

MINUTES OF THE PHARMACEUTICAL MANAGEMENT AGENCY (PHARMAC)

BOARD MEETING HELD 2 DECEMBER 2022

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))

Claudia Wyss ((BHB, MBChB, MBA Harvard))

Talia Anderson-Town (BBS, PG Dip Professional
Accounting, CA, CPP)

Chair

Deputy Chair (by zoom)

Board member

Board Observers

Peter Bramley

Lisa Lawrence

Jane Thomas

Board Observer, Te Whatu Ora representative

Board Observer, CAC Chair

Observer, PTAC Chair (by zoom)

Pharmac staff in attendance

Sarah Fitt

Michael Johnson

Peter Alsop

Lisa Williams

Kathryn McInteer

Trevor Simpson

David Hughes

Carol Morris

Chief Executive

Director of Strategic Initiatives

Director of Engagement and Implementation

Director of Operations

Director of Finance and Corporate

Kaituruki Māori - Director Māori

Chief Medical Officer

Board Secretary

Attendees joined the meeting to present relevant papers: Graham Durston, Geraldine MacGibbon, Ashton Rounthwaite, Sean Dougherty, Josh Cronin-Lampe, Caroline De Luca, Andrew Oliver, Jannel Fisher, Mako Osborne, Andrew Davies, Danae Staples-Moon (by zoom), Sandy Bhawan, and Yazmin Juned.

The Board Meeting started with a Karakia.

1. Director-only Discussion

The Board had a director-only discussion.

1.1 Glossary of Terms

1.2 Board Actions

The Board **noted** the Board Actions.

Kaituruki Māori will check alignment with Talia Anderson-Town and Anthony Jordan, Board members, in relation to attending a Rōpū meeting which is currently being organised.

Te Tiriti capability assessment anticipated to be trialled and rolled out before end of the year.

1.3 Board Annual Agenda 2022

The Board **noted** the Annual Agenda 2022.

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.

1.6 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

Anthony Jordan (BHB, MBChB, FRACP)	Board member
Diana Siew (PhD)	Board member

3. Record of Previous Board and Committee Meetings

3.1 Minutes of Board Meeting held 28 October 2022

The Board **resolved** to adopt the minutes of the 28 October 2022 meeting as being a true and correct record.

Talia Anderson-Town and Claudia Wyss **Carried**

3.2 Minutes of Health and Safety Committee Meeting of 28 October 2022

The Board **noted** the Health and Safety Committee minutes of the 28 October 2022 meeting. The minutes will be ratified at the 24 February 2023 Board meeting.

3.3 Summary of 2 December Audit and Risk Committee meeting

3.4 Minutes of 14 October 2022 CAC meeting

The Board **noted** the minutes of the 14 October 2022 CAC meeting.

3.5 Summary of August PTAC Meeting

An update of the August PTAC meeting was provided to the Board.

Equitable Access and Use discussion

A panel of external stakeholders was organised to share thoughts with Board members and to give them the opportunity to hear different perspectives on how we can work better together to improve/enhance access to and optimal use of pharmaceuticals. While it is acknowledged that medical devices and vaccines are also pharmaceuticals, the primary focus for the session was on access and use of medicines.

Each of the following members gave a short talk about what was important to them about improving access and use for optimal use of pharmaceuticals:

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- Dr Joe Bourne: Chief Medical Officer, Manatū Hauora - Ministry of Health
- Dr Margaret Wilsher: Chief Medical Officer of Te Whatu Ora Te Toka Tumai Auckland
- Dr Janice Wilson: Chief Executive, Health Quality and Safety Commission
- Dr Rawiri McKree Jansen (Ngāti Raukawa): Chief Medical Officer, Te Aka Whai Ora

The Chair thanked panellists for their input and observed messages of collaborating together and expressed the Board is excited about the joining up of a system.

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

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.

- Pharmac's Final Review response has been sent to the Minister of Health. We will look to publicly release our response once the Minister has reviewed
- Health Select Committee annual review of Pharmac questions have been received. The Committee have advised that they do not require Pharmac to provide an oral submission.

7.2 Financial Report

- The Board **noted** the October 2022 Financial report and the attached financial statements
- The Board thanked the Finance Manager for the work on the report and found the new report on forecast cashflow very useful.

8. Schedule and Funding

8.1 Pharmaceutical Expenditure and Transactions Report

The purpose of this paper is to update the Board on the combined pharmaceutical budget, COVID-19 related expenditure, associated risks, and our approach to managing the CPB.

This paper also provides the Board with an advanced overview of current issues, including COVID-19 treatments, vaccines, current significant supply issues and the contentious, large or significant pharmaceutical transactions and investments that staff are currently progressing.

Talia Anderson-Town and Claudia Wyss

Carried

8.2 Proposal to fund ustekinumab for inflammatory bowel disease and infliximab for inflammatory bowel disease-associated arthritis

This paper seeks a decision from the Board on a significant pharmaceutical transaction that would result in a new listing, widened access and amendments to contractual arrangements for an already funded treatment. It also proposes ancillary amendments to funding eligibility criteria for three treatments to align the criteria

between inflammatory bowel disease biologics, as well as between adult and paediatric patients with ulcerative colitis.

The Board, having regard to the decision-making framework set out in Pharmac's Operating Policies and Procedures:

resolved to list ustekinumab (Stelara) and widen access to infliximab (Remicade) in the Pharmaceutical Schedule

resolved to approve the amendments to the Pharmaceutical Schedule relating to infliximab (Remicade), vedolizumab (Entyvio), and adalimumab (Amgevita)

resolved to approve the 4 October 2022 listing agreement for ustekinumab (Stelara) with Janssen-Cilag Pty Ltd (Janssen)

resolved to approve the 5 October 2022 letter of amendment to the terms of listing for infliximab (Remicade) with Janssen

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

Talia Anderson-Town and Claudia Wyss

Carried

8.3 Proposal to fund nusinersen and amend listings of multiple sclerosis treatments

This paper seeks a decision from the Board on a significant pharmaceutical transaction that would result in a new listing and amendments to contractual arrangements for already funded treatments.

The Board, having regard to the decision-making framework set out in Pharmac's Operating Policies and Procedures:

resolved to list nusinersen (Spinraza) on the Pharmaceutical Schedule

resolved to approve the amendments to the Pharmaceutical Schedule relating to dimethyl fumarate (Tecfidera), interferon beta-1-alpha (Avonex and Avonex Pen) and natalizumab (Tysabri)

resolved to approve the 21 September 2022 agreement with Biogen NZ Biopharma Limited

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

noted their desire for the Board Chair or Board member to attend part of the Rare Disorders Advisory Committee meeting scheduled for 7 March 2023.

Claudia Wyss and Talia Anderson-Town

Carried

8.4 Multiproduct proposal to widen access to meningococcal B vaccine and secure ongoing supply of zoster vaccine

This paper seeks a decision from the Board on a significant pharmaceutical investment transaction that would widen access to an existing listing and secure ongoing supply for another existing listing.

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The Board, having regard to the decision-making framework set out in Pharmac's Operating Policies and Procedures:

resolved to amend the restriction for meningococcal B multicomponent vaccine (Bexsero) inj 175 mcg per 0.5 ml prefilled syringe in Section I of the Pharmaceutical Schedule from 1 March 2023 as follows (additions in bold, deletions in strikethrough):

Any of the following:

1. Three doses for children up to 12 months of age (inclusive) for primary immunisation; or
2. Up to three doses (dependent on age at first dose) for a catch-up programme for children from 13 months to 59 months of age (inclusive) for primary immunisation, from 1 March 2023 to 31 August 2025; or

Either:

1. ~~Both:~~
 1. ~~Child is under one year of age; and~~
 2. ~~Any of the following:~~
 - a) ~~up to three doses for patients pre- and post-splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post-solid organ transplant; or~~
 - b) ~~up to three doses for close contacts of meningococcal cases of any group; or~~
 - c) ~~up to three doses for child who has previously had meningococcal disease of any group; or~~
 - d) ~~up to three doses for bone marrow transplant patients; or~~
 - e) ~~up to three doses for child pre- and post-immunosuppression*[†]; or~~
3. Both:
 1. Person is one year of age or over; and
 2. Any of the following:
 - a) up to two doses and a booster every five years for patients pre- and post-splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post-solid organ transplant; or
 - b) up to two doses for close contacts of meningococcal cases of any group; or
 - c) up to two doses for person who has previously had meningococcal disease of any group; or
 - d) up to two doses for bone marrow transplant patients; or
 - e) up to two doses for person pre- and post-immunosuppression*[†]; **or**
4. Both:
 - a) Person is aged between 13 and 25 years (inclusive); and
 - b) Either:
 - i. Two doses for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons; or
 - ii. Two doses for individuals who are currently living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons, from 1 March 2023 to 28 February 2024.

*Immunosuppression due to corticosteroid or other immunosuppressive therapy must be for a period of greater than 28 days.

resolved to amend the Indication Restriction for meningococcal B multicomponent vaccine (Bexsero) inj 175 mcg per 0.5 ml prefilled syringe in Part II of Section H of the Pharmaceutical Schedule from 1 March 2023 as follows (additions in bold, deletions in strikethrough):

Restricted

Initiation – Primary immunisation for children up to 12 months of age

Therapy limited to three doses

Either:

1. Three doses for children up to 12 months of age (inclusive) for primary immunisation; or

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2. Up to three doses (dependent on age at first dose) for a catch-up programme for children from 13 months to 59 months of age (inclusive) for primary immunisation, from 1 March 2023 to 31 August 2025

~~Initiation – Infants under one year of age~~

~~Any of the following:~~

- ~~1. up to three doses for patients pre- and post-splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post-solid organ transplant; or~~
- ~~2. up to three doses for close contacts of meningococcal cases of any group; or~~
- ~~3. up to three doses for child who or has previously had meningococcal disease of any group; or~~
- ~~4. up to three doses for bone marrow transplant patients; or~~
- ~~5. up to three doses for person pre- and post-immunosuppression*~~

Initiation – Person is one year of age or over

Any of the following:

1. up to two doses and a booster every five years for patients pre- and post-splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post-solid organ transplant; or
2. up to two doses for close contacts of meningococcal cases of any group; or
3. up to two doses for person who has previously had meningococcal disease of any group; or
4. up to two doses for bone marrow transplant patients; or
5. up to two doses for person pre- and post-immunosuppression*

Initiation – Person is aged between 13 and 25 years (inclusive)

Therapy limited to two doses

Both

1. Person is aged between 13 and 25 years (inclusive); and
2. Either:
 - 2.1. Two doses for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons; or
 - 2.2. Two doses for individuals who are currently living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons, from 1 March 2023 to 28 February 2024.

*Immunosuppression due to corticosteroid or other immunosuppressive therapy must be for a period of greater than 28 days.

resolved to approve the 21 October 2022 agreement with GlaxoSmithKline NZ Limited

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

Claudia Wyss and Talia Anderson-Town

Carried

8.5 Medical Devices Transaction Report

This paper provides a monthly update to the Board on progress with medical devices national contracting activity. National contracting is the key mechanism we are using to build a list of medical devices, as we work towards our strategic goal to achieve best health outcomes from hospital medical devices with the funding available.

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

8.6 Summary of Decisions made under Delegated Authority for October 2022

This report contains a summary of all decisions made by Pharmac staff under delegated authority during October 2022. These are listed under the following headings:

1. PTAC, Subcommittee, Panels and Advisory Committee Appointments
2. Pharmaceutical Schedule Listing Decisions - Medical Devices
3. Covid-19 Contingency Fund – Medicines and Medical Devices
4. Pharmaceutical Schedule Listing Decisions – Medicines
5. NPPA initial application approvals made by Director of Operations
6. Other NPPA initial and renewals made by Director of Operations

The Board **noted** the summary of decisions made under Delegated Authority during October 2022 by the Chief Executive, Director of Operations, Manager Pharmaceutical Funding, Senior Advisor/Team Leader and Senior Therapeutic Group Managers/Team Leaders.

9. Key Items

9.1 Consumer Advisory Committee's Report

The purpose of this paper is to inform the Board of where the Consumer Advisory Committee (CAC) has contributed to and influenced Pharmac's work in the last year. It was noted that this was the first time that CAC had provided such an annual summary. The Board:

noted that this paper is a record of the views of the Consumer Advisory Committee and the content has been signed off by the members

noted the contributions and influence the Consumer Advisory Committee has had on Pharmac's work in the last year

noted the Consumer Advisory Committee will produce an annual report for the Board at the end of each year

noted that a register, separate to the actions register, has been created to record advice from Consumer Advisory Committee and how that advice has been used

A video was shown to the Board on the experiences of CAC members. The Board noted that they found the video to be extremely useful.

The Board suggested that the CAC Report be made publicly available going forward.

9.2 Report-back on Vancouver Group meeting and Agency for Care Effectiveness Conference

In May 2022, the Board approved attendance at both the Vancouver Group meeting and the Agency for Care Effectiveness (ACE) Value based Healthcare Conference. This paper summarises the highlights and observations from the Chief Executive's attendance at the meetings.

The Board **noted** the international travel report on the 2022 Vancouver Group Annual

Meeting and 2022 Agency for Care Effectiveness Value-based Healthcare Conference.

9.3 Appointment of PTAC Deputy Chair

This paper seeks Board agreement on the recommended appointment of the new Deputy Chair of the Pharmacology and Therapeutics Advisory Committee (PTAC). The Board:

resolved to recommend to the Director-General of Health the appointment of Professor Rhiannon Braund, as Pharmacology and Therapeutics Advisory Committee Deputy Chair for a period of three years beginning December 2022

noted that the appointment of the current Pharmacology and Therapeutics Advisory Committee Deputy Chair, Associate Professor Marius Rademaker, is due to expire at the end of November 2022.

Talia Anderson-Town and Claudia Wyss **Carried**

9.4 Review of PTAC, SACs and fees

This paper seeks your approval, consistent with the Cabinet Fees Framework, to increase the fees paid to members of Pharmacology and Therapeutics Advisory Committee (PTAC), Specialist Advisory Committee (SAC) and Consumer Advisory Committee (CAC). The Board:

noted that fees paid to PTAC, SAC and CAC members are significantly outdated

noted that fee levels are governed by the *Cabinet Office Circular CO (22) 2 Revised Fees Framework* ("the "Fees Framework") for members appointed to bodies in which the Crown has an interest

noted that Pharmac staff have applied the Fees Framework, including to consider the appropriate classification for the committees, and the resultant fee ranges.

Talia Anderson-Town and Claudia Wyss **Carried**

Claudia Wyss left the meeting at 12.40pm.

10. Strategic Planning and Policy

10.1 Medical Devices programme update

This paper provides the Board with further detail is about what our Medical Devices Programme is delivering for the move into the second phase of the Programme - Investment Management (Fairer Access); and how the Programme plans to deliver it including an overview of the governance in place.

The Board:

noted the key deliverables, progress and dependencies detailed in this paper for the move to the second phase of the programme - Investment Management (Fairer Access); and how the Programme plans to deliver it

noted the expanded Medical Device Programme Governance Group

noted that more regular updates on progress with the Investment Management Project and overall Programme will be provided to the Board from its next meeting.

10.2 Annual Report update

This paper provides the Board with an update on the 2021/22 audit of Pharmac's financial and non-financial performance measures as part of finalising our 2021/22 Annual Report. Given that Audit NZ are still undertaking audit activity, the paper requests agreement to the Board Chair and the Audit and Risk Committee Chair approving and signing the Annual Report, Statement of Responsibility and the Letter of Representation for the year ended 30 June 2022. The Board:

noted Audit New Zealand has not yet finished their audit of Pharmac's financial and non-financial performance measures

noted that the annual audit has not been completed due to Audit NZ having not completed their audit of financial and non-financial measures. It was hoped that Audit NZ will have completed their audit activity to enable to 2021/22 Annual Report to be ready to be signed on 9 December by the Board Chair and Audit NZ Committee Chair

noted that the Board Chair and the Audit and Risk Committee Chair will approve and sign the Annual Report, Statement of Responsibility and the Letter of Representation for the year ended 30 June 2022 once Audit New Zealand have confirmed the financial and non-financial reporting in the Annual Report when it becomes available

noted the final annual report will be sent to all Board members when it is finalised.

10.3 Equitable Access and Use update

The purpose of this paper is to provide the Board with an update on:

- our equitable use and access strategic priority work for 2022/23
- the current and future context of how we do more for health equity through enhancing access and optimal use of medicines
- our progress to facilitate collective action with our health and disability system partners.

The paper is also intended to support the Board for its discussion with the Panel of external speakers, focussed on optimal use and collective action, presenting earlier on Board's agenda.

The Board:

noted that we have continued to make progress with the 2022/23 equitable access and use strategic priority initiatives (refer to Appendix One)

noted that we are evolving our understanding of how we maximise our contribution to health equity

noted that engagement and collaboration with other system agencies has commenced with the intention of facilitating collective action to enhance access and optimal use of medicines (our primary focus for now)

noted that our next Statement of Intent will reflect a more cohesive and integrated internal strategy for strengthening our own performance to improve health equity.

10.4 Te Tiriti Policy

This paper provides the Board with an update on the work to develop and finalise Te Pātaka Whaioranga Pharmac's te Tiriti o Waitangi Policy. The Board:

noted that Pharmac's Chief Executive and Director Māori have jointly approved Te Pātaka Whaioranga Pharmac's te Tiriti o Waitangi policy

noted the content of the policy and the accompanying addendum to the policy

agreed that the te Tiriti Policy will be presented to the Board at the February 2023 Board meeting for their endorsement.

10.5 Review of Māori Advisory Rōpū and next steps

This paper provides the Board with an update on the review of the Rōpū Māori together with an outline of the next steps required to complete the review.

The Board **noted** the next steps for the Rōpū review as outlined by Te Rōpū Māori. It was noted that this is still in the phase of building relationships due to COVID-19 restrictions but currently progressing to a partnership.

11.0 Regular Reporting

11.1 Communications Report

This paper summarises communications and engagement activity for October 2022 and the impact of our work.

The Board:

noted that the four proactive media releases in October resulted in a reasonable amount of positive coverage

noted that distribution of the Year in Review will begin in early December

noted that we are advancing work to mature our approach to stakeholder engagement, including Senior Leadership Team members taking a sponsor role across 10 key agencies

noted the "You are a Priority" campaign is a finalist in the Communications Council Pressie Awards.

11.2 Legal Report

This paper provides the Board with advice on the Pae Ora (Healthy Futures) Act 2022 (Pae Ora Act), as relevant to Pharmac, and an assessment of litigation risk associated with the Act.

11.3 Q1 Risk Register

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.

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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 Board:

noted the exception risk report provides an update on items on the Board risk register that have materially changed since the 2022/23 quarter one risk register which was reviewed by the Board on 28 October 2022

noted that the Audit and Risk Committee reviewed the 2022/23 quarter two report and risk register at the November meeting (2 December 2022) and the Board will receive this report at the first meeting in 2023.

12. Interest Articles

The Board **noted** the interest articles.

13. General Business

A farewell and appreciation were given to Peter Bramley who will be leaving the Board as a Board Observer.

The meeting closed at 2.00pm with a karakia.

Date of Next Meeting

The date for the next Board meeting is set for Friday 24 February 2022.

Chair: _____
Steve Maharey

Date: _____