

MINUTES OF THE PHARMACEUTICAL MANAGEMENT AGENCY (PHARMAC)

BOARD MEETING HELD 31 MARCH 2023

The meeting was held at Pharmac offices, Level 9, 40 Mercer Street, Wellington, and by zoom, and started at 9.05am with the following attendees:

Board members

Steve Maharey ((MA (Hons), CNZM))	Chair
Anthony Jordan (BHB, MBChB, FRACP)	Board member
Talia Anderson-Town (BBS, PG Dip Professional Accounting, CA, CPP)	Board member

Apologies

Claudia Wyss ((BHB, MBChB, MBA Harvard))	Deputy Chair
Jane Thomas	Observer, PTAC Chair
Diana Siew (PhD)	Board member

Board Observers

Lisa Lawrence	Board Observer, CAC Chair
Rhiannon Braund	Board Observer, PTAC Deputy Chair
Peter Bramley	Board Observer

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
Arohia Dunn	Board Secretary

Attendees joined the meeting to present relevant papers: *Graham Durston, Gillian Anderson, Brent McPherson, Leanne Manson, Geraldine MacGibbon, Lauren Ramanos, Chris Gilman, Caroline de Luca, Jared Solloway, Andrew Davies, Davina Carpenter, Jane Wright, Yazmin Juned and Ishani Noble*

1. Director-only Discussion

The Board had a director-only discussion.

1.1 External Speaker

The Board welcomed Victor Goldsmith, Director, The Office for Māori Crown Relations, as the external speaker. Victor addressed the Te Arawhiti guidelines for engagement, which Pharmac have committed to as a strategic priority in Te Whaioranga and now a component of our Tiriti o Waitangi policy. This links back to the overall kaupapa of Te Whaioranga for this meeting. Victor shared some examples of public sector organisations who have implemented the framework to a very high standard and how Te Whaioranga might get there, key elements involved in developing our own engagement strategy etc.

Victor also touched on the Te Arawhiti cultural capability framework- cultural capability being another strategic priority in Te Whaioranga.

1.2 Glossary of Terms

1.3 Board Actions

The Board **noted** the Board Actions.

1.4 Board Annual Agenda 2023

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

1.5 Board and Committee Member Terms

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

3. Record of Previous Board and Committee Meetings

3.1 Minutes of February 2023 Board Meeting held on 24 February 2023

The Board **resolved** to adopt the minutes of the February 2023 meeting as being a true and correct record.

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

3.2 Minutes of Health and Safety Committee Meeting 24 February 2023

The Board **resolved** to adopt the minutes of the February 2023 meeting as being a true and correct record.

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

3.3 Audit and Risk Committee Recommendations

The Audit and Risk Committee Chair provided a verbal update on the Audit and Risk Committee recommendations.

3.4 Health and Safety Terms of Reference

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.

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

3.5 Summary of PTAC Meeting

This paper sought to inform the Board of recommendations made and advice given by PTAC at its November 2022 meeting held on 17 and 18 November 2022 in

person. It was noted that PTAC has updated its Terms of Reference, which also aligned with changing of the Chair.

The Committee:

noted the following summary of the record of the Pharmacology and Therapeutics Advisory Committee (PTAC) meeting held on 17 and 18 November 2022 in person

noted the November 2022 PTAC record was signed off by the Chair on 14 February 2023 and is published on the Pharmac website.

3.6 **Summary of CAC Meeting**

This paper informed the Board of advice received from the Consumer Advisory Committee at the 17 February 2023 Zoom meeting.

The Committee:

noted the minutes from the February Consumer Advisory Committee meeting.

noted the summary of key issues across the meeting.

4. **Interests Register**

The Board **noted** and **updated** 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.

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.

7.2 **Financial Report**

This paper provided the Board with an update on the pharmaceutical budget expenditure, associated risks, and our approach to managing the CPB, to update the Board on COVID-19 expenditure and forecasting, and to provide the Board with an overview of financials for February 2023.

The Committee:

noted the February 2023 financials.

8. Key Items

8.1 PTAC Appointments

This paper provided the Board with the process followed and final recommendation with regards to appointing six new members to PTAC.

The Committee:

noted that there are a number of current and upcoming vacancies on PTAC

resolved to recommend to the Director-General of Health the appointment of Matthew Dawes as a member of Pharmacology and Therapeutics Advisory Committee (PTAC) for a period of three years beginning 20 April 2023

resolved to recommend to the Director-General of Health the appointment of John Mottershead as a member of Pharmacology and Therapeutics Advisory Committee (PTAC) for a period of three years beginning 20 April 2023

resolved to recommend to the Director-General of Health the appointment of Paul Vroegop as a member of PTAC for a period of three years beginning 20 July 2023

resolved to recommend to the Director-General of Health the appointment of Liza Lack as a member of PTAC for a period of three years beginning 20 July 2023

resolved to recommend to the Director-General of Health the appointment of James Le Fevre as a member of PTAC for a period of three years beginning 20 October 2023

resolved to recommend to the Director-General of Health the appointment of Helen Maria Evans as a member of PTAC for a period of three years beginning 20 October 2023.

Anthony Jordan and Talia Anderson-Brown

(Carried)

8.2 Supply Chain Update

This paper is the six-monthly update to the Board on Pharmac's supply chain risk mitigation and management. Included in this report are updates on the following key areas:

- Due diligence – Supplier social sustainability
- Supply chain impacts
- Engagement with other agencies
- Event management 'in practice'
- Market exits
- Improvements in supply chain management
- Supply issues of note.

The Committee:

- **noted** that a continuous improvement and wānanga approach continues to be used for how Pharmac manages and mitigates risks in the supply chain
- **noted** the tūhono with other government agencies Pharmac engages with in relation to supply chain management
- **noted** we have tested the Event Management Plan in response to Cyclone Gabrielle.

9. Strategic Planning and Policy

9.1 Draft 2023/24 – 2026/27 Statement of Intent and 2023/24 Statement of Performance Expectations

This paper presented Pharmac's draft accountability documents, the 2023/24 - 2026/27 Statement of Intent (SOI) and the 2023/24 Statement of Performance Expectations (SPE). The Board is asked to consider the attached drafts and provide any feedback before revised draft versions are prepared for consideration by the Minister of Health and other stakeholders.

The Board noted at this time that the draft SPE is less well advanced as we have not yet received the annual Letter of Expectation from the Minister of Health and we have not had final confirmation around aspects of our operating budget for 2023/24.

noted the 2023/24 Annual Letter of Expectations from the Minister of Health has not yet been received

noted Pharmac's draft accountability documents:

- Statement of Intent 2023/24 – 2026/27 (refer to Appendix One)
- Statement of Performance Expectations 2023/24 (refer to Appendix Two)

noted that the draft Statement of Performance Expectations contains forecast financial information based on Pharmac's operating budget, which was considered by the Audit and Risk Committee on 31 March 2023

noted that further development of initiatives, performance measures and financial information will take place during April and early May

noted that the draft Statement of Intent and draft Statement of Performance Expectations will be sent to Manatū Hauora and Audit NZ for feedback and review

noted the draft Statement of Intent and draft Statement of Performance Expectations will be provided to the Minister of Health in early May for feedback

noted the final draft Statement of Intent and final draft Statement of Performance Expectations will be brought back to the Board for approval at its May 2023 meeting

noted that following Board approval at its May 2023 meeting, the Statement of Intent and Statement of Performance Expectations will be presented to the House of Representatives by 30 June 2023.

9.2 Te Whaioranga Strategy Update

This paper provided the Board with an update on *Te Rautaki o te Whaioranga*, Te Pātaka Whaioranga Pharmac's Māori Responsiveness Strategy (Te Whaioranga strategy) and an overview of work planned for the remainder of the 2022/23 year. The Board last received an update in July 2022.

The Committee:

noted progress made in 2022/23 in implementing Te Whaioranga Strategy

noted Te Whaioranga Strategy is due to be renewed in 2023 and Te Pātaka Whaioranga Pharmac staff will ensure it aligns to and reflects the direction of the Pae Ora (Healthy Futures) Act 2022 (Pae Ora), the commitments made in Te Pātaka Whaioranga Pharmac's final response to the Review and the on-going programme of work described in the current Te Whaioranga Strategy.

9.3/ Te Ropu Update

This paper provided the Board with an update on our work with Te Pātaka Whaioranga Te Rōpū Māori (Te Rōpū) and the work planned over the next three months.

The Committee:

noted the content of this paper

agreed to continue to tautoko and support this partnership and working together towards Pae Ora.

10. Schedule and Funding

10.1 Pharmaceutical Transactions Report

This paper provided the Board with an advanced overview of current issues relating to pharmaceuticals funded through the Combined Pharmaceutical Budget (CPB), including vaccines, current significant supply issues and the contentious, large or significant pharmaceutical transactions and investments that staff are currently progressing.

The Committee:

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

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

10.2 Proposal to decline NPPA applications for belzutifan

This paper sought a decision from the Board on two NPPA funding applications for belzutifan for the treatment of von Hippel-Lindau syndrome (VHLS). It also requests that the Board delegate all future decision-making for similar future NPPA funding applications for belzutifan for VHLS to the Chief Executive.

resolved to delegate decision-making on all future NPPA applications for funding for belzutifan for treatment of tumours secondary to von Hippel-Lindau syndrome to the Chief Executive

noted that funding for NPPA applications comes from the Combined Pharmaceutical Budget (CPB) and there is no ring-fenced amount set aside within the CPB for NPPA

noted that a thorough evaluation has been undertaken and all available information considered when assessing these NPPA applications.

Talia Anderson-Town and Anthony Jordan

(Carried)

10.3 Proposal to fund risdiplam for spinal muscular atrophy

This paper sought a decision from the Board on a significant pharmaceutical investment transaction that would result in a new listing.

The Committee:

resolved to list risdiplam (Evrysdi) on the Pharmaceutical Schedule, as set out in Appendix One

Chemical	Presentation	Brand	Pack size	Proposed price and subsidy
Risdiplam	Powder for oral soln 750 mcg per ml, 60 mg per bottle	Evrysdi	80 ml OP	\$14,100.00

Special Authority for Subsidy

Initiation application – (spinal muscular atrophy (SMA)) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1. Patient has genetic documentation of homozygous SMN1 gene deletion, homozygous SMN1 point mutation, or compound heterozygous mutation; and
2. Patient is 18 years of age or under; and
3. Either:
 - 3.1. Patient has experienced the defined signs and symptoms of SMA type I, II or IIIa prior to three years of age; or
 - 3.2. Both:
 - 3.2.1. Patient is pre-symptomatic; and
 - 3.2.2. Patient has three or less copies of *SMN2*

Renewal – (spinal muscular atrophy (SMA)) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1. There has been demonstrated maintenance of motor milestone function since treatment initiation; and
2. Patient does not require invasive permanent ventilation (at least 16 hours per day) in the absence of a potentially reversible cause while being treated with risdiplam; and
3. Risdiplam not to be administered in combination other SMA disease modifying treatments or gene therapy.

Restricted

Initiation

Re-assessment required after 12 months

All of the following:

1. Patient has genetic documentation of homozygous SMN1 gene deletion, homozygous SMN1 point mutation, or compound heterozygous mutation; and

VERSION FOR PUBLIC RELEASE, SOME INFORMATION
MAY HAVE BEEN EXCLUDED DUE TO CONFIDENTIALITY

2. Patient is 18 years of age or under; and
3. Either:
 - 3.1. Patient has experienced the defined signs and symptoms of SMA type I, II or IIIa prior to three years of age; or
 - 3.2. Both:
 - 3.2.1. Patient is pre-symptomatic; and
 - 3.2.2. Patient has three or less copies of *SMN2*

Continuation

Re-assessment required after 12 months

All of the following:

1. There has been demonstrated maintenance of motor milestone function since treatment initiation; and
2. Patient does not require invasive permanent ventilation (at least 16 hours per day), in the absence of a potentially reversible cause while being treated with risdiplam; and
3. Risdiplam not to be administered in combination other SMA disease modifying treatments or gene therapy.

resolved to approve the 16 January 2023 agreement with Roche Products (New Zealand) Limited

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

Anthony Jordan and Talia Anderson-Town

(Carried)

10.4 COVID-19 Vaccines and Treatments Update

This paper provided the Board with an overview of Pharmac's work to secure COVID-19 treatments and vaccines. We intend to provide a regular update to the Board.

The Committee:

noted the update on Pharmac's COVID-19 treatments and vaccines work.

Anthony Jordan and Talia Anderson-Town

(Carried)

10.5 Medical Devices Transactions Report

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

The Committee:

noted the update on progress with medical devices national contracting activity.

10.6 Summary of Decisions made under Delegated Authority – February 2023

The report presented to Board contained a summary of all decisions made by Pharmac staff under delegated authority during February 2023.

The Committee:

noted the summary of decisions made under Delegated Authority during February 2023 by the Chief Executive, Director of Operations, Manager Pharmaceutical

Funding, Senior Advisor/Team Leader and Senior Therapeutic Group Manages/Team Leaders.

11.0 Regular Reporting

11.1 Risk Report

The full risk register is 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.

For Board meetings in the intervening months, an exceptions report updates the Board on the items on the risk register that have materially changed.

The Committee:

noted the exception risk report provides an update on items on the Board risk register that have materially changed since the 2022/23 quarter two risk register which was reviewed by the Board on 24 February 2023.

11.2 Communications and Engagement Report

This paper summarised the communications and engagement activity for February 2023 and the impact of our work.

The Committee:

noted that Pharmac issued its inaugural quarterly newsletter, sharing our final response to the Pharmac Review

noted that tables on the website are now more mobile responsive, increasing accessibility and transparency

noted the engagement work occurring in the Engagement and Implementation Directorate

noted that in February there were three proactive media releases, which resulted in positive coverage

noted that Pharmac proactively released documents in response to OIA requests on the Trikafta consultation.

11.3 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, as well as regular reporting on matters where the Legal Risk Fund has been accessed.

12. Interest Articles

The Board **noted** the interest articles.

13. General Business

The meeting closed at 2.30pm with a karakia.

Date of Next Meeting

The date for the next Board meeting is set for 28 April 2023.

Chair: _____
Steve Maharey

Date: _____