PHARMAC
TE PĀTAKA WHAIORANGA

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MEMORANDUM FOR BOARD MEETING 28 FEBRUARY 2020

To: PHARMAC Directors

From: Chief Executive

Date: February 2020

Chief Executive's Report

Past and upcoming activities

Out of Scope

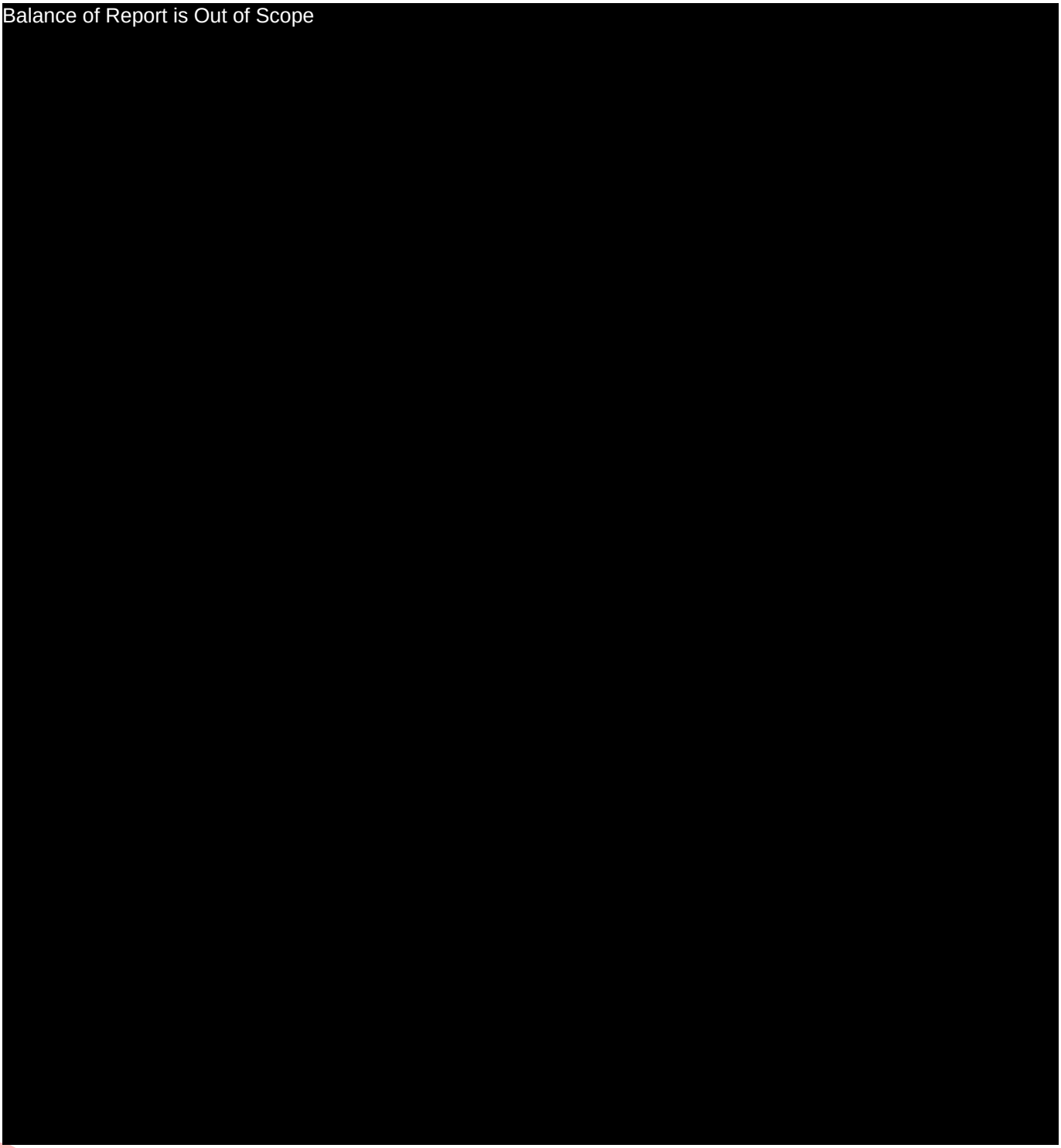
[redacted]

COVID-19

PHARMAC have proactively engaged with the Ministry of Health on their response to the current COVID 19 outbreak in China and preparation for a potential outbreak in New Zealand. PHARMAC have also contacted all contracted medicine and device suppliers and asked for status updates on any current or predicted impact to their supply chains PHARMAC staff have also checked with suppliers of Additional Stock Pharmaceuticals (ASPs) identified by the Anti Infective subcommittee in 2009 as being likely to be required for secondary infections Suppliers of ASPs are required to hold a minimum of four months stock in New Zealand. Currently there are no concerns with supply of the ASP antibiotics identified

There is the potential that 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 has engaged with influenza vaccine suppliers however there is no ability for Seqirus (the contracted supplier for 2020) to bring additional doses into New Zealand The manufacturing campaign commenced in Q3 2019, manufacturing capacity is fully committed and about to switch to the Northern Hemisphere vaccine and currently there are 1 468M doses due for delivery to New Zealand Fortunately, PHARMAC staff have been able to secure 300,000 additional doses from Mylan (the only other supplier updating their strains for Medsafe registration in 2020).

Balance of Report is Out of Scope



PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM FOR BOARD MEETING 27 MARCH 2020

To: PHARMAC Directors

From: Chief Executive

Date: March 2020

Chief Executive's Report

Past and upcoming activities

Out of Scope [redacted]

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 and preparation for a potential outbreak in New Zealand 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

There is the potential that 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

More detail on the COVID 19 response and risk management is provided in the Supply Chain Risk Maintenance update

Balance of Report is Out of Scope [redacted]

PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM FOR BOARD MEETING 27 March 2020

To: PHARMAC Directors

From: Chief Executive

Date: March 2020

Risk in the Supply Chain Update

Recommendations

It is recommended that you:

note the contents of this paper; and

note that an update report will be provided to the Board in October 2020

Executive Summary & Background

- In May 2017 PHARMAC staff presented the Board with information relating to medicine supply risk following a high profile stock issue (metoprolol succinate) that occurred during 2016.
- At that meeting a Risk Matrix that we proposed to use to review supply chain risks for all listed chemicals listed in both Section B (community) and Section H (hospital) of the Pharmaceutical Schedule was endorsed, with the intent being to find options to reduce the potential for a supply outage that would have a significant clinical impact on patients.
- The Board is provided with an update on this work every six months This paper provides the Dashboard being used to track our work, and brief updates on four of the workstreams.
- Out of Scope
- In addition to standard updates about our risk review activities, we have commenced this paper with a detailed summary of the work we are undertaking to manage and prepare for the immediate potential supply chain impacts from COVID-19.

COVID-19 – supply chain risks and management activities

COVID 19 is an issue with a number of elements requiring risk assessment and management. The two main areas of risk are:

- impacts to the supply chain from the COVID 19 pandemic due to manufacturing or transportation delays; and
- a potential surge in demand responding to the pandemic

A secondary aspect to the potential surge in demand is managing the possibility of stock piling at all stages of the supply chain, wholesaler, DHB, community pharmacy and patients

Our risk assessment activities

PHARMAC staff management activities include contacting all contracted medicine and device suppliers to ascertain any potential impact to their supply chain To date responses have been received from the suppliers of most contracted products. Currently 43 suppliers have identified the potential for an issue at some stage in the coming weeks or months.

The only product with a current supply issue attributed to COVID-19 is paracetamol 500 mg tablet. s9(2)(b)(ii) & 9(2)(j) The active pharmaceutical ingredient is manufactured in China and their finished product is manufactured in India The active pharmaceutical ingredient manufacturing sites in China have been closed due to quarantines, and export of the finished product from India has been restricted by the Indian government There is currently four months' supply in New Zealand, PHARMAC staff have restricted supply at the patient level. This restriction should ensure the current stock would last for six months (absent any significant surges in demand). This will allow the contracted supplier and PHARMAC staff to source an alternative and/or see a resolution to manufacturing or Indian export controls. Alternatives are not readily available, so it may be necessary to enter short term agreements to maintain continuity of supply.

Transportation

Global supply routes for transport of all goods are currently very constrained and suffering from under capacity. This will impact lead times and may lead to supply issues in future.

Sea freight has been reduced somewhat, but most of transportation impacts have been on airfreight. Although PHARMAC staff have limited visibility of supply chain routes, it is estimated close to 100% of innovator medicines and cold chain products will come to New Zealand by airfreight. Generic medicines and medical devices will utilise more sea freight but a significant volume of product will arrive by air freight. Air freight routes into New Zealand have been severely compromised by the recently imposed border controls Most air freight comes on commercial passenger planes and with Air New Zealand reducing flights by 85%, capacity is limited.

The Indian government restrictions currently apply to a limited range of products. PHARMAC staff anticipate additional impacts if the COVID 19 pandemic has an impact on the Indian population. Approximately 40% of global generic medicines are manufactured in India

Demand

To manage surge demand for pandemic response medicines and devices PHARMAC staff are meeting weekly with the Ministry of Health's National Health Coordination Centre (NHCC). The NHCC has a number of advisory groups, one of which will make treatment

recommendations. At this stage there have been no requests from the NHCC to secure any additional stock over and above the items the Ministry of Health already holds at national pandemic store

PHARMAC staff have contacted suppliers of the Additional Stock Pharmaceuticals (ASPs) that may be required for a pandemic response These include injectable antibiotics, suppliers of ASPs are required to hold at least four months of stock in New Zealand. None of the contracted suppliers has a current issue with supply of the ASPs

There has been a huge surge in demand for sanitizing solutions and personal protective equipment (PPE) resulting in limited supply of PPE and sanitizers PHARMAC does not manage PPE contracts and holds limited sanitizing solution contracts.

Some demand will be for genuinely higher usage, some may be stock piling for anticipate usage. PHARMAC staff have contacted wholesalers, suppliers, pharmacists and DHBs to ask them to try to ensure ordering patterns are maintained at normal levels. This will allow distribution of stock if there are shortages to be managed at a national level

There have not been any substantiated reports of stock piling of medicines or medical devices; however, we've heard (anecdotally) from multiple sources (Wholesalers & distributors, DHBs, Pharmacy Guild, TAS, Individual pharmacies) that pharmacies are seeing significant script increases since Feb and that wholesalers and distributors are seeing significant order volume increases

Some pharmacies are reporting patients stockpiling, with GPs writing multiple scripts for patients to fill at several pharmacies.

We have raised this with the Ministry of Health and suggested that clear messaging from the centre would be useful to call for sensible prescribing and advising that individual patients stockpiling medicines or devices is neither necessary or appropriate. We've noted that we are willing to include these types of messages in our sector engagement, but that we would like agreement from the Ministry that they would be appropriate.

Coordination activities

We understand that DHBs have set up a number of workstreams to support the Ministry of Health/NHCC as the lead agency for the COVID 19 response One of the workstreams is logistics/supply chain. s9(2)(a) is lead CE, and s9(2)(a) is likely to be the GM P&F rep (to be confirmed) PHARMAC has been invited, and has welcomed the opportunity, to be engaged in the workstream The workstreams are just being stood up now, so it's early days in terms of sorting out how they will run we may have a verbal update on this for the Board when it meets. The aim is to ensure DHBs work with other agencies in a coordinated way, to ensure the right parts of the system are well connected and working together

Summary

Covid 19 is a rapidly changing situation and managing expectations and demand is a critical element in minimizing the risk of out of stock situations There is some urgency that needs to be applied to establishing if there are medicines or devices which may have demand that could out strip current pandemic stock holdings.

Dashboard for Risk Matrix Development

An overview by individual workstream, along with a visual guide identifying what stage each workstream is at, is set out below. A detailed summary of work in each activity is provided on the subsequent three pages. The stages are as follows:

P	Planning
A	Assessing
I	Implementing

Not started In progress Complete

	Activity	Status P	Status A	Status I	Estimated Completion	Overview
1	Risk mitigation actions for identified high risk products				COMPLETE	The completed assessments will be used for any required Covid-19 response. The general approach is being utilised to respond to the [redacted] market withdrawal (see below).
2	Therapeutic groups reviews (16 high level categories)				Ongoing, 2 groups substantively completed to date	Two Therapeutic Groups (TGs) have been reviewed using the matrix, with some further work required to finalise them. The remaining TGs are estimated to take approximately 18 months (depending on other priorities); triaging assessments of high risk groups first, such as cardiology.
3	Information collation and comparison				Dependent on assessment phase and other ICT priorities	ICT led work (i.e. data mapping) to gather and collate information required from existing sources to complete an up to date risk matrix has commenced. Some further work required to identify ICT solutions to maintaining an up to date record.
4	Review of stock issues against the matrix				COMPLETE	Staff are using a subset of the matrix to review actual or potential stock issues to assist with determining appropriate actions in response.
5	Review of Tender Medical decisions against the risk matrix				Dependent on completion of all matrices	Initial conceptual discussion about how the matrices could be applied to tender decisions. Work to implement in tender processes still required. This would not be undertaken until all matrices are complete.

s9(2)(j), 9(2)(ba) & 9(2)(b)(ii)

Activity 2: Therapeutic Group Reviews (16 high level categories)

As noted in the March 2019 update to the Board, the Ophthalmology and Anti Infectives therapeutic groups have been reviewed using the risk matrix tool. There was feedback from the groups involved that it was significant work to complete the matrix Management of the data is manual and without a database to store and manipulate information, wider adoption of the tool is difficult

PHARMAC staff are exploring the opportunity to engage external experts to help complete the content required for the outstanding 14 categories This approach would assist with completion while allowing the Therapeutic Group Managers to focus on business as usual.

Activity 4: Review of stock issues against the matrix

This activity was completed in April 2018. PHARMAC staff have used information gained from the first two therapeutic group reviews to aid in managing recent stock issues The information provided regarding indications and alternatives has been the most useful component of the matrix at point of issue as it allows PHARMAC staff to move forward to find suitable alternatives faster The risk matrix for anti infectives will be useful if there is increased demand from secondary infections during any Covid-19 response.

Financial risk is considered as part of PHARMAC's overall risk profile and is assessed during due diligence when considering supply arrangements This can be via the annual invitation to tender, RFP process or direct contracting. Suppliers which are new to PHARMAC are asked to provide proof of financial stability. Often firms will supply copies of audited financial records This is easily available for publicly listed companies, which covers a large number of PHARMAC's suppliers. Proof of ownership is also requested and for New Zealand registered companies this is verified via the New Zealand Companies register Most multinational

organisations have a registered legal entity in New Zealand that contracts with PHARMAC. If deemed necessary during the due diligence assessment related party guarantees can be sought if further financial security is required This is required infrequently

During mergers and acquisitions the same level of due diligence is applied. Mergers are not uncommon and are subject to review by the Commerce Commission The Commerce Commission typically consults with PHARMAC on pharmaceutical mergers to inform their decision making. If a merger is deemed to reduce competition the Commerce Commission can direct companies to divest products prior to merger to maintain competition.

More common than mergers, are changes in distribution rights or brand ownership from one company to another. The same level of due diligence is applied to financial stability as for a new supplier However, most commonly products are transferred between companies that already contract with PHARMAC. Novation of contracts is common place and typically straight forward.

The Board expressed an interest in the proportion of generic suppliers' vs innovator companies. The distinction is in some cases slightly arbitrary as various companies operate in both markets. A list is included as Appendix One.

Activity 5: Review of Tender Medical Decisions against the matrix

Initial discussions have been held with the Tender Medical Committee about how the matrix can be applied to decisions in the annual tender. Work is required from relevant PHARMAC staff to scope how the Tender list can be cross referenced against the risk matrix The benefit of this work is contingent upon completing the analysis of the remaining therapeutic categories