

MINUTES OF THE PHARMACEUTICAL MANAGEMENT AGENCY (PHARMAC)

BOARD MEETING HELD 24 FEBRUARY 2023

The meeting was held at Pharmac offices, Level 9, 40 Mercer Street, Wellington, and by zoom, and started at 9.00am with the following attendees:

Board members

Steve Maharey ((MA (Hons), CNZM))	Chair
Claudia Wyss ((BHB, MBChB, MBA Harvard))	Deputy Chair
Anthony Jordan (BHB, MBChB, FRACP)	Board member
Diana Siew (PhD)	Board member
Talia Anderson-Town (BBS, PG Dip Professional Accounting, CA, CPP)	Board member (by zoom)

Board Observers

Lisa Lawrence	Board Observer, CAC Chair (by zoom)
Jane Thomas	Observer, PTAC Chair

Pharmac staff in attendance

Sarah Fitt	Chief Executive
Michael Johnson	Director of Strategic Initiatives
Lisa Williams	Director of Operations
Kathryn McInteer	Director of Finance and Corporate
Trevor Simpson	Kaituruki Māori - Director Māori
David Hughes	Chief Medical Officer
Jannel Fisher	Acting Director of Engagement & Implementation
Lizzy Cohen	Executive Assistant to Chief Executive (minute taker)

Attendees joined the meeting to present relevant papers: Graham Durston, Evan Hinds, Geraldine MacGibbon, Ishani Noble, Jared Solloway, Josh Wiles, Logan Heyes, Sam Bright, Alexandra Compton, Andrew Davies, Danae Staples-Moon, Yazmin Juned, Brent McPherson, Jacqui Mettam, Anna Pai, Davina Carpenter, Arohia Dunn

1. Director-only Discussion

1.1 Glossary of Terms

1.2 Board Actions

The Board **noted** the Board Actions.

1.3 Board Annual Agenda 2023

The Board **noted** the Annual Agenda 2023.

1.4 Board and Committee Member Terms

The Board **noted** the Board and Committee Member terms.

1.5 Chief Executive Interim Performance Review

The Board **noted** the verbal update from the Board Chair on the Chief Executive's Interim Performance Review for 2022/23.

2. Apologies

None.

3. Record of Previous Board and Committee Meetings

3.1 Minutes of November 2022 Board Meeting held on 2 December 2022

The Board **resolved** to adopt the minutes of the November 2022 meeting as being a true and correct record.

Claudia Wyss and Talia Anderson-Town (Carried)

3.2 Minutes of Audit and Risk Committee Meeting November 2022

The Board **resolved** to adopt the minutes of the November 2022 meeting (held on 2 December 2022) as being a true and correct record.

Talia Anderson-Town and Claudia Wyss (Carried)

3.3 Annual report from Audit and Risk Committee

The 2021/22 Audit and Risk Committee's Annual Report provides the Board with an update of the Committees activities for 2021/22. The Board:

noted the 2021/22 Annual Report from the Audit and Risk Committee

noted that this report was discussed at the December 2022 Audit and Risk Committee meeting.

Talia Anderson-Town and Claudia Wyss (carried)

3.4 Health and Safety Committee Meeting Recommendations

The Board Health and Safety Committee met on 24 February 2023. The Committee Chair provided a verbal update of the meeting. The Board:

noted that the Board Health and Safety Committee reviewed the Committee's Terms of Reference which will be presented for Board endorsement at the March Board meeting.

3.5 Summary of CAC Meeting

This paper informed the Board of advice received from the Consumer Advisory Committee (CAC) at the 11 November Zoom meeting. The Board noted an update from the CAC Chair.

The Board Chair asked if the Committee have engaged enough with Medical Devices work. The CAC Chair noted that this is a topic of discussion on the Committee's annual agenda and that they can include as a topical discussion as relevant.

4. Interests Register

The Board **noted** the interests register

5. **Matters Arising**

The Board **noted** the matters arising and actions progressed.

6. **Chair's Report**

6.1 **Verbal Report**

The Board Chair provided a verbal update on the following topics:

- staff are working with the Ministers office to secure a meeting with the Minister of Health
- the Board Health and Safety office audit has been postponed, likely to happen at the March meeting
- the Chair met with Pharmac staff at the February staff meeting
- the Chair has been attending Crown Entity meetings for Board Chairs, coordinated by the Public Service Commission (PSC), noting that PSC have established a unit dedicated to providing information to support Board's in their roles, a new course at Victoria University and a new Future Directors Programme.
- noted that there is a strong focus on climate change and that staff will need to provide regular reporting to the Board

6.2 **Correspondence**

The Board **noted** the correspondence report.

7. **CE Report**

7.1 **Chief Executive's Report**

The Board **noted** the Chief Executive's Report.

noted that since the report was written, Pharmac's Briefing to the Incoming Minister of Health (BIM) had been sent on 23 February and circulated to Board members for their information. The Chief Executive noted that we are yet to have confirmation of the Ministerial List and portfolio split

noted that the Chief Executive has accepted the invitation to extend her membership on Singapore's Agency for Care Effectiveness (ACE) International Advisory Panel (IAP) and has subsequently received another request to ask Pharmac to host a visit to New Zealand in July

noted that the Ombudsman investigation into OIA timeliness and processes includes Pharmac along with six other agencies

noted that the new quarterly newsletter to the sector provides a good opportunity for us to tell our story and be open, honest and transparent with the sector and others.

7.2 **Financial Report**

This paper provides the Board with an overview of the financials for December 2022 to accompany the December 2022 financial statements.

8. Schedule and Funding

8.1 Prioritisation Report

This report described prioritisation activity since the last report presented to the Board at its October 2022 meeting. The Board:

noted the prioritisation activity undertaken by Pharmac staff since October 2022 and the progress of selected items from Pharmac's prioritisation list

noted in particular the commentary from staff in the report on equity and Māori health impact considerations in the prioritisation meetings.

8.2 CPB Management Report

This paper provided the Board with an update on the Combined Pharmaceutical Budget, including the February 2023 expenditure forecast. This aims to enable a wider discussion by the Board regarding planned activities to manage expenditure in 2022/23 and out-years. It also provided an update on COVID-19-related CPB costs incurred and any associated risks.

noted that expenditure and budget management options for COVID-19 treatments and vaccines is discussed as a separate paper at this Board meeting.

8.3 Pharmaceutical Transactions Report

This paper provided the Board with an advanced overview of current issues relating to management of the Combined Pharmaceutical Budget (CPB), including (non-COVID-19) vaccines, current significant supply issues and the contentious, large or significant pharmaceutical transactions and investments that staff are currently progressing. An update on Pharmac's work on vaccines and treatments for COVID-19 is presented in a separate paper at this Board meeting. The Board:

noted the update on current issues and the large and/or significant medicines transactions that are currently planned or in progress

noted that the Combined Pharmaceutical Budget expenditure update that is usually provided in this paper is addressed in the separate budget management options paper (refer to CPB Management Report)

noted that content relating to COVID-19 vaccines and treatments, that was previously in this report, has been presented as a separate item (refer to COVID-19 Treatments and Vaccine Update)

8.4 COVID-19 Treatments and Vaccine Update

This paper provided the Board with an overview of Pharmac's work to secure COVID-19 treatments and vaccines. The Board:

noted the update on Pharmac's COVID-19 treatments and vaccines work and that that staff intend to provide a regular update to the Board on this work.

Anthony Jordan and Diana Siew

(carried)

8.5 Proposal to fund immune checkpoint inhibitors for the treatment of advanced non-small cell lung cancer

This paper was presented for Board decision on a significant pharmaceutical transaction which would result in a new listing and amendments to contractual arrangements for an already funded treatment. The Board:

resolved to list atezolizumab (Tecentriq) in the Pharmaceutical Schedule

resolved to approve the 13 December 2022 agreement with Merck Sharp & Dohme (New Zealand) Limited

resolved to approve the 8 December 2022 agreement with Roche Products (New Zealand) Limited

resolved that the consultation on this proposal was appropriate, and no further consultation is required

noted that the consultation responses were supportive of this proposal

noted the significant service impact on the sector which staff have been proactively working with sector partners on. For example, staff have been in discussions with Sector partners (Te Whatu Ora, Te aho o Te Kahu, Te Aka Whai Ora) to support increasing capacity to accommodate the significant increase in service requirements. In addition, the Cancer Society are looking into increasing capacity to support travel for people to their appointments to access treatment. It was also noted that staff have been discussing service impacts with Te Whatu Ora, noting that compounding is required

noted that after releasing the RFP, in August 2022, Pharmac staff ran a multi-stakeholder meeting with sector representatives, clinicians and consumer groups to raise awareness of the potential outcomes of this RFP, as well as the significant impacts that would be expected to occur as a result at this early juncture. The Board were pleased to hear that this meeting was well attended with over 30 people in attendance

noted that Pharmac staff are working with the sector on horizon scanning and planning for future funding decisions, particularly for cancer treatments to ensure service impacts of these decisions are worked through to aid with implementation

noted that impact data is held by Te Whatu Ora

resolved to approve the amendments to the Pharmaceutical Schedule relating to pembrolizumab (Keytruda) as set out below.

Claudia Wyss and Anthony Jordan

(carried)

Special Authority for Subsidy

Initial application - (non-small cell lung cancer first-line monotherapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist.

Approvals valid for 3 months for applications meeting the following criteria:

Either:

1. Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
2. All of the following:

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- 2.1. Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
- 2.2. Patient has not had chemotherapy for their disease in the palliative setting; and
- 2.3. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
- 2.4. There is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
- 2.5. Pembrolizumab to be used as monotherapy; and
- 2.6. Either:
 - 2.6.1. There is documentation confirming the disease expresses PD-L1 at a level $\geq 50\%$ as determined by a validated test unless not possible to ascertain; or
 - 2.6.2. Both:
 - 2.6.2.1. There is documentation confirming the disease expresses PD-L1 at a level $\geq 1\%$ as determined by a validated test unless not possible to ascertain; and
 - 2.6.2.2. Chemotherapy is determined to be not in the best interest of the patient based on clinician assessment; and
- 2.7. Patient has an ECOG 0-2; and
- 2.8. Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 12 weeks; and
- 2.9. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal – (non-small cell lung cancer first line monotherapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following

1. Any of the following:
 - 1.1. Patient's disease has had a complete response to treatment; or
 - 1.2. Patient's disease has had a partial response to treatment; or
 - 1.3. Patient has stable disease; and
2. Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
3. No evidence of disease progression; and
4. The treatment remains clinically appropriate and patient is benefitting from treatment; and
5. Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
6. Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application - (non-small cell lung cancer first-line combination therapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

1. Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
2. All of the following:
 - 2.1. Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
 - 2.2. The patient has not had chemotherapy for their disease in the palliative setting; and
 - 2.3. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
 - 2.4. There is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
 - 2.5. Pembrolizumab to be used in combination with platinum-based chemotherapy; and
 - 2.6. Patient has an ECOG 0-2; and
 - 2.7. Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 12 weeks; and
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- ~~1. Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or~~
2. All of the following:
 - ~~2.1.~~ 1. Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
 - ~~2.2.~~ 2. Patient has not had chemotherapy for their disease in the palliative setting; and
 - ~~2.3.~~ 3. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
 - ~~2.4.~~ 4. There is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
 - ~~2.5.~~ 5. Pembrolizumab to be used as monotherapy; and
 - ~~2.6.~~ 6. Either:
 - ~~2.6.1.~~ 6.1 There is documentation confirming the disease expresses PD-L1 at a level $\geq 50\%$ as determined by a validated test unless not possible to ascertain; or
 - ~~2.6.2.~~ 6.2 Both:
 - ~~2.6.2.1.~~ 6.2.1 There is documentation confirming the disease expresses PD-L1 at a level $\geq 1\%$ as determined by a validated test unless not possible to ascertain; and
 - ~~2.6.2.2.~~ 6.2.2 Chemotherapy is determined to be not in the best interest of the patient based on clinician assessment; and
 - ~~2.7.~~ 7. Patient has an ECOG 0-2; and
 - ~~2.8.~~ 8. Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 12 weeks; and
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4. The treatment remains clinically appropriate and patient is benefitting from treatment; and
5. Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and

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6. Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

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Either:

- ~~1. Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or~~
2. All of the following:
 - ~~2.1.~~ 1. Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
 - ~~2.2.~~ 2. The patient has not had chemotherapy for their disease in the palliative setting; and
 - ~~2.3.~~ 3. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
 - ~~2.4.~~ 4. There is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
 - ~~2.5.~~ 5. Pembrolizumab to be used in combination with platinum-based chemotherapy; and
 - ~~2.6.~~ 6. Patient has an ECOG 0-2; and
 - ~~2.7.~~ 7. Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 12 weeks; and
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5. Pembrolizumab to be used at a maximum dose of 200mg every three weeks (or equivalent); and
6. Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent).

Restricted

Initiation - non-small cell lung cancer first-line monotherapy

Medical oncologist or any relevant practitioner on the recommendation of a medical oncologist

Reassessment required after 3 months

Either:

1. Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
2. All of the following:
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2.6.2.1. There is documentation confirming the disease expresses PD-L1 at a level $\geq 1\%$ as determined by a validated test unless not possible to ascertain; and

2.6.2.2. Chemotherapy is determined to be not in the best interest of the patient based on clinician assessment; and

- 2.7. Patient has an ECOG 0-2; and
- 2.8. Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 12 weeks; and
- 2.9. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Continuation - non-small cell lung cancer first-line monotherapy

Medical oncologist or any relevant practitioner on the recommendation of a medical oncologist
Re-assessment required after 3 months

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1. Any of the following:
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2. All of the following:
 - ~~2.1.~~ 1. Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
 - ~~2.2.~~ 2. The patient has not had chemotherapy for their disease in the palliative setting; and

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- ~~2-3.~~ 3. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
- ~~2-4.~~ 4. There is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
- ~~2-5.~~ 5. Pembrolizumab to be used in combination with platinum-based chemotherapy; and
- ~~2-6.~~ 6. Patient has an ECOG 0-2; and
- ~~2-7.~~ 7. Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 12 weeks; and
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3. No evidence of disease progression; and
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6. Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Special Authority for Subsidy

Initial application - (non-small cell lung cancer second line monotherapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist.

Approvals valid for 3 months for applications meeting the following criteria:

Either:

1. Patient is currently on treatment with atezolizumab and met all remaining criteria below prior to commencing treatment; or
2. All of the following:
 - 2.1. Patient has locally advanced or metastatic non-small cell lung cancer; and
 - 2.2. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
 - 2.3. There is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
 - 2.4. Patient has an ECOG 0-2; and
 - 2.5. Patient has documented disease progression following treatment with at least two cycles of platinum-based chemotherapy; and
 - 2.6. Atezolizumab is to be used as monotherapy at a dose of 1200 mg every three weeks (or equivalent) for a maximum of 12 weeks; and
 - 2.7. Baseline measurement of overall tumour burden is documented clinically and radiologically.

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 - ~~2.2.~~ 2. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
 - ~~2.3.~~ 3. There is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
 - ~~2.4.~~ 4. Patient has an ECOG 0-2; and
 - ~~2.5.~~ 5. Patient has documented disease progression following treatment with at least two cycles of platinum-based chemotherapy; and
 - ~~2.6.~~ 6. Atezolizumab is to be used as monotherapy at a dose of 1200 mg every three weeks (or equivalent) for a maximum of 12 weeks; and
 - ~~2.7.~~ 7. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal – (non-small cell lung cancer second line monotherapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist.

Approvals valid for 3 months for applications meeting the following criteria:

All of the following

1. Any of the following:
 - 1.1. Patient's disease has had a complete response to treatment; or
 - 1.2. Patient's disease has had a partial response to treatment; or
 - 1.3. Patient has stable disease; and
2. Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
3. No evidence of disease progression; and
4. The treatment remains clinically appropriate and patient is benefitting from treatment; and
5. Atezolizumab to be used at a maximum dose of 1200 mg every three weeks (or equivalent); and
6. Treatment with atezolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Restricted

Initiation - non-small cell lung cancer second line monotherapy

Medical oncologist or any relevant practitioner on the recommendation of a medical oncologist

Reassessment required after 3 months

Either:

1. Patient is currently on treatment with atezolizumab and met all remaining criteria below prior to commencing treatment; or
2. All of the following:
 - 2.1. Patient has locally advanced or metastatic non-small cell lung cancer; and
 - 2.2. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
 - 2.3. There is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
 - 2.4. Patient has an ECOG 0-2; and
 - 2.5. Patient has documented disease progression following treatment with at least two cycles of platinum-based chemotherapy; and
 - 2.6. Atezolizumab is to be used as monotherapy at a dose of 1200 mg every three weeks (or equivalent) for a maximum of 12 weeks; and
 - 2.7. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Continuation - non-small cell lung cancer second line monotherapy

Medical oncologist or any relevant practitioner on the recommendation of a medical oncologist

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Re-assessment required after 3 months

All of the following

1. Any of the following:
 - 1.1. Patient's disease has had a complete response to treatment; or
 - 1.2. Patient's disease has had a partial response to treatment; or
 - 1.3. Patient has stable disease; and
2. Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
3. No evidence of disease progression; and
4. The treatment remains clinically appropriate and patient is benefitting from treatment; and
5. Atezolizumab to be used at a maximum dose of 1200 mg every three weeks (or equivalent); and
6. Treatment with atezolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initiation - non-small cell lung cancer second line monotherapy

Medical oncologist or any relevant practitioner on the recommendation of a medical oncologist

Reassessment required after 3 months

~~Either:~~

- ~~1. Patient is currently on treatment with atezolizumab and met all remaining criteria below prior to commencing treatment; or~~
2. All of the following:
 - ~~2.1.~~ 1. Patient has locally advanced or metastatic non-small cell lung cancer; and
 - ~~2.2.~~ 2. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
 - ~~2.3.~~ 3. There is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
 - ~~2.4.~~ 4. Patient has an ECOG 0-2; and
 - ~~2.5.~~ 5. Patient has documented disease progression following treatment with at least two cycles of platinum-based chemotherapy; and
 - ~~2.6.~~ 6. Atezolizumab is to be used as monotherapy at a dose of 1200 mg every three weeks (or equivalent) for a maximum of 12 weeks; and
 - ~~2.7.~~ 7. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Continuation - non-small cell lung cancer second line monotherapy

Medical oncologist or any relevant practitioner on the recommendation of a medical oncologist

Re-assessment required after 3 months

All of the following

1. Any of the following:
 - 1.1. Patient's disease has had a complete response to treatment; or
 - 1.2. Patient's disease has had a partial response to treatment; or
 - 1.3. Patient has stable disease; and
2. Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
3. No evidence of disease progression; and
4. The treatment remains clinically appropriate and patient is benefitting from treatment; and
5. Atezolizumab to be used at a maximum dose of 1200 mg every three weeks (or equivalent); and
6. Treatment with atezolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

8.6 Proposal to fund elxacaftor with tezacaftor and ivacaftor (Trikafta) for cystic fibrosis for people 6 years of age and older

This paper was presented for Board decision on a significant pharmaceutical investment transaction that would result in a new listing to address a high unmet health need. The Board:

resolved to approve the 1 December 2022 agreement with Vertex Pharmaceuticals (Australia) Pty. Ltd

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resolved that the consultation on this proposal was appropriate, and no further consultation is required

noted that consultation feedback was supportive and as such, there were no changes made to this proposal

noted that while the feedback from pharmacists was around access to treatments rather than the impact on pharmacies due to dispensing fees, the Board noted the challenges with the Pharmacy contract model and high cost medicines

noted the cost of funding treatments like this in the longer-term and that if Pharmac was to experience budget constraints, there are mitigation strategies

resolved to list elexacaftor with tezacaftor, ivacaftor and ivacaftor (Trikafta) on the Pharmaceutical Schedule, as set out below

Anthony Jordan and Diana Siew

(carried)

Chemical	Presentation	Brand	Pack Size	Price and subsidy (ex-man., ex. GST)
Elexacaftor with tezacaftor, ivacaftor and ivacaftor	Tab elexacaftor 100 mg with tezacaftor 50 mg, ivacaftor 75 mg and ivacaftor 150 mg	Trikafta	84	\$27,647.39
Elexacaftor with tezacaftor, ivacaftor and ivacaftor	Tab elexacaftor 50 mg with tezacaftor 25 mg, ivacaftor 37.5 mg and ivacaftor 75 mg	Trikafta	84	\$27,647.39

Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

1. Patient has been diagnosed with cystic fibrosis; and
2. Patient is 6 years of age or older; and
3. Either:
 - 3.1. Patient has two cystic fibrosis-causing mutations in the cystic fibrosis transmembrane regulator (CFTR) gene (one from each parental allele); or
 - 3.2. Patient has a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system; and
4. Either:
 - 4.1. Patient has a heterozygous or homozygous F508del mutation; or
 - 4.2. Patient has a G551D mutation or other mutation responsive in vitro to elexacaftor/tezacaftor/ivacaftor (see note a); and
5. The treatment must be the sole funded CFTR modulator therapy for this condition; and
6. Treatment with elexacaftor/tezacaftor/ivacaftor must be given concomitantly with standard therapy for this condition.

Notes

- a) Eligible mutations are listed in the Food and Drug Administration (FDA) Trikafta prescribing information

https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212273s004lbl.pdf.

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Restricted

Initiation

All of the following:

1. Patient has been diagnosed with cystic fibrosis; and
2. Patient is 6 years of age or older; and
3. Either:
 - 3.1. Patient has two cystic fibrosis-causing mutations in the cystic fibrosis transmembrane regulator (CFTR) gene (one from each parental allele); or
 - 3.2. Patient has a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system; and
4. Either:
 - 4.1. Patient has a heterozygous or homozygous F508del mutation; or
 - 4.2. Patient has a G551D mutation or other mutation responsive in vitro to elexacaftor/tezacaftor/ivacaftor (see note a); and
5. The treatment must be the sole funded CFTR modulator therapy for this condition; and
6. Treatment with elexacaftor/tezacaftor/ivacaftor must be given concomitantly with standard therapy for this condition.

Notes

Eligible mutations are listed in the Food and Drug Administration (FDA) Trikafta prescribing information https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212273s004lbl.pdf.

Two Board papers were moved up the meeting agenda to accommodate the CAC Chair needing to leave the meeting at 12.00 pm.

9.1 Board Statutory Committee Appointment Recommendation

This paper was presented seeking Board agreement on the recommended appointment of a new member of the Consumer Advisory Committee (CAC). The Board:

resolved to appoint Georgina Johnson to the Consumer Advisory Committee for a period of three years from 1 March 2023.

Claudia Wyss and Talia Anderson-Town

(carried)

9.3 Update to Board Governance Manual

This paper was presented for Board feedback on a revised approach to Board attendees/Observers. It also sought Board agreement to update the Board Governance Manual to reflect COI Model Standards issued by Te Kawa Mataaho | Public Service Commission The Board:

Board Observers

noted that the Consumer Advisory Committee (CAC) and Pharmacology and Therapeutics Advisory Committees (PTAC) are Board advisory committees established by the Board under the Crown Entities Act and that the Chairs attendance at Board offers a long-standing link to the expertise of those two committees

noted that with system changes introduced by the Pae Ora (Healthy Futures) Act 2022 (Pae Ora Act), including the disestablishment of the District Health Boards and establishment of Te Whatu Ora and Te Aka Whai Ora, and, separately, the establishment of te Rōpū, as well as the expectations created by the Health Sector Principles around engagement and collaboration, it is timely to review the purpose and responsibilities of Board Observer roles

noted the Health Sector Principles elevate the importance of good engagement and that there are a range of potential mechanisms available to develop and build

strategic relationships with key partners such as Te Whatu Ora, Te Aka Whai Ora, Whaikaha and te Rōpū that may better deliver on this expectation and support the delivery of a more integrated health system

noted that staff are developing an engagement strategy with key stakeholders and that this work will assist in identifying how we best engage and grow these strategic partnerships and what this engagement looks like, including at Board level engagement

Conflicts of Interest

noted that staff have updated the Board Governance Manual Conflicts of Interest (COI) guidance to reflect recently issued Te Kawa Mataaho | Public Service Commission Model Standards

approved the proposed minor amendments to the COI guidance

Anthony Jordan and Talia Anderson-Town **(carried)**

Lisa Lawrence, CAC Chair left the meeting.

8.7 Medical Devices Transactions Report

This paper provided a monthly update to the Board on progress with medical devices national contracting activity.

The Board

agreed that for future Board reporting, this report and the medical devices programme update report will now be discussed together.

8.8 Medical Devices Programme Update – Dashboard Report

This paper provided a bi-monthly update to the Board on progress of the Medical Device Programme. The Board:

noted the update on progress with the Medical Device Programme

noted that Pharmac, along with others internationally, are still working on a definition of medical devices. In the meantime, Pharmac is mirroring the definition of the World Health Organisation

noted that the Board Chair had a FPIM governance group meeting on 23 February and that some issues have been identified to the group by the project team. The Chair noted that while these are not issues within Pharmac's control, it is important to be aware of, and encourage people to surface any issues with FPIM, due to the impact on Pharmac's medical devices programme and so we can be ready to deliver. Staff also noted that another foreseeable issue is the integration of FPIM and the Health Sector Catalogue.

8.9 Summary of Decisions made under Delegated Authority – November 2022 to January 2023

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This report provided the Board with a summary of all decisions made by Pharmac staff under delegated authority during December 2022 and January 2023. The Board:

noted the summary of decisions made under Delegated Authority during November and December 2022, and January 2023 by the Chief Executive, Director of Operations, Manager Pharmaceutical Funding, Senior Advisor/Team Leader and Senior Therapeutic Group Manages/Team Leaders

noted the error in the report under Teva price increase (Roxithromycin, Flecainide and Cetirizine), the cetirizine hydrochloride dose is 10mg not 100 mg.

9. Key Items

9.1 Board Statutory Committee Appointment Recommendation

This paper was discussed earlier in the meeting.

9.2 International Travel Plan - 2023/24

The international travel plan provided the Board with estimated costs for international travel that staff may take for the 2023/24 financial year. This will assist the Board in assessing future business cases for specific international travel requests. The paper does not consider travel to Australia given such travel does not require Board approval under the Pharmac Travel Policy. The Board:

noted the 2023/24 plan for Pharmac staff international travel

noted their support for staff to travel and re-engage with international relationships, particularly after travel restrictions due to COVID-19

requested that staff include in international travel requests the rationale for staff travel being essential to attend in person rather than remotely

noted that Anthony Jordan will share the details of a Rare Diseases Forum which may be of interest for staff to attend.

9.3 Update to Board Governance Manual

This paper was discussed earlier in the meeting.

10. Strategic Planning and Policy

10.1 Update on Strategy Work Programme

This paper provided an update to the Board on progress of our strategic work programme following the Board strategy workshop held on 29 September 2022. It included an outline of next steps over coming months that will lead to the publication of Pharmac's next Statement of Intent 2023/24 – 2026/27 and the 2023/24 Statement of Performance Expectations by 30 June 2023. The Board:

noted the progress to refine the organisational vision and proposed strategic priorities since the Board strategy workshop held on 29 September 2022

noted that the Board will consider the draft 2023/24 – 2026/27 Statement of Intent and draft 2023/24 Statement of Performance Expectations at its March 2023 meeting

noted the next steps and timeframes for finalising the Statement of Intent, Statement of Performance Expectations and future work programme.

10.2 Pharmac 2022/23 Quarter Two Performance Report

This paper provided a summary of the progress of our reporting commitments (initiatives and measures) as outlined in Pharmac's 2022/23 Statement of Performance Expectations (SPE). Pharmac staff have also undertaken a mid-year assessment of our ability to report against our SPE performance measures and presented detail to the Board on the measures which we may not be able to report on at year end and subsequently in our 2022/23 Annual Report. The Board:

noted the quarterly performance report and that the measures are likely to change with the development of our new Statement of Intent

noted the summary assessment of performance measures at risk, which are largely due to factors outside of our control

agreed there will be no stakeholder survey conducted in 2023

noted that all initiatives are underway and that we can demonstrate progress for all of them

noted that Te Aka Whai Ora are planning a forum for Māori to have strategic, across sector discussions, noting that there are limited specialist Māori clinicians and that organisations are working to achieve te Tiriti accountability

noted that the Tupu Toa internship provides a good pipeline of Māori staff coming into our organisation

noted that the next report to the Board will include, what measures are coming off and the messaging, and the framework to assess the measures which identifies what is in our control and outside of our control, resource implications etc.

10.3 People and Capability Strategy Progress Report

This paper provided the Board with an overview of the People and Capability Strategy (Strategy) work programme that is driven by the Human Resources (HR) team. The paper also provided an update on our areas of future focus.

noted the work programme update of the people and capability strategy programme and the progress made since the last Board update in September 2022

noted the work scheduled for the next quarter

noted that they would like staff to report back on hybrid working – what is our policy for working from home, what is the research showing us, what are other organisations doing.

10.4 Te Pātaka Whaioranga Pharmac's te Tiriti o Waitangi policy

noted that Te Pātaka Whaioranga Pharmac's te Tiriti o Waitangi policy was noted by the Board at the November 2022 meeting

noted that the Chief Executive and Director Māori jointly approved Te Pātaka Whaioranga Pharmac's te Tiriti o Waitangi Policy in 2022

endorsed the content of the policy and the accompanying addendum to the policy.

Anthony Jordan and Talia Anderson-Town

(carried)

11.0 Regular Reporting

11.1 Legal Report

Pharmac's legal team provides legal oversight of all contracts, and supports decision making processes as required, including for those matters that come before the Board. The legal report provides an update regarding any specific legal matters where awareness at Board level is appropriate, but which are not otherwise addressed in reports to the Board.

11.2 Communications Report

This paper provided the Board with a summary of the communications and engagement activity for December 2022 and January 2023 and the impact of our work. The Board:

noted that in December and January there were seven proactive media releases, which resulted in a significant amount of positive coverage

noted that we have modified our approach to issuing media releases under embargo following feedback about our approach used for the Trikafta announcement

noted that Pharmac's media impact score for the last quarter (October to December) was 1.2 which was the most positive score for the year

noted that information about brand changes and supply issues is reaching more people because of our partnership with Health Navigator

noted that Health Navigator is just one communication tool that we use to distribute information to people

noted that we do not intend to run an external stakeholder survey in 2022/23

noted that Pharmac and HQSC funded consumer research and the findings will influence our implementation and communications activities.

11.3 Quarter Two Risk Report and Register

The full risk register has been considered by the Audit and Risk Committee and provided to the Board as an information item. The purpose of the risk management programme, and this paper summarising its status, is to identify potential problems before they occur, or, in the case of mitigation or improvement opportunities, to ensure that positive action steps are taken. The Board:

noted the risk register (attached as Appendix One), which provides a summary of current and ongoing risks of relevance to the Board for the second quarter

noted that the quarter two risk register will be included in the quarterly report to the Minister of Health following the February Board meeting

12. Interest Articles

The Board **noted** the interest articles.

13. General Business

A farewell and appreciation were given to Claudia Wyss who plans to resign from the Board as Deputy Chair and Board member.

The meeting closed at 2.24pm with a karakia.

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Date of Next Meeting

The date for the next Board meeting is set for 31 March 2023

Chair: _____
Steve Maharey

Date: _____