MINISTRY OF HEALTH
MANATŪ HAUORA

Memorandum

Quality Review of Personal Protective Equipment (PPE)

Date due to MO:	N/A	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	20200932
To:	Hon Dr David Clark, Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Keriana Brooking	Deputy Director-General, COVID-19	section 9(2)(a)
Kelvin Watson	COVID19 Health Supply Chain Manager	section 9(2)(a)

Action for Private Secretaries

N/A

Date dispatched to MO:

Quality Review of Personal Protective Equipment (PPE)

Purpose of report

1. This report is to provide you with an update on work that the Ministry of Health (Ministry) has underway to review the quality of all Ministry-funded personal protective equipment (PPE) sourcing (not from our regular supply arrangements) from 1 January 2020.

Background

2. During the height of the recent COVID-19 pandemic in New Zealand approximately $243 million of PPE was purchased to support the national response to the pandemic. Much of this PPE was purchased at speed from suppliers outside of the Ministry's normal supply arrangements for the New Zealand health system. Many orders were through public/private collaborations who had Chinese-based broker capability rather than directly through the manufacturer or existing well-established medical device distributors.

3. At the height of the pandemic, the Ministry, through its procurement partners, sourced PPE in a highly distressed and overly inflated competitive global market. This meant that many orders were placed under urgency with less due diligence than would normally be undertaken. Orders were being confirmed with new suppliers within hours during this period to secure manufacturing and freight windows. There would otherwise be a risk of prolonged delivery delays. Business as usual procurement processes would normally take place over weeks/months.

4. Due diligence during the height of the pandemic included reviewing certifications provided by the broker/supplier and assessing whether the product being purchased met New Zealand specification requirements and international standards. Some on-the-ground due diligence of the manufacturing sites by the broker, and supplier/broker company information review was also undertaken.

5. With the transitions down alert levels and reduced procurement driven under urgency, our attention has turned to undertaking further due diligence into the PPE orders that have been placed throughout this period of unprecedented urgency of PPE supplies. This has included some analysis on the legitimacy of certificates, labelling and packaging of PPE products.

6. Upon receiving a shipment of N95 masks in late May that raised concerns regarding labelling, we have proactively undertaken a full quality review of orders placed on our behalf from alternative suppliers and brokers. Through this review, we have uncovered some concerns about the quality of other PPE orders between the period of January and May 2020.

7. Parallel to this, we are now getting reports of potential non-compliant masks being imported to New Zealand by other organisations. There is the potential for media interest in this issue.

Initial Review Results

8. section 9(2)(f)(iv) [redacted]

9. section 9(2)(f)(iv) [redacted]

Product	Our supplier	Number of Orders	Quantity EA	section 9(2)(b)(ii)	Nature of the concern	Rating
			ADHB P			
Goggles (anti mist or equivalent)	section [redacted]	1	100,000		Further information required	
Hand Sanitiser (500mL equivalents)		1	100,000		Further information required	
N95 Mask (or equivalent)		2	2,000,000		High levels of media coverage internationally. In UK for testing.	
Procedure Mask (or equivalent)		1	1,000,000		Further information required	
			MoH P			
Isolation Gown (or equivalent)	section 9(2)(b) [redacted]	8	2,105,000		In circulation. Canterbury DHB has raised concerns. FDA published guidelines on Isolation Gowns sent to Regional Leads to check products labels and requirements for IG in COVID-19	
N95 Mask (or equivalent)	section 9 [redacted]	2	150,400		Testing lab can not be verified. Further work required. Didn't pass Fit Test. Labelling concerns	
Procedure Mask (or equivalent)		1	2,482,500		Testing lab can not be verified. Further work required. Didn't pass Fit Test. Labelling concerns	
Face shield (or equivalent)		1	30,000		Further information required	
N95 Mask (or equivalent)	section 9(2)(b)(ii) [redacted]	1	10,000,000		In UK for further testing. Package and labelling concerns	
Procedure Mask (or equivalent)	section 9 [redacted]	1	9,562,044		Further information required	
Procedure Mask (or equivalent)	section 9(2)(b)(ii) [redacted]	2	5,000,000		Further information required	
Procedure Mask (or equivalent)	section 9(2)(b)(ii) [redacted]	1	20,000,000		Further information required	
		22	**52,529,944**			

10. Products rated as red are those where a concern has been identified and further investigation is required. These products have a mix of issues including incorrect product labelling, possible product non-compliance and/or questions regarding certification validity. This consists of five products (four masks, one isolation gown) covering 16.7 million items of PPE and $44.9 million of spend.

11. Products rated as amber are those where we have a suspicion of an issue based on other issues with the same supplier for another product, or where we have as yet been unable to sight the relevant documentation for the order. This consists of seven products covering 35.8 million items of PPE and $34.7 million of spend.

12. We have identified 3.5 million red products that have been distributed into circulation. We are undertaking a process to have those that are in circulation identified and put on hold until our investigations are complete. A further 1.3 million red products have been put on hold in the central warehouse. Complicating the investigation of what is in circulation is that some shipments from these suppliers for the same items were from different manufacturing suppliers and we have been able to establish the veracity of some manufacturing certifications but not others.

Next steps

13. Our immediate focus is to:

    a. identify what additional red products are in circulation and quarantine these while we undertake further analysis, including independent testing on the products

    b. obtain further information needed on the amber products to assess whether there is an actual concern requiring further investigation

    c. confirm the initial assessments of the remaining products which are not currently identified to have concerns.

14. We are assessing our inventory levels based on an assumption that at least some of the red/amber products will not be suitable for the intended purpose. This will help us establish how much PPE we have available for use in the short term and whether more PPE needs to be ordered pending a further outbreak of COVID-19.

15. Where products are confirmed as non-compliant, we will need to assess our approach to responding on a case-by-case basis. Many of these orders were placed at speed and detailed contractual disciplines were often not completed. This means the Ministry may have limited solutions available in some instances.

16. Our goal is to have sufficient quantities of good quality PPE on shore in New Zealand pending a potential further outbreak of COVID-19. We will be placing orders for replacement stock where required to ensure we achieve this.

17. The Ministry will report back to you about progress on the quality review of PPE, no later than 24 June.

18. Officials can provide further information about this topic at your request.

Dr Ashley Bloomfield

Director-General, Ministry of Health