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MINUTES OF THE PHARMACEUTICAL MANAGEMENT AGENCY (PHARMAC)

BOARD MEETING 28 FEBRUARY 2020

The meeting was held at Level 9, 40 Mercer Street, Wellington, starting at 8.51am with the following attendees:

Board members

Steve Maharey	Chair
Jan White	Deputy Chair
Ross Lawrenson	Board Member
Nicole Anderson	Board Member
Claudia Wyss	Board Member
David Lui	Observer, CAC Chair
Mark Weatherall	Observer, PTAC Chair
Peter Bramley	Observer, DHB Representative

PHARMAC staff in attendance

Sarah Fitt	Chief Executive
Lisa Williams	Director of Operations
Alison Hill	Director of Engagement & Implementation
Michael Johnson	Director of Strategic Initiatives
Mark Woodard	Director of Corporate Services/CFO
Lizzy Cohen	Board Secretary

Geraldine MacGibbon, Sarah Beri, Andrew Davies, Josh Wiles, Danae Staples-Moon, Catherine Kingsbury, Angela Cathro, Rachel Read, Tal Sharrock, Graham Beever, Jannel Fisher and Janet Mackay (PHARMAC staff) attended for relevant items.

9.00am Guest speaker – John Whaanga Ministry of Health joined to Board to share the *Ministry of Health's work to address Māori health needs and equity and meeting Te Tiriti o Waitangi obligations.*

1. Directors' Only Discussion

1.1 Glossary of Terms

1.2 Board Actions

1.3 Board Annual Agenda

2. Apologies

Ken Clark, Acting Medical Director

3. Record of Previous Board and Committee Meetings

3.1 Minutes of January 2020 Board and Committee Meetings

resolved to adopt the minutes of the January 2020 meeting as being a true and correct record.

Ross Lawrenson and Jan White **(carried)**

3.2 Minutes of January Health and Safety Committee

noted the minutes of the January 2020 Health and Safety Committee meeting.

3.3 Audit and Forecast Committee recommendations

noted the verbal update from the Committee Chair;

resolved to appoint Claudia Wyss, Board member to the Audit and Forecast Committee;

noted that staff will present an operating budget to the Audit and Forecast Committee meeting in March for consideration and recommendations presented to the Board; and

resolved to adopt the recommended risk tolerance framework and requested the Audit and Forecast Committee conduct a review of the framework in 12months.

Nicole Anderson and Ross Lawrenson

3.4 Summary of November 2019 PTAC advice and recommendations

noted the following summary of the record of the Pharmacology and Therapeutics Advisory Committee (PTAC) meeting held on 14 and 15 November 2019; and

noted the November 2019 PTAC record was signed off by the Chair on 29 January 2020 and will be published on the PHARMAC website once applicants have been given the opportunity to review it and provide feedback on any aspects that they consider should be withheld in accordance with the Official Information Act 1982.

4. Interests Register

noted the interests register; and

noted any decisions by the Chair to manage actual or potential conflicts of interest, as follows:

[None required]

5. Matters Arising

noted the matter's arising.

6. Chair's Report

6.1 Verbal Report

noted the Chair's verbal report;

noted the Chair and Chief Executive attended Health Select Committee hearing on 19 February for PHARMAC's 2018/19 Annual Review;

noted that the Chair and Chief Executive met with the DHB Chairs to provide an overview of PHARMAC and the funding arrangements; and

noted the outbreak of COVID-19 and that staff will continue to update the Board as required.

10.19am Mark Weatherall, Observer, PTAC Chair joined the meeting.

6.2 Correspondence

noted the correspondence report.

7. Chief Executive's Report

noted the Chief Executive's Report.

8. Key Items

8.1 Pharmaceutical Budget Management Update

noted the contents of this report.

8.2 Summary Risk Report

noted the contents of this report; and

noted that a paper exploring risk tolerance will be discussed at the February Audit and Forecast Committee meeting.

9. Schedule and Funding

9.1 Medical Devices Transaction and Investment Report

noted the contents of this paper.

9.2 Pharmaceutical Transaction Report

noted the contents of this paper.

9.3 Proposal to fund palbociclib for advanced breast cancer

resolved to list palbociclib (Ibrance) cap 75 mg, cap 100 mg, cap 125 mg in the Protein-tyrosine Kinase Inhibitors, Oncology agents and Immunosuppressants therapeutic group in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 April 2020 as follows:

Chemical	Presentation	Brand	Pack Size	Price and subsidy (ex-man., ex. GST)
Palbociclib (Ibrance)	Cap 75 mg	Ibrance	21	$4,000.00
Palbociclib (Ibrance)	Cap 100 mg	Ibrance	21	$4,000.00
Palbociclib (Ibrance)	Cap 125 mg	Ibrance	21	$4,000.00

resolved to list palbociclib (Ibrance) in Section B of the Pharmaceutical Schedule subject to the following Special Authority criteria from 1 April 2020 (amended version from that consulted on shown below, additions in bold, deletions in strikethrough):

Special Authority for Subsidy – Retail Pharmacy-Specialist
Initial application - only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Patient has unresectable locally advanced or metastatic breast cancer; and
2. There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
3. Patient has an ECOG performance score of 0-2; and
4. **Any of the following** ~~Either~~:
   - 4.1. Disease has relapsed or progressed during prior endocrine therapy **(second or subsequent line setting)**; or
   - 4.2. **(first-line setting)** Both:
     - 4.2.1. Patient is amenorrhoeic ~~for 12 months of greater~~, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and
     - 4.2.2. **Either:**
       - **4.2.2.1.** Patient has not received prior systemic **endocrine** treatment for metastatic disease; ~~and~~ **or**
       - **4.2.2.2. All of the following:**
         - **4.2.2.2.1. Patient commenced treatment with palbociclib in combination with an endocrine agent prior to 1 April 2020; and**
         - **4.2.2.2.2. Patient had not received systemic endocrine treatment for metastatic disease prior to commencing treatment with palbociclib; and**
         - **4.2.2.2.3. There is no evidence of disease progression; and**
5. Treatment must be used in combination with an endocrine partner.

Renewal - only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1. Treatment must be used in combination with an endocrine partner; and
2. There is no evidence of progressive disease; and
3. The treatment remains appropriate and the patient is benefitting from treatment.

resolved to apply the wastage rule to the Ibrance brand of palbociclib cap 75 mg, 100 mg and 125 mg in Section B of the Pharmaceutical Schedule from 1 April 2020;

resolved to list palbociclib (Ibrance) in Part II of Section H of the Pharmaceutical Schedule subject to the following restrictions from 1 April 2020 (amended version from that consulted on shown below, additions in bold, deletions in strikethrough):

Initiation
Medical oncologist
Reassessment required after 6 months
All of the following:

1. Patient has unresectable locally advanced or metastatic breast cancer; and
2. There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
3. Patient has an ECOG performance score of 0-2; and
4. **Any of the following** ~~Either~~:
   - 4.1. Patient has relapsed or progressed during prior endocrine therapy **(second or subsequent line setting)**; or
   - 4.2. **(first-line setting)** Both:
     - 4.2.1. Patient has been amenorrhoeic ~~for 12 months of greater~~, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and
     - 4.2.2. **Either:**
       - 4.2.2.1. Patient has not received prior systemic **endocrine** treatment for metastatic disease; ~~and~~ **or**
       - **4.2.2.2. All of the following:**
         - **4.2.2.2.1. Patient commenced treatment with palbociclib in combination with an endocrine agent prior to 1 April 2020; and**
         - **4.2.2.2.2. Patient has not received prior systemic endocrine treatment for metastatic disease; and**
         - **4.2.2.2.3. There is no evidence of progressive disease; and**
5. Treatment must be used in combination with an endocrine partner.

Continuation
Medical oncologist
Reassessment required after 12 months
All of the following:

1. Treatment must be used in combination with an endocrine partner; and
2. No evidence of progressive disease; and
3. The treatment remains appropriate and the patient is benefitting from treatment.

resolved to approve the 9 January 2020 agreement with Pfizer New Zealand Ltd;

noted that the 9 January 2020 agreement with Pfizer New Zealand Ltd includes Sole Supply Status for Ibrance to be the only funded brand of CDK4/CDK6 inhibitor for the treatment of HR-positive, HER2-negative, locally advanced or metastatic breast cancer from 1 April 2020 until 30 June 2023.

resolved to amend the following resolutions approved by the PHARMAC Board in November 2019 as follows (deletions in strikethrough, additions in bold):

resolved to list fulvestrant in the Oncology Agents and Immunosuppressants Therapeutic Group (Endocrine Therapy) in Section B and Part II of Section H of the Pharmaceutical Schedule, ~~at a date to be determined~~ **from 1 April 2020**, as follows (ex-manufacturer, excluding GST):

Chemical	Formulation	Brand	Pack size	Price and subsidy
Fulvestrant	Inj 50 mg per ml, 5 ml prefilled syringe	Faslodex	2	$1,068.00

resolved to apply the following Special Authority to fulvestrant in Section B of the Pharmaceutical Schedule ~~at a date to be determined~~ **from 1 April 2020 (amended version from that consulted on and previously notified shown below, deletions in strikethrough)**:

Special Authority for Subsidy – Retail Pharmacy - Specialist
Initial application - only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Patient has oestrogen-receptor positive locally advanced or metastatic breast cancer; and
2. Patient has disease progression following prior treatment with an aromatase inhibitor or tamoxifen for their locally advanced or metastatic disease; and
3. ~~Patient is amenorrhoeic for 12 months or greater, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and~~
4. Treatment to be given at a dose of 500 mg monthly following loading doses; and
5. Treatment to be discontinued at disease progression.

Renewal – only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Treatment remains appropriate and patient is benefitting from treatment; and
2. Treatment to be given at a dose of 500 mg monthly; and
3. There is no evidence of disease progression.

resolved to apply the following restrictions to fulvestrant in Part II of Section H of the Pharmaceutical Schedule, ~~at a date to be determined~~ **from 1 April 2020 (amended version from that consulted on and previously notified shown below, deletions in strikethrough)**:

Initiation
Medical Oncologist
Re-assessment required after 6 months
All of the following:

1. Patient has oestrogen-receptor positive locally advanced or metastatic breast cancer; and
2. Patient has disease progression following prior treatment with an aromatase inhibitor or tamoxifen for their locally advanced or metastatic disease; and
3. ~~Patient is amenorrhoeic for 12 months or greater, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and~~
4. Treatment to be given at a dose of 500 mg monthly following loading doses; and
5. Treatment to be discontinued at disease progression.

Continuation
Medical Oncologist
Re-assessment required after 6 months
All of the following:

1. Treatment remains appropriate and patient is benefitting from treatment; and
2. Treatment to be given at a dose of 500 mg monthly; and
3. No evidence of disease progression.

resolved to apply the section 29 symbol and wastage to the Faslodex brand of fulvestrant inj 50 mg per ml, 5 ml prefilled syringe in Section B of the Pharmaceutical Schedule of the Pharmaceutical Schedule from 1 April 2020;

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

noted that, following consideration of consultation feedback, the proposed criteria for palbociclib have been amended to remove the requirement for patients to have postmenopausal endocrine levels for 12 month or greater, to clarify the intended pre-treated population and to provide access to eligible patients who started palbociclib treatment prior to 1 April 2020; and

noted that while this proposal includes amendments to the listing criteria for fulvestrant from that consulted on and notified, given that the proposed amendments are to widen access it is proposed that no further consultation is required; and that should the proposal be approved, notification of the amended fulvestrant criteria would occur at the same time as any decision regarding palbociclib.

Jan White and Ross Lawrenson **(carried)**

9.4 Proposal to decline a Named Patient Pharmaceutical Assessment (NPPA) application

resolved to decline Named Patient Pharmaceutical Assessment (NPPA) funding application.

Nicole Anderson and Jan White **(carried)**

10. Strategic Planning and Policy

10.1 Te Whaioranga Strategy Refresh

resolved to endorse the refreshed Te Whaioranga strategy 2013-2023;

noted that the refreshed strategy aligns with PHARMAC's new strategic direction and responds to wider system expectations for Crown agents to partner with Māori to meet our Te Tiriti o Waitangi obligations;

noted the refreshed strategy focuses on six areas: Te Tiriti o Waitangi, Māori leadership, Māori/Crown partnerships, equity, accountability and cultural intelligence;

noted that the review and refresh built on information received from Māori over almost two decades of community engagement as well as input from staff, stakeholder partners and advisory and governance boards that included Māori experts;

noted that the refreshed strategy and associated actions and measures will be reflected in PHARMAC's Statement of Intent 2020-2024 and incorporated into strategic planning across the organisation; and

noted the contents of this paper.

The Board requested staff provide an update on the approach and timing to establish a Māori capability programme for PHARMAC including options for further developing Board members' Māori capability for consideration.

Nicole Anderson and Claudia Wyss **(carried)**

10.2 Consumer Input and Engagement

noted the changes made, and work underway, to address feedback following PHARMAC's Consumer Voices review in 2018;

noted that following the review of the Consumer Advisory Committee, recruitment has commenced to replace Committee members whose terms expire in July 2020, including the Committee Chair;

resolved to appoint Lisa Lawrence to the role of Deputy Chair of the Consumer Advisory Committee, effective from 1 March 2020, and to the role of Chair of the Consumer Advisory Committee, effective 1 August 2020; and

noted that the work across our six new strategic priorities, being planned for the next four years, includes activity to further enhance our consumer engagement and input.

The Board suggested that when the core principles in the action plan are being reviewed, that staff consider reflecting in the principles the agreed approach going forward with regards to consumer engagement in our decision making.

The Board noted that progress on this work will be reported through our regular reporting on the strategic priorities.

Claudia Wyss and Jan White **(carried)**

10.3 Strategies and Expectations Update

noted the contents of this paper.

10.4 2020/21 International Travel Plan

noted the 2020/21 plan for PHARMAC staff international travel.

10.5 International Travel Request - 2020 Health Technology Assessment International conference

resolved to approve international travel for a Senior Health Economist to China in June 2020, to attend the 2020 Health Technology Assessment International (HTAi) conference;

noted that this travel was included in the 2019/20 International Travel Plan which was noted by the Board in February 2019; and

noted that, if this proposal is approved, a report will be delivered to the Board following the trip.

Jan White and Ross Lawrenson **(carried)**

10.6 International Travel Request - Vancouver group meeting in Vienna - August 2020

resolved to approve international travel to enable the Chief Executive to accept an invitation to take part in the 16th annual series of the Vancouver Group international forum, Vienna, Austria, 25 – 27 August 2020;

noted that this travel is included in the 2020/21 International Travel Plan which is being considered by the Board at the February 2020 Board meeting (agenda item 10.5);

noted there is no fee to attend the forum however the cost of travel and accommodation would be covered by PHARMAC; and

noted that, if this proposal is approved, the Chief Executive would provide a report back to the Board following the Forum.

Nicole Anderson and Claudia Wyss **(carried)**

11. Regular Reports and Noting Papers

11.1 Confidential and Legally Privileged Legal Report

noted the legal report.

11.2 Communications Report

noted the content of the Communications Report covering January 2020.

11.3 Implementation Update

noted the contents of this paper.

11.4 Summary of Decisions Made Under Delegated Authority – January 2020

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

1.32pm Alison Hill, Director of Engagement and Implementation left the meeting.

12. Interest Articles

13. General Business

Date of Next Meeting

The date for the next Board meeting is set for Friday 27 March 2020 in Wellington, commencing with the Directors Only from 9.45am, and attendees and relevant staff from 10.15am.

The meeting closed at 1.37pm.

Chair: Date: