

Email 2020-03-16

From: Steve Maharey s9(2)(a)
Sent: Monday, 16 March 2020 5:32 pm
To: Sarah Fitt s9(2)(a)
Cc: PHARMAC Board Members s9(2)(a)
Subject: Re: PHARMAC Update on COVID 19 activities

Thanks Sarah. Very comprehensive. Let's keep the idea of a virus briefing for the Board in mind as you plan over the coming days - a very dynamic situation! Best wishes and thanks to all the staff. Steve

Sent from my iPhone

On 16/03/2020, at 5:18 PM, Sarah Fitt <s9(2)(a)> wrote:

Dear Board Members,

Here is an update on the two streams of work underway at PHARMAC in relation to COVID 19. One is around supply chain of medicines Out of Scope

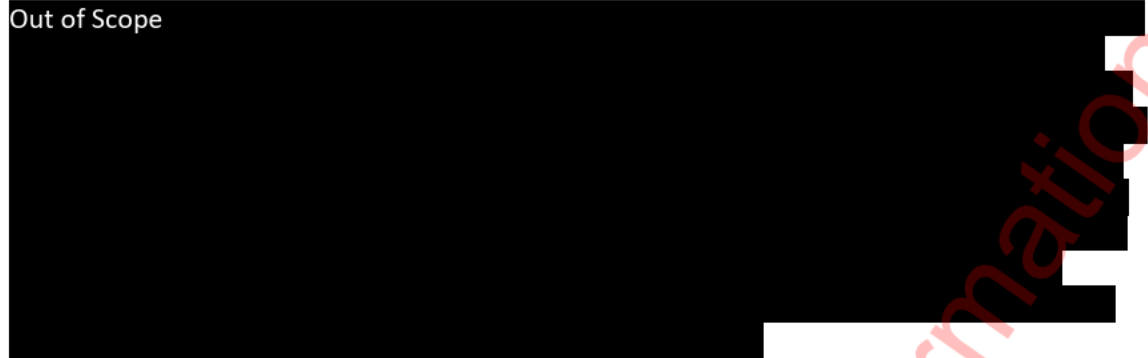
COVID-19 medicines and devices stock management

PHARMAC continues to proactively engage with the Ministry of Health on their response to the current COVID-19 outbreak. PHARMAC has contacted all contracted medicine and device suppliers and received updates from suppliers of the majority of contracted products. Most suppliers have indicated they have contingency plans which will maintain continuity of supply. Approximately 40 suppliers indicated they will potentially have an issue with supply in the coming weeks or months. There are likely to be supply issues that suppliers are currently not predicting due to the complex nature of the global supply chain and rapidly changing environment. We are also watching developments on potential treatments for COVID 19, many of which are in clinical trials overseas

There is the potential that public and media interest in COVID-19 could drive increased demand for the seasonal influenza vaccine. Additional influenza vaccine uptake would also have the benefit of potentially decreasing demand on primary and secondary care during any COVID-19 response. PHARMAC staff have secured an additional 300,000 doses of vaccine from Mylan (the only other supplier with a registered product for 2020). The additional 300,000 doses would allow for a total of 1.768 million doses to be available, a 30% (400,000 doses) increase on 2019 distribution. This would allow for approximately 34% of the population to receive a vaccination, up from 27% in 2019. We are also still working with other suppliers to source additional stock of flu vaccine.

We have set up an internal team that is meeting three times weekly to manage the issues and the associated comms to the public and the sector. We have also set up a webpage with a lot of the relevant information at <https://www.pharmac.govt.nz/information-for/coronavirus-covid19/>

Out of Scope



Out of Scope



Best wishes

Sarah

Sarah Fitt | Chief Executive

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Email 2020-03-24

From: Lizzy Cohen < s9(2)(a) >
Sent: Tuesday, 24 March 2020 6:28 pm
To: PHARMAC Board Members < s9(2)(a) >
Subject: March meetings this Friday + 2020/21 LoE + 'no surprises' to the Minister of Health

Kia ora,

I hope this email find you well and you are starting to settle into this new temporary working/living arrangement.

Out of Scope

Out of Scope

Out of Scope

Out of Scope

'No surprises' to the Minister of Health on influenza vaccine

This evening we sent a 'no surprises' to the Minister of Health regarding flu vaccine. Please find a copy below for your information and in confidence.

'No surprises' - influenza vaccines supply

Due to the situation with COVID-19 and an emphasis on completing influenza vaccinations before COVID-19 dominates the health sector, General Practitioners and other vaccinators have been ordering influenza vaccines at higher than expected rates. This, coupled with bringing forward the vaccination start date for eligible people, has resulted in the exhaustion of the current vaccine stocks held by the distributor.

All stock in NZ has either already been delivered or is already committed for delivery to pharmacies, medical centres, and other clinics. It is important to note that all orders received by the distributor, by 20 March 2020, have been filled, meaning that it is likely that all vaccinators have received some stock.

This means eligible people will still be able to receive their influenza vaccinations, but stock may start to run low at individual pharmacies or medical centres if there is high demand from eligible people.

894,000 influenza vaccines were in NZ when the vaccination season commenced, and the next shipment of 140,000 vaccines is due to be ready for distribution to vaccinators by 6 April 2020.

A further shipment of 300,000 influenza vaccines is being sent from the Netherlands, but a timeframe for receiving this has not been established due to international flight restrictions. We are working with the suppliers and airlines to ensure this stock reaches NZ as soon as possible.

We will be providing messaging to the Ministry of Health for the Director General of Health's stand up for tomorrow on not stock piling medicines and to reiterate earlier messages that the influenza vaccine is, until 13 April, only for those people who are funded to receive it.

Ngā mihi

Lizzy

Lizzy Cohen | Board Secretary/Executive Advisor

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Email 2020-03-25

From: Lizzy Cohen <s9(2)(a)> On Behalf Of Sarah Fitt

Sent: Wednesday, 25 March 2020 12:44 pm

To: PHARMAC Board Members <s9(2)(a)>

Subject: For decision - Proposal to move to monthly dispensing of all medicines

Importance: High

s9(2)(ba) & s9(2)(g)(i)



Sarah

Sarah Fitt | Chief Executive

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Email 2020-03-30

From: Lizzy Cohen <s9(2)(a)>

Sent: Monday, 30 March 2020 8:52 am

To: PHARMAC Board Members <s9(2)(a)>

Subject: PHARMAC - Briefing to MoH re planning for supply chain management

Morena,

It was nice to see you all on Friday.

Please find attached for your information and in confidence, a briefing to the Ministry of Health which was sent yesterday, Sunday 29 March regarding PHARMAC's planning for supply chain management.

Ngā mihi

Lizzy

Lizzy Cohen | Board Secretary/Executive Advisor

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PHARMAC Briefing

COVID-19: Update on PHARMAC planning for supply chain management

Date due: 29 March 2020

Security level: IN CONFIDENCE

To: Ashley Bloomfield, Director General of Health
Maree Roberts, COVID 19 Strategy and Policy
Ministry of Health

Copy to: PHARMAC Board

Contact for telephone discussion

Name	Position	Telephone
Sarah Fitt	Chief Executive, PHARMAC	Section 9(2)(a)

COVID-19: Update on PHARMAC planning for supply chain management

Purpose of report

This report provides information on PHARMAC's activities to plan for continuity of supply of medicines and medical devices that it has responsibilities for. It provides information on:

- PHARMAC's usual approach to ensuring continuity of supply
- PHARMAC's recent activities to prepare for COVID 19 impacts on continuity of supply
- Information required to further support response planning activities

Background

COVID 19 has slowed or halted activities in manufacturing plants and impacted the importation and transportation of medicines and medical devices globally.

Responsibilities for sourcing and managing supply chains for medicines and medical devices are spread across a number of agencies. PHARMAC is responsible for deciding which medicines will be publicly funded in New Zealand, and it has contracts in place for the supply of many of the medicines used in either community or public hospital settings.

PHARMAC is also contracting for hospital medical devices and around 45% of District Health Board (DHB) expenditure on devices has been secured under PHARMAC contracts. Non PHARMAC contracted devices are managed by New Zealand Health Partnerships (NZHP) and/or individual DHBs.

PHARMAC is working closely with the National Health Coordination Centre (NHCC), the National Crisis Management Centre (NCMC), New Zealand Health Partnerships (NZHP) and DHBs to get an understanding of their needs and to ensure any issues raised by the sector are directed to the correct entity.

PHARMAC's usual approach to maintaining continuity of supply

The majority of medicines used in New Zealand are sourced from overseas. The Pharmaceutical Schedule, managed by PHARMAC, contains over 2,000 different chemicals and over 4,000 line items (different presentations and strengths of medicines).

PHARMAC's typical contract management approach does not involve any significant oversight of, or involvement in, logistics or supply chain interactions. This is the responsibility of the contracted suppliers who have resources and expertise in these areas.

For most medicines there is generally a minimum of two months' supply held by distributors, and a further four to six weeks' supplies at pharmacy and wholesaler level however PHARMAC has no direct visibility of how much product is sitting in which part of the supply chain.

Where continuity of supply is at risk, PHARMAC has some tools to try to ensure that use of stock in the country can be optimised until more stock is able to arrive. One of these tools is to put restrictions on the quantity of community medicines that can be dispensed at a time.

The first example of PHARMAC doing this in response to COVID 19 was the decision from 9 March 2020 to restrict dispensing for paracetamol 500 mg tablets to one month's funded supply at a time. This was in response to information that the paracetamol active ingredient manufacturing plants in China had temporarily closed due to the coronavirus outbreak. This closure is impacting on the global supply of paracetamol. We believe the plant has now reopened but there will be a delay until the supply chain is fully refilled.

PHARMAC's recent approach given COVID-19 impacts on continuity of supply

Medicines

PHARMAC has been in constant contact with all its medicine suppliers (around 250), requesting status updates on any current or predicted impact to their supply chains since early February 2020, and is working on a medicine by medicine basis to resolve issues.

The approach to maintaining continuity of supply is not medicine specific, as most of the medicines listed on the Pharmaceutical Schedule are considered critical, although PHARMAC is taking a different approach for generic medicines than for innovator medicines.

- Generic medicines, which are typically much cheaper, high volume medicines, are mostly sourced from India and China by local New Zealand based distributors or generic medicine companies. Oftentimes these companies are working with intermediaries and may not have direct relationships with the manufacturers of the products they are importing. This can make it very difficult to access information about priorities being given to New Zealand medicine supply or details that might be required in order to smooth logistics hurdles, such as shipping details. PHARMAC staff are needing to provide additional support and assistance to suppliers of generic medicines to secure ongoing supply.
- Suppliers of innovator medicines (first or original brand of a medicine) generally have more direct control of their supply chains, so information on supply chains is easier to get, and they are better placed to absorb increased freight costs.

Most suppliers have indicated they have contingency plans which will maintain continuity of supply. Approximately 50 suppliers of medicines and medical devices indicated they will potentially have an issue with supply in the coming weeks or months.

It is unlikely that the supply chain will strengthen in the coming weeks. PHARMAC is anticipating significant future impact, especially from India's recent shutdown, as approximately 40% or more of New Zealand's medicines come from India. We are currently working closely with the Ministry of Foreign Affairs and Trade (MFAT) on the release of a number of medicines such as paracetamol and erythromycin.

There is increasing disruption in Europe, where some medicines come from and a significant proportion of devices are manufactured or assembled, and there are significant reductions in air freight availability.

PHARMAC has been in very regular contact with local wholesalers and distributors to monitor the demand they are seeing from community and hospital pharmacies and to evaluate stocks of in demand medicines. It was in response to information from this monitoring, and from our engagement with suppliers and community pharmacies, that PHARMAC made the decision to restrict the dispensing of all funded community medicines to just one month's supply at a time from 27 March 2020.

Despite there being no significant current medicine shortages, stockpiling by individual patients has put a major strain on supply chains for community medicines. PHARMAC made this change to ensure that remaining medicines stocks in wholesalers, distributors and community pharmacies are appropriately managed. The aim is to ensure people continue to have access to the medicines they need and that vulnerable communities don't miss out.

Specific medicines to respond to COVID-19

ICU 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 (ICU). These include sedatives, opioids, vasopressor agents, and muscle relaxants. Where PHARMAC's contracted suppliers cannot meet this additional demand, PHARMAC is engaging with other suppliers on the open market to find stock. Dealing with suppliers outside of contracts means prices are market driven, and negotiations on price are not always possible. There is difficulty in obtaining stock of some critical medicines as other countries are restricting exports to maintain their own supply chain.

An example of this is propofol, a commonly used anaesthetic sedative, which PHARMAC is attempting to source from an alternative supplier to ensure projected additional demand can be met. s9(2)(ba) & s9(2)(b)(ii)

PHARMAC has also secured additional intravenous fluids from its usual supplier, albeit via an alternate manufacturing site in Australia, which will likely incur significant freight costs.

PHARMAC has received feedback from ICU specialists that actions could be taken to reduce usage of treatments in a way that would not impact on optimal patient care. This has been proposed in order to extend the availability of existing stock for responding to COVID 19 in the event that further stocks from overseas cannot be secured in a timely way.

COVID 19 specific treatments

PHARMAC is working with its clinical advisors to get advice on specific antibiotics or antivirals that might be required for treatment of patients with COVID 19.

There has been a lot of interest in the use of hydroxychloroquine to treat COVID 19 cases. However, there has not been any definitive evidence to confirm its efficacy for this indication.

In order to preserve the continuity of supply for existing patients and for new patients who need it for its registered indications, effective from Tuesday 24 March, PHARMAC has restricted funded access to hydroxychloroquine for its Medsafe approved indications only, which include arthritis, lupus and malaria.

There is also an interest in antivirals, such as Kaletra (ritonavir/lopinavir) indicated for the treatment and prevention of HIV, being used to treat COVID 19. Early trials of these medicines may put pressure on New Zealand to make these types of medicines available.

Out of Scope

Influenza vaccine

With the potential increased demand for influenza vaccine due to COVID 19, PHARMAC ordered an additional 300,000 vaccines in early February, in addition to the 1.468 million doses already on order (which was an 100,000 increase on the 1.36 million doses available in 2019) to give a total of 1.768 million doses to be available for the 2020 season.

PHARMAC staff have been working closely with the Ministry of Health's Immunisation team and the decision was to bring forward the start of the vaccination season, from 1 April to mid March, and prioritise patients eligible for funded access as well as healthcare workers. When the vaccination season commenced 894,000 influenza vaccines were in New Zealand. The next shipment of 140,000 vaccines is due to be ready for distribution to vaccinators by 6 April 2020.

The additional shipment of 300,000 influenza vaccines is being sent from the Netherlands, and is due this week, and PHARMAC has been working very closely with the supplier, freight forwarder and airlines to ensure this stock reaches New Zealand. PHARMAC has also received very good support from MFAT to reduce the risk of delays in transit. The remainder of the stock (of the total 1.768 million doses) will be coming from Australia timeframes to be confirmed. PHARMAC continues to work to source additional stock, however, the chance of securing more stock reduces as manufacturers have started moving to production for the Northern Hemisphere winter.

Vaccinators have been ordering influenza vaccines at much higher than expected rates. This, coupled with bringing forward the vaccination start date for eligible people, has resulted in the exhaustion of current vaccine stocks held by the distributor. All stock in New Zealand has either already been delivered or is already committed for delivery to pharmacies, medical centres, and other clinics.

This means eligible people will still be able to receive their influenza vaccinations, but stock may start to run low at individual pharmacies or medical centres if there is high demand from eligible people.

However there is still an additional 874,000 doses of vaccine to arrive into the country and be distributed in time for the start of the flu season.

Medical devices

PHARMAC is also maintaining close contact with its medical devices suppliers to establish where supply issues might arise and work out alternative sources of supply. This includes regular engagement with the Medical Technology Association of New Zealand (MTANZ) to discuss supply management.

PHARMAC has been supporting NZHP on its work to scale up the number of ventilators and associated ICU devices (PHARMAC does not have national contracts in place for these items as yet).

The biggest supply issue for PHARMAC contracted devices has been in sourcing hand sanitizer, which is in short supply due to significant increase in demand. In New Zealand this is complicated by the fact that it needs to be a registered medicine to be used in health settings. This means the medicine must be approved by Medsafe, and manufactured in accordance with standards for Good Manufacturing Practice (GMP). PHARMAC's main contracted supplier has been able to increase production in Australia. PHARMAC is also working with other suppliers that have Medsafe approval and is engaging with Medsafe on potential alternative suppliers gaining approval. PHARMAC has identified one manufacturing site in New Zealand that already has met GMP standards as assessed by Medsafe, and potentially another site that could also be used to manufacture hand sanitiser for use in health settings. Essential services such as supermarkets can use, and sell, retail hand sanitiser products (i.e. not registered as a medicine) and therefore have many more options for supply, and PHARMAC has been sharing possible options with providers like Countdown.

Freight, logistics and pricing impacts

One of the main challenges PHARMAC currently faces in sourcing medicines and medical devices is around air freight capacity, given the limited number of international flights, as well as the devaluation of the New Zealand dollar which is putting significant pressure on pricing. It is likely that PHARMAC will require contingency funding to support these additional costs.

The closure of borders and international air travel restrictions has had an impact on PHARMAC's usual arrangements to air freight stock. A recent example of this has seen the shipment of influenza vaccine being sourced from the Netherlands. Vaccines have the additional requirement of needing refrigeration, making it essential to maintain the cold chain throughout transport and storage. PHARMAC is working with MFAT and directly with airlines and freight agents to assist with resolving these types of freight delays.

When seeking additional supplies, PHARMAC is also taking the following steps to minimise freight disruptions:

- Contacting medicines and devices suppliers to build an estimate of volume and frequency of freight deliveries to New Zealand.
- Switching to sea freight where appropriate for future orders as it is experiencing less disruption than air freight.
- Splitting orders, where possible, across geographical regions and/or suppliers, e.g. Australia and Europe for fentanyl, which is a controlled drug, to reduce the risk of regulatory, logistical or other interruption to supply.
- Running a detailed log of logistical and freight issues. This information will be used to combine shipments and requests for assistance with shipping from places such as India and Europe.

Medicines Regulation

PHARMAC and Medsafe are maintaining close communication on regulatory issues. In some situations an accelerated regulatory review may be required for approval of an alternative brand of medicine, changes to a currently registered medicine, and/or approval of an alternative manufacturing site.

New Zealand is required to meet international drug control conventions restricting the quantity of controlled drugs that can be imported into New Zealand and these limits may need to be exceeded. Increased quantities of controlled drugs such as fentanyl and morphine, used in ICU, may be required for COVID 19 treatment.

Information required to further support response planning activities

The main challenge in maintaining supplies of medicines and medical devices in New Zealand is lack of clarity about current stockholdings of medicines or medical devices in DHB hospitals.

This information would assist in planning on a national basis for which medicines or medical devices should have additional orders placed for them to increase stockholdings in New Zealand, and would assist with decision making about redeployment or re allocation of stock around the country to the areas that need it most.

The NCMC is leading the work on a national stocktake, in conjunction with PHARMAC and NZHP, and the NHCC is working to identify a list of medicines and additional volumes that might be required to respond to COVID 19.

Recommendations

- a) **Note** that the majority of medicines and devices used in New Zealand are sourced from overseas **Yes/No**
- b) **Note** that there are global supply chain issues due to COVID 19 disrupting the manufacturing and transportation of medicines and medical devices **Yes/No**
- c) **Note** that PHARMAC is in constant contact with all its suppliers, requesting status updates on any current or predicted impact to their supply chains, and is working to resolve issues **Yes/No**
- d) **Note** that additional costs are being incurred to maintain the regular supply chain, and this may require a contingency budget for PHARMAC to secure continuity of supply for medicines and devices **Yes/No**

Sarah Fitt

Sarah Fitt

Chief Executive