

# Briefing

## COVID-19 Vaccine Portfolio Update – Concluding the AstraZeneca Advance Purchase Agreement

**Date due to MO:** 8 July 2022 **Action required by:** 15 July 2022

**Security level:** Commercially Sensitive **Health Report number:** HR 20221014

**To:**

- Rt Hon Jacinda Ardern, Prime Minister
- Hon Grant Robertson, Minister of Finance
- Hon Andrew Little, Minister of Health
- Hon Nanaia Mahuta, Minister of Foreign Affairs
- Hon Peeni Henare, Associate Minister of Health
- Hon Dr Ayesha Verrall, Minister for COVID-19 Response
- Hon Aupito William Sio, Associate Minister of Health

### Contact for telephone discussion

Name	Position	Telephone
<b>Maree Roberts</b>	Deputy Director-General, Strategy, Policy and Legislation	§ 9(2)(a)
<b>Allison Bennett</b>	Acting Group Manager, Strategy, Policy and Legislation	§ 9(2)(a)

### Minister's office to complete:

- |   |                                    |  |
|---|------------------------------------|--|
| <input type="checkbox"/> Approved             | <input type="checkbox"/> Decline   | <input type="checkbox"/> Noted               |
| <input type="checkbox"/> Needs change         | <input type="checkbox"/> Seen      | <input type="checkbox"/> Overtaken by events |
| <input type="checkbox"/> See Minister's Notes | <input type="checkbox"/> Withdrawn |  |

Comment:

# COVID-19 Vaccine Portfolio Update – Concluding the AstraZeneca Advance Purchase Agreement

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## Purpose of report

1. This paper provides an update on the management of the Advance Purchasing Agreement (APA) with AstraZeneca for its COVID-19 vaccine. This paper seeks your agreement to:
  - a. use existing draw down to cover additional costs in relation to the APA
  - b. conclude the use of AstraZeneca in the COVID-19 Vaccine Immunisation Programme (CVIP).
2. This paper also provides an update on the transfer of COVID-19 vaccine purchasing and portfolio management to Pharmac. It seeks your agreement to the novation of the APA with AstraZeneca to Pharmac.

## Summary

3. In December 2020, New Zealand signed an APA with AstraZeneca to secure access to 7.6 million doses of its viral vector COVID-19 vaccine as part of a broader portfolio of potential COVID-19 vaccine candidates.
4. New Zealand has since implemented a COVID-19 Immunisation Programme (the Programme) primarily based around the Pfizer vaccine. Small volumes of AstraZeneca's vaccine have been made available as an alternative, non-mRNA COVID-19 vaccine since November 2021.
5. New Zealand has offered to donate the remaining doses from the APA to the COVAX Advance Market Commitment (AMC) to support global vaccination efforts. We have donated 835,000 doses from our APA to developing countries. However, this year COVAX has had to write off large volumes of vaccines (including some of New Zealand's doses) s 9(2)(g)(i) [HR 20220573 refers]. COVAX has therefore declined our

most recent offer to donate the 991,000 doses remaining under our APA with AstraZeneca.

6. s 9(2)(b)(ii)  
[REDACTED]  
[REDACTED]  
[REDACTED] We are able to decline delivery if we meet the costs of disposal. AstraZeneca has also advised of an additional cost linked to the repacking of successfully donated doses and the destruction of doses that could not be allocated by COVAX on New Zealand's behalf.
7. Officials estimate the total additional costs of disposal and donation to be between s 9(2)(b)(ii) which can be met through the underspend of the existing draw down for AstraZeneca doses.
8. Officials note in finalising these payments, the APA will be concluded, with no further deliveries of AstraZeneca doses to New Zealand planned. Officials are considering the phasing out of AstraZeneca's vaccine from the current programme with low domestic uptake and ongoing availability of both Pfizer and Novavax.
9. The Programme has noted the remaining doses in New Zealand are due to expire in September 2022. The programme is planning for no further AstraZeneca deliveries and assurance that those who previously received or are eligible for AstraZeneca have access to Novavax or Pfizer COVID-19 vaccines.
10. AstraZeneca has advised some residual contractual obligations remain after doses have been donated or disposed of (e.g, confidentiality obligations). In line with the transfer of COVID-19 vaccine purchasing and portfolio management to Pharmac, a deed of novation is being prepared to formalise this handover.

## Recommendations

We recommend you:

### *Previous decisions on the utilisation of AstraZeneca's vaccine*

- a) **Note** that 7.6 million doses of AstraZeneca's vaccine were purchased under an APA in December 2020, and **§ 9(2)(b)(ii)** was agreed by Vaccine Ministers to be drawn down from the 'Minimising the health impacts of COVID-19 – Tagged Operating Contingency' to enable this purchase [MBIE 2021-1537 refers]
- b) **Note** that Vaccine Ministers have previously agreed to donate AstraZeneca doses from our APA to COVAX AMC including
- August 2021: 708,400 doses marked for the Pacific [HR 20210765 refers]
  - December 2021: 5.8 million doses unmarked [HR 20212485 refers]
  - March 2022: 991,000 doses unmarked [HR 20222060 refers]
- c) **Note** that Vaccine Ministers were previously advised of the risk of wastage of doses donated to COVAX, including **§ 9(2)(b)(ii)** of AstraZeneca's vaccine [HR 20220573 refers]
- d) **Note** that in April 2022, Vaccine Ministers were advised that COVAX was unable to accept the proposed donation of 991,000 (the remaining AstraZeneca doses under our APA) [HR 20220573 refers]
- e) **Note** that of the **§ 9(2)(b)(ii)** drawn down for the AstraZeneca APA, an estimated **§ 9(2)(b)(ii)** will remain unspent as a result of the margin included in the original draw down to address foreign exchange rate fluctuations

### *Additional costs under the APA with AstraZeneca*

- f) **Note** that Vaccine Ministers agreed to officials managing the remaining 991,000 doses **§ 9(2)(b)(ii)** or to refuse receipt **§ 9(2)(b)(ii)** [HR 20220573 refers]
- g) **Note** **§ 9(2)(b)(ii)** officials have been advised of the additional costs to dispose of both these doses (rather than taking receipt) and unallocated COVAX doses
- h) **Note** that there are other additional costs for the donation of successfully allocated COVAX doses
- i) **Note** that the total additional costs (estimated to be between **§ 9(2)(b)(ii)** can be met through the underspend of the existing draw down (which included a **§ 9(2)(b)(ii)** margin to address the risk of foreign exchange rate fluctuations)
- j) **Agree** that the additional costs in recommendation h) above be met through an estimated underspend of **§ 9(2)(b)(ii)** from the funds previously drawn down for the AstraZeneca APA and allocated to the Non-Departmental

**Yes/No**

Output Expense Appropriation, *Purchasing Potential and Proven COVID-19 Vaccines and Other Therapeutics*, with no impact on the operating balance or net core Crown debt

- k) **Agree** subject to recommendation i), to invite the Director-General of Health to sign, on behalf of the Crown, a Letter of Agreement to pay final costs to AstraZeneca **Yes/No**
- l) **Note** that any unspent funding drawn down for the AstraZeneca APA after the payment agreed in recommendation j) above will be returned to the Crown

*Phasing out AstraZeneca from the vaccination programme*

- m) **Note** that AstraZeneca has been made available domestically since November 2021 when 100,000 doses were imported from Australia [HR 20212271 refers]
- n) **Note** that the existing doses will expire on 5 September 2022 and New Zealand does not currently have access to further doses (additional purchase arrangements would be required)
- o) **Note** that demand for AstraZeneca's vaccine is low and Ministers have previously agreed to Novavax being the non-mRNA option in the portfolio longer term [HR 20220023 refers]
- p) **Agree** that officials phase out AstraZeneca from the programme, primarily through proactive communications and engagement with the health sector **Yes/No**

*Transfer of COVID-19 vaccine purchasing and portfolio management*

- q) **Note** that officials are progressing the transfer of COVID-19 vaccine purchasing and portfolio management from the Ministry of Health to Pharmac as directed by Cabinet [CAB-22-MIN-0189 refers]
- r) **Note** the Ministry of Health, Pharmac and the interim Health NZ are finalising an agreement to confirm the roles and responsibilities of each agency and to ensure New Zealand meets its APA and portfolio management obligations

- s) **Note** subject to recommendation j) and p), the remaining obligations and portfolio management of the AstraZeneca APA will be transferred to Pharmac through a future novation deed
- t) **Agree** that officials invite the Director-General of Health, the Minister of Finance and the Chief Executive and Chair of Pharmac to execute the deed of novation once finalised  **Yes**  **No**

Rt Hon Jacinda Ardern

**Prime Minister**

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Hon Andrew Little

**Minister of Health**

8/7/22

Hon Grant Robertson

**Minister of Finance**

...../...../.....

Hon Nanaia Mahuta

**Minister of Foreign Affairs**

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Hon Peeni Henare

**Associate Minister of Health**

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Hon Aupito William Sio

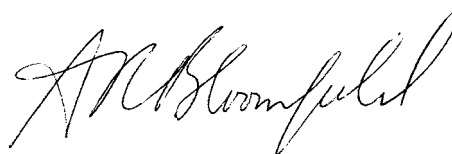
**Associate Minister of Health**

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Hon Dr Ayesha Verrall

**Minister for COVID-19 Response**

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Dr Ashley Bloomfield

**Director-General of Health**

7/07/2022

# COVID-19 Vaccine Portfolio Update – Concluding the AstraZeneca Advance Purchase Agreement

## Background

### *Vaccine Portfolio utilisation to date*

1. The four COVID-19 vaccines in our vaccine portfolio (supplied by Pfizer, Novavax, AstraZeneca, and Janssen) have been utilised in different ways to support our national response to the COVID-19 pandemic.
2. Vaccine Ministers have agreed to maintain an mRNA-based COVID-19 immunisation programme in 2022 through the primary use of the Pfizer vaccine, but previously agreed to the use of AstraZeneca’s vaccine as an alternative non-mRNA vaccine for those hesitant or unable to receive Pfizer from November 2021.
3. The programme has managed all 7.6 million doses of the AstraZeneca’s vaccine purchased through our APA as part of the portfolio approach. These volumes were agreed to in the early stages of the pandemic to secure access to doses, subject to successful development. At the time of purchase, Vaccine Ministers agreed to the drawdown of **§ 9(2)(b)(ii)** to cover the cost of vaccine doses and to include a contingency to manage exchange rate fluctuations [MBIE 2021-1537 refers].
4. As the COVID-19 Immunisation Programme shifted to a primarily Pfizer vaccine, officials have utilised AstraZeneca doses through a series of dose donation agreements, summarised in Table 1 below.

*Table 1. Dose donation for AstraZeneca*

Date	Agreed action by Vaccine Ministers
July 2021	Donate 708,400 doses from our APA to the COVAX AMC [HR 2021664 refers]
Late Oct 2021	Access 100,000 doses from Australia’s in exchange for later repayment due to delays in Janssen vaccine availability [HR 20212271 refers]
Nov 2021	Donate 5.8 million doses to COVAX AMC, and to maintain access to 1 million doses for domestic use [HR 20212485 refers]
Jan 2022	Obtain 10,000 – 20,000 doses to ensure enough supply to support primary and booster requirements [HR 20220023 refers]
Apr 2022	<b>§ 9(2)(b)(ii)</b> the remaining 991,000 doses available under the APA <b>§ 9(2)(b)(ii)</b> decline delivery of doses [HR 20220260 refers]

5. In 2022, the global supply of AstraZeneca's vaccine has exceeded demand. In June 2022, we advised Ministers that 3.5 million of our donated doses were not needed by developing countries and would expire in May 2022 without being used. As doses with later expiry dates have reached the end of their shelf life this volume has since increased to 5.67 million.

#### *COVID-19 Vaccine APAs to transfer to Pharmac*

6. In May 2022, Cabinet agreed to transfer the responsibility of purchasing and management of COVID-19 vaccines to Pharmac from 1 July 2022 [SWC-22-MIN-0092]. The timing was considered appropriate with the continued stabilisation of the pandemic.
7. Through the transfer, the Ministry has been working with Pharmac and suppliers to ensure any contractual obligations under the current APAs continue to be met.

### **Remaining financial payments for AstraZeneca doses**

8. The AstraZeneca APA was drafted in line with its not-for-profit approach to COVID-19 vaccines. § 9(2)(b)(ii)  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]
9. New Zealand has also entered a Tripartite Dose Sharing Agreement with AstraZeneca and COVAX to enable the donation of doses from our AstraZeneca APA to COVAX. New Zealand agreed to pay for ancillary costs using the Ministry of Foreign Affairs and Trade International Development Cooperation budget.

#### *Additional costs under the APA*

10. § 9(2)(b)(ii) the remaining 991,000 doses under the APA § 9(2)(b)(ii) are expected to expire unutilised. Following the previous direction by Ministers to not accept receipt of doses [HR 20220573 refers], officials have been working with AstraZeneca to finalise the associated payments and manage any remaining obligations.
11. AstraZeneca has separately advised of additional costs related to New Zealand's previous donations of doses to COVAX. These include the disposal costs for expiring doses donated by New Zealand, and other costs linked to the successful donation of doses (such as local value-added taxes in the countries of manufacture).
12. In total, an estimated 6.8 million doses will incur additional costs linked to:
  - a. a destruction cost for expired doses or repacking cost for successful donations of § 9(2)(b)(ii) per dose
  - b. an indirect tax per dose for donations or destruction depending whether it occurred § 9(2)(b)(ii)  
[REDACTED]
13. AstraZeneca has advised that of the total 6.8 million doses, the majority have been manufactured and stored in the United States (approximately 6 million doses) and will not incur an additional tax. Officials are seeking clarification on the approximately



800,000 remaining doses, which were either stored or donated from s 9(2)(b)(ii) or the s 9(2)(b)(ii) impacting the total additional costs.

14. Officials estimate the total additional costs and taxes range between s 9(2)(b)(ii) and s 9(2)(b)(ii). Officials note the costs can be met through the underspend of the original s 9(2)(b)(ii) of funding drawn down. An estimated s 9(2)(b)(ii) will remain unspent as a result of the margin included in the original draw down to address foreign exchange rate fluctuations.

*Ancillary costs cannot be used to cover these additional costs*

15. Officials advise it is not appropriate to require COVAX to use the ancillary cost grant (from the Ministry of Foreign Affairs and Trade International Development Cooperation budget) to pay for the disposal of these doses, which were surplus to requirement in New Zealand or the additional taxes associated with successfully donated doses. We will agree with COVAX how to redirect leftover ancillary costs to support vaccine roll-out and uptake in developing countries. This will help improve vaccination coverage globally and is consistent with the purpose of the International Development Cooperation budget and Official Development Assistance guidelines.
16. While this option incurs an additional cost to manage the disposal of doses; it remains preferred as it reduces the logistical burden and associated costs to transport and dispose of doses in New Zealand, which do not have an expected use case domestically.
17. **Officials are seeking your agreement:**
  - a. to cover the costs (estimated at s 9(2)(b)(ii)) from underspends in the previously agreed drawn down of s 9(2)(b)(ii)
  - b. to invite the Director-General of Health to sign a Letter of Agreement on behalf of the Crown to pay final costs associated with the APA.
18. Upon completion of these payments, AstraZeneca has advised there are no further deliveries under the APA, allowing New Zealand to conclude its agreement. We note in concluding the APA, there are enduring obligations (such as confidentiality) which will be managed by Pharmac in line with the ongoing transfer of the COVID-19 vaccine portfolio management function.

## **Phasing out AstraZeneca doses from the programme**

19. As agreed by Ministers, the programme has maintained a small volume of AstraZeneca doses to support primary and booster doses (off-label) to those unable or hesitant to receive the Pfizer mRNA vaccine. As of 27 June 2022, 8,800 AstraZeneca doses have been administered.<sup>1</sup>
20. In the Programme, 5,400 doses of AstraZeneca's vaccine remains in central storage with a shelf life until 5 September 2022. Officials judge this is sufficient to provide the remaining primary and boosters doses to those who have received at least one dose of AstraZeneca.

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<sup>1</sup> As of 21 June 2022, a total of 8,800 AstraZeneca has been administered by way of 1<sup>st</sup> primary (3,312), 2<sup>nd</sup> primary (3,616), 3<sup>rd</sup> primary (27) and booster (1,845)

21. As the remaining supply of AstraZeneca doses held in New Zealand is set to expire in September 2022 and no further deliveries are planned, it is recommended officials begin planning to phase out the domestic use of AstraZeneca from the Programme.
22. The Programme estimates a small number of people who are eligible but have yet to complete their courses of AstraZeneca may be affected.<sup>2</sup> Planning will be centred on ensuring they are notified of the intended change and encouraged to complete their vaccination before it takes effect.
23. The Programme will also seek to support vaccination providers and sites in managing the phasing. Changes to the booking systems, training requirements and clinical guidance as required will be made in coordination with the proposed timeline.
24. **Officials are seeking your agreement to phase out the AstraZeneca from the Programme**, primarily through proactive communications and engagement with the health sector
25. Officials note with the phasing out of AstraZeneca's vaccine from the programme, Novavax (as a non-mRNA option) and Pfizer will continue to remain available for those eligible.

### **No further action required to complete the dose exchange with Australia**

26. In October 2021, Ministers agreed a dose exchange with Australia. This enabled New Zealand to access 100,000 AstraZeneca doses from Australia's APA to provide an alternative to Pfizer and mitigate delays in receiving the Janssen vaccine. It was agreed New Zealand would return 100,000 doses at a later date.
27. AstraZeneca will redirect 100,000 doses from our APA to Australia in July. This is covered in an existing side letter agreement and no further action is required. Officials will advise if there are any issues that arise with this process.

### **Progress on the transfer of portfolio management**

28. On 18 May 2022, Cabinet agreed to transfer the purchasing and portfolio management of COVID-19 vaccines to Pharmac, including the current vaccine supplier agreements and related obligations from 1 July 2022 [SWC-22-MIN-0092]. Cabinet separately noted the continuation of the National Immunisation Programme and service provider contracts in 2022 to support the administration of COVID-19 vaccines [SWC-22-SUB-0057 refers].
29. Officials note that while suppliers are amenable to transferring the agreements to Pharmac, the novation deeds will be executed after 1 July 2022. This means agreements will be transitioned over a staggered period of time with contractual responsibility remaining with Ministry of Health until the novations have been executed.
30. To ensure the seamless transition and continued performance of the Programme, officials will finalise a joint memo between the Ministry of Health, Pharmac and Health NZ which confirms:

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<sup>2</sup> As of 27 June 2022, of the persons who have received at least 1 AstraZeneca dose, 395 persons are eligible for their second AstraZeneca dose and a further 3500 are eligible for their booster vaccination.

- a. the new roles and responsibilities of each of the agencies while noting the continuing roles of the Treasury and the Ministry of Foreign Affairs and Trade
  - b. the support each agency will provide to ensure New Zealand meets its obligations under APA contracts and portfolio management of COVID-19 vaccines.
31. This agreement is to be finalised after 1 July 2022 and signed by the respective delegates of Health NZ, the Ministry of Health and Pharmac.

*A novation has been drafted to transfer the AstraZeneca APA*

32. Officials have received the proposed novation to transfer the AstraZeneca APA and remaining obligations to Pharmac. Under this agreement, Pharmac will assume the obligations and liabilities under the APA held by the Ministry, except for the indemnities which will continue to be held by the Crown under the currently agreed arrangements.
33. Officials note, depending on Ministers' agreement to conclude the APA and finalise other commitments, that Pharmac would only manage a minimal number of responsibilities under the APA. This includes meeting existing confidentiality obligations and managing the remaining doses in New Zealand from the Programme.
34. With the signing of the joint memo outlined above, Pharmac would be supported in meeting these continuing responsibilities by the Ministry of Health and Health NZ.
35. A review of the draft novation has been completed by Health Legal, Pharmac Legal and Bell Gully, with no major concerns raised with the proposed terms of the APA. Minor amendments have been suggested for AstraZeneca to incorporate into a finalised deed for signing.
36. Pending a final legal review, the Director-General of Health, the Minister of Finance, and the Chief Executive and the Chair of Pharmac will be invited to sign and finalise the novation deed.
37. **Officials seek your agreement to transfer the remaining obligations to Pharmac through the proposed novation deed.**

## **Next steps**

38. Subject to your agreement to meet the additional costs of disposal, officials will inform AstraZeneca and COVAX of your decision and seek to finalise the additional cost of disposal and donation. Officials will invite the Director-General of Health to sign Letter of agreement on behalf of the Crown to pay final costs.
39. Subject to your agreement to phasing out the domestic use of AstraZeneca, the Programme will commence planning to utilise the remaining doses before their expiry.
40. Subject to your agreement, officials will finalise the novation deed to transfer the remaining APA obligations to Pharmac. Officials will invite the Director-General of Health, the Minister of Finance, and the Chief Executive and the Chair of Pharmac to execute the deed once it is finalised.

**ENDS.**