessment.

In a number of cases we have sought additional information and advice from our clinical advice network.

After careful consideration, we have decided that we will not be progressing the proposals as a part of our short term COVID-19 response activities. We will of course be monitoring the impacts of COVID-19 on the health sector carefully, and we will continue to review our position on all requested rapid changes that we are not progressing if we consider it necessary or appropriate due to impacts of COVID-19.

Consideration through our usual processes

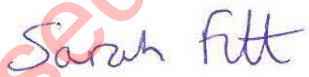
We note that PHARMAC has open funding applications for several of these proposals which are currently being considered via our usual decision-making processes. Information on our assessment to date can be found through the links below.

- Subcutaneous trastuzumab for breast cancer
- Subcutaneous rituximab for Non-Hodgkin lymphoma
- Ibrutinib for relapsed/refractory mantle cell lymphoma
- Ibrutinib for first-line for CLL in unfit patients and Waldenstrom's macroglobulinaemia
- Ibrutinib for relapsed/refractory chronic lymphocytic leukaemia
- Eltrombopag for idiopathic thrombocytopenic purpura (ITP)
- Enzalutamide for metastatic castrate-resistant prostate cancer

Some of the other treatments proposed by the Southern Cancer Network are not currently registered with Medsafe and we are not aware of them being supplied in New Zealand. We would welcome funding applications from the supplier when the products are submitted to Medsafe for registration.

Thank you again for taking the time to engage with us on these proposals.

Yours sincerely



Sarah Fitt
Chief Executive

PHARMAC
TE PĀTAKA WHAIORANGA

REPORT FOR QUARTER THREE 2019/20
INCORPORATING MONTHLY REPORT FOR APRIL 2020

COMMERCIAL IN CONFIDENCE

Date **6 May 2020**

Attention **Hon Dr David Clark**
Minister of Health

Copies to:

PHARMAC Board
Lead DHB CE, Pharmaceuticals
Director-General of Health – Ministry of Health
Manager Governance and Crown Entities Ministry of Health
Principal Advisor, Crown Entity Monitoring and Appointments Ministry of Health

Contact(s)

Sarah Fitt, Chief Executive
Alison Hill, Director Engagement and Implementation S9(2)(a)

Key Items

COVID-19 Response and medicines management

Medicines and Device supply management

PHARMAC continues to follow up with all contracted medicine and device suppliers on a regular basis. Most suppliers have indicated they have contingency plans that will maintain continuity of supply At any one time approximately 50 suppliers potentially have an issue with supply in the coming weeks or months; however, to date all low stock issues have been managed and alternative supply options have been secured where required.

Ongoing supply issues

- Increased demand for **medical grade hand sanitiser** continues and the main supplier (Schulke) is ensuring continuity of supply to DHB hospitals as a priority while working on a contingency for additional bulk supplies PHARMAC has contracted with a second supplier, 3M, to supply the DHBs
- **Paracetamol** supply is still impacted by lockdown in India, despite export restrictions having been lifted NZ has approximately two months' supply available and dispensing restrictions remain in place PHARMAC continues to work with the supplier on sourcing an alternative brand

Changes to Schedule criteria and rules

On 27 March 2020 PHARMAC put in place Pharmaceutical Schedule rule changes that restricted the dispensing of funded community medicines to just one month's supply at a time (or three months for oral contraceptives) This was in response to stockpiling of medicines

Additionally, all Special Authorities, Named Patient Pharmaceutical Assessment (NPPA) and other exceptional circumstances approvals that were due to expire on 31 March or 30 April 2020 have been extended for three months Many prescribers found it difficult to access the Ministry of Health online system) during lockdown because they are working remotely. This blanket change means prescribers do not need to apply online to extend Special Authorities or NPPA which were due to expire at the end of March or April.

PHARMAC intends to change most criteria back to the original requirements, including removal of the requirement for monthly dispensing, once health services, and medicines supplies, have stabilised to a point where it becomes practical to reinstate them.

COVID 19 specific treatments

PHARMAC is working to ensure there is sufficient stock of standard antibiotics and other anti infective treatments. PHARMAC is engaging with its clinical advisors to get advice on specific antibiotics or antivirals that might be required for treatment of patients with COVID 19, and has asked suppliers to increase stock holdings of antibiotics that have been identified as potential treatments in the management of COVID 19.

There are numerous clinical trials for potential COVID 19 treatments underway and, although some have reported early data, no treatments are yet showing significant promise.

Intensive care medicines

PHARMAC has been working to secure an additional six months' supply, at normal demand volume, of all medicines that may be required for patients in intensive care units.

PHARMAC is working to secure further stocks of propofol, an anaesthetic. PHARMAC has sent out communications to clinical networks encouraging careful management of existing stocks by District Health Boards (DHBs).

Logistics channels

PHARMAC is advising suppliers to continue to use existing commercial sea shipping and airfreight as much as possible and is providing support to them where this is challenging. We have provided information to suppliers on how to access information on air freight services through Mainfreight and NZTE. We are also escalating issues through all-of-government channels to prioritise freight that has an urgent medical need

Funding requests

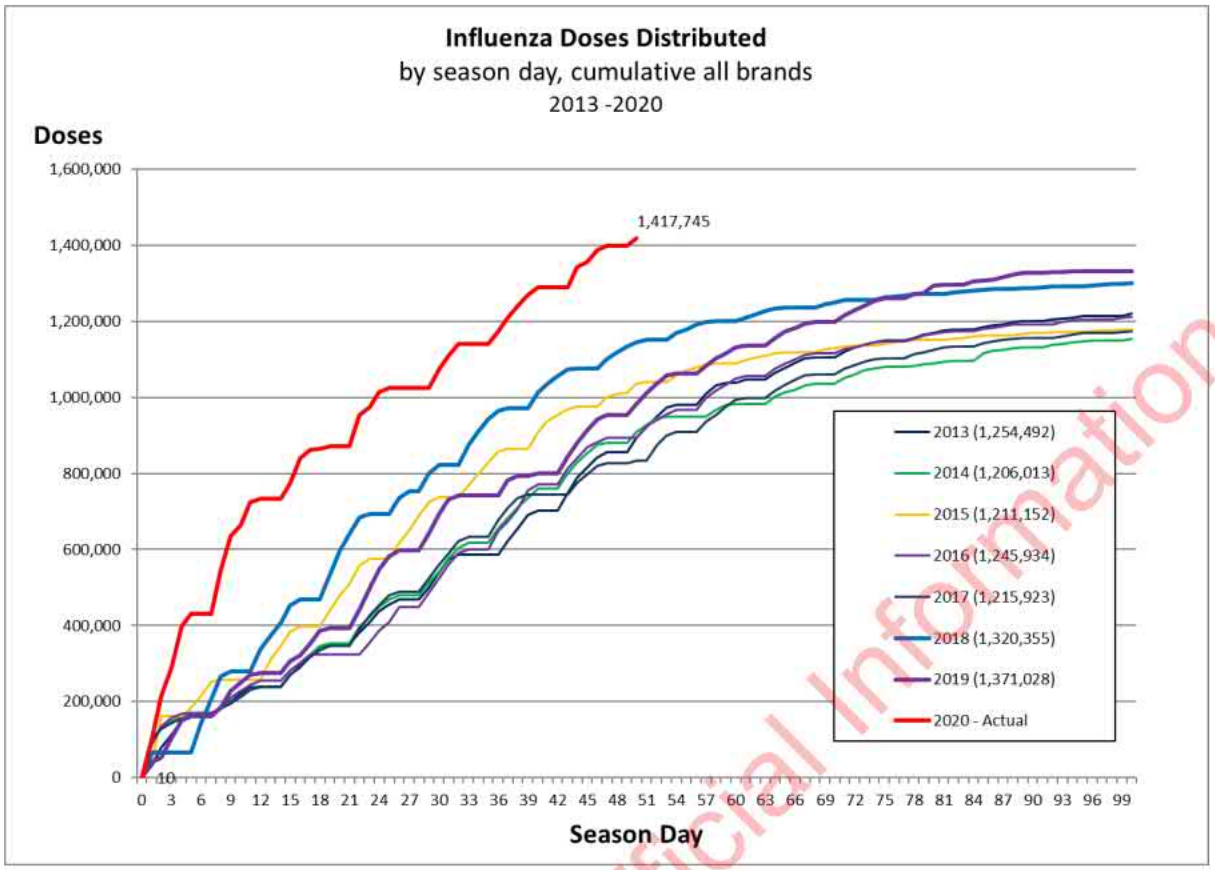
PHARMAC has received numerous requests, for new medicines funding or widened access to existing medicines funding. In most cases the rationale is that this would keep patients out of hospitals For the majority, we have determined that considering the funding through our usual processes would be the most appropriate route at this time however we remain open to revisiting our position should impacts of COVID-19 on hospital services change.

Influenza vaccine supply

Interest in COVID 19 has driven increased demand for the seasonal influenza vaccine and uptake has been much higher than was envisaged when vaccines were ordered last year Initially the Ministry of Health asked vaccinators to vaccinate only eligible (funded) patients and frontline essential workers, this restriction ended on 27 April.

Influenza vaccine stock movements

- A total of 1.768 million vaccines have been secured for the 2020 season.
- 1.39 million doses have been distributed as at 30 April 2020 this is more than has ever been distributed in New Zealand in a single year. Orders are reviewed and approved by Ministry of Health staff before dispatch and a 60 dose order limit remains in place.
- As at 1 May, approximately 20,000 doses remain available for distribution. 110,000 doses are due to arrive in NZ in the second week of May and will undergo quality checks prior to release for distribution (expected date for distribution is 13 May).
- Given recent ordering patterns there are likely to be orders that cannot be filled in the week beginning 4 May 2020.
- PHARMAC is currently supporting the Ministry of Health by taking steps to secure an additional 400,000 doses of Northern Hemisphere vaccine which the Ministry's clinical experts advise could be used for private market patients.



Increase to CPB to support impact of COVID 19

The $35 million increase to the 2019/20 Combined Pharmaceutical Budget (CPB) will support ongoing funding of all current listed medicines, accommodate the costs incurred from delayed savings transactions and ensure we can continue to get funded medicines into the country.

Further additional funding to accommodate increased costs will o be needed in the 2020/2021 financial year, as price effects and supply disruption are expected to persist for some time and a budget bid for an additional $115M for 2020/21 has been submitted

Balance of report is Out of Scope

PHARMAC
TE PĀTAKA WHAIORANGA

MONTHLY REPORT FOR MAY 2020

COMMERCIAL IN CONFIDENCE

Date **4 June 2020**

Attention **Hon Dr David Clark**
Minister of Health

Copies to:

PHARMAC Board
Lead DHB CE, Pharmaceuticals
Director-General of Health – Ministry of Health
Manager Governance and Crown Entities Ministry of Health
Principal Advisor, Crown Entity Monitoring and Appointments Ministry of Health

Contact(s)

Sarah Fitt, Chief Executive
Alison Hill, Director Engagement and Implementation

S9(2)(a)

Out of Scope

COVID 19 response and medicines management

Medicines and Device supply management

PHARMAC continues to follow up with all contracted medicine and device suppliers on a regular basis Most suppliers have indicated they have contingency plans that will maintain continuity of supply. At any one time approximately 50 suppliers potentially have an issue with supply in the coming weeks or months; however, to date all low stock issues have been managed and alternative supply options have been secured where required

Increase to CPB to support impact of COVID 19

PHARMAC has submitted an additional budget bid of $115M for COVID 19 related costs to the CPB for 2020/21, as well as a bid for $15M for 2019/20 for additional COVID 19 related hospital medical devices costs. Price effects and supply disruption are expected to persist for some time

Diabetes RFP and immune checkpoint inhibitor RFP

We are continuing to evaluate the Request for Proposals (RFP) for new diabetes treatments but due to uncertainty around headroom arising from the impacts of COVID 19 (increased costs and reduced and delayed savings) it appears that there are not sufficient investment funds to progress in the 2020/21 financial year (and beyond) to support an investment of this magnitude.

We have also decided not to issue a planned immune checkpoint inhibitor RFP (including lung cancer indications) at this time, which has had significant media coverage to date. Planning for the RFP is well progressed but we have now put this proposal on hold until such time as we have enough certainty that there would be sufficient headroom in 2020/21 and beyond to support an investment of this magnitude.

Ongoing supply issues

- There has been disrupted supply of several brands of oral contraceptives, including the Norimin and Microlut brands PHARMAC is working with suppliers to ensure continuity of supply, and sourcing alternative products where necessary This has included products with packaging designed for other markets, such as the UK and Australia. Medsafe has now approved the alternative products for use in New Zealand We have put out detailed communications to health professionals and the public There were previously supply issues with another oral contraceptive, Noriday 28, but this is now resolved
- Current stock levels of fluoxetine 20 mg dispersible tablets, an antidepressant, are running low until the next shipment arrives in mid-June. Supplies should be adequate to avoid an out of stock situation that impacts patients. However, there may be some uneven distribution of the stock of tablets between pharmacies, which could delay

access for some patients. There is ample stock of fluoxetine 20 mg capsules (the most widely used presentation); only the tablet presentation is currently impacted

Changes to Schedule criteria and rules

On 27 March 2020 PHARMAC put in place Pharmaceutical Schedule rule changes that restricted the dispensing of funded community medicines to just one month's supply at a time (or three months for oral contraceptives) This was in response to stockpiling of medicines

Additionally, all Special Authorities, Named Patient Pharmaceutical Assessment (NPPA) and other exceptional circumstances approvals that were due to expire on 31 March or 30 April 2020 were extended for three months. Many prescribers found it difficult to access the Ministry of Health online Special Authority application system during lockdown because they were working remotely. This blanket change meant that prescribers did not need to apply online to extend Special Authorities or NPPA that were due to expire at the end of March or April.

PHARMAC also made a number of changes to Special Authority criteria to ensure minimal interruption to access to health care for people and practical access to treatments as needed. This included changes such as removing requirements for fixed timelines for medicines administered in a hospital setting, removing requirements for specific testing or scanning that could have been challenging for the sector, increasing access to some preventative treatments and removing the requirements for applications to be made by certain types of specialists

PHARMAC intends to change many criteria back to the original requirements, including removal of the requirement for monthly dispensing, once health services and medicines supplies have stabilised to a point where it becomes practical to reinstate them. We are working towards 1 August 2020 for this but are consulting with affected parties before making a decision.

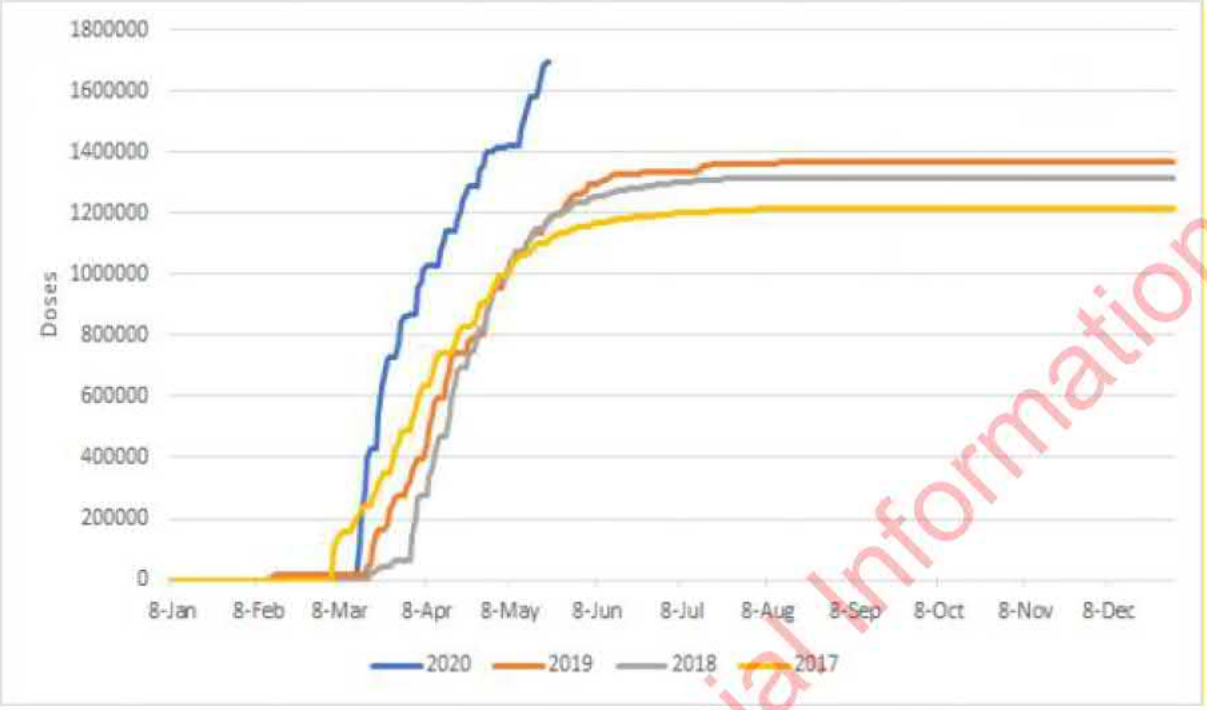
Influenza vaccine supply

Interest in COVID 19 has driven increased demand for the seasonal influenza vaccine and uptake has been much higher than was envisaged when vaccines were ordered last year Initially the Ministry of Health asked vaccinators to vaccinate only eligible (funded) patients and frontline essential workers, this restriction ended on 27 April. More recently, to boost the number of vaccines for supply in the private market, PHARMAC assisted the Ministry of Health by securing just over 400,000 doses of a Northern Hemisphere vaccine, bringing the total number of vaccines available for distribution in New Zealand to 2.169 million for the 2020 influenza season.

Influenza vaccine stock movements

- A total of 1.768 million Afluria Quad vaccines have been secured for the 2020 season.
- 1.72 million doses of Afluria Quad have been distributed as at 26 May 2020 – this is more than has ever been distributed in New Zealand in a single year.
- Approximately 48,000 doses of Afluria Quad, and 300 doses of the paediatric vaccine are still available, albeit ringfenced for eligible funded patients.
- An additional 355,000 doses of the Northern Hemisphere vaccine, Influvac Tetra Saison, are now available for the private market. A further 56,000 doses are due to arrive in early June 2020.

Influenza Doses Distributed by calendar day, cumulative all brands: 2017 2020 as at 22 May 2020



Balance of report is Out of Scope