MINUTES OF THE PHARMACEUTICAL MANAGEMENT AGENCY (PHARMAC)

BOARD MEETING SEPTEMBER 2019

The meeting was held at Level 9, 40 Mercer Street, Wellington, starting at 9:45am with the following attendees:

Board members

Steve Maharey	Chair
Jan White	Deputy Chair
Ross Lawrenson	Board Member
Nicole Anderson	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
Ken Clark	Acting Medical Director
Jane Wallace	Acting Board Secretary
Steph Tims	Acting Board Secretary (from 12.45pm)

Jannel Fisher, Geraldine MacGibbon, Danae Staples-Moon, Adrienne Martin, Andrew Davies, Fiona Rutherford, Catherine Proffitt, Rachel Read, Rachel Watt, Graham Beever, Ben Campbell-Macdonald, Sarah Beri (PHARMAC staff) attended for relevant items.

1. Directors' Only Discussion

2. Apologies

Lizzy Cohen, Board Secretary

3. Record of Previous Board and Committee Meetings

3.1 Minutes of July 2019 Board Meeting

resolved to adopt the minutes of the July 2019 meeting as being a true and correct record.

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

3.2 Recommendations from September Audit and Forecast Committee Meeting

noted the recommendations of the September Audit and Forecast Committee meeting.

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. Chairman's Report

6.1 Verbal Report

noted the Chair's verbal report.

6.2 Correspondence

noted the correspondence report.

7. Chief Executive's Report

noted the Chief Executive's Report.

noted the discussion on SSC model standards.

8. Key Items

8.1 Public Perception of PHARMAC – Colmar Brunton Survey

noted the results of the 2019 Public Sector Reputation Index;

noted the approach to improve public trust and confidence in PHARMAC during 2019/20.

8.2 Year in Review Scoping Paper

noted the approach to the 2019 Year in Review.

8.3 2020/21 Combined Pharmaceutical Budget Bid Process

noted the approach for confirming with District Health Boards the 2020/21 Combined Pharmaceutical Budget level and indicative out-year funding pathway; and

noted the Board will consider the draft preliminary joint budget bid at its October 2019 meeting.

8.4 Faster, Clearer, Simpler Decision-making

noted the nine stages of PHARMAC's funding decision-making process;

noted the work underway to improve timeliness; and

noted that options to further improve timelessness and quality of the decision-making process, including resource required, will be presented to the Board at the November 2019 meeting.

9. Schedule and Funding

9.1 Pharmaceutical Transaction and Investment Report

noted the contents of this paper.

9.2 Roche Multi Product Agreement

resolved to approve the amendments to the Pharmaceutical Schedule relating to alectinib, trastuzumab emtansine, ocrelizumab and pirfenidone as set out in Appendix One of this Board Paper;

resolved to approve the 6 August 2019 agreement with Roche Products (NZ) Limited; and

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

Alectinib

resolved to list alectinib cap 150 mg in the Oncology Agents and Immunosuppressants Therapeutic Group (Chemotherapeutic agents - Protein-Tyrosine Kinase Inhibitors subgroup) of Section B and Part II of Section H of the Pharmaceutical Schedule, from 1 December 2019, as follows (ex-manufacturer, excluding GST):

Chemical	Formulation	Brand	Pack size	Price and subsidy
Alectinib	Cap 150 mg	Alecensa	224	$7,935.00

resolved to apply the following Special Authority to alectinib in Section B of the Pharmaceutical Schedule from 1 December 2019:

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

1. Patient has locally advanced, or metastatic, unresectable, non-small cell lung cancer; and
2. There is documentation confirming that the patient has an ALK tyrosine kinase gene rearrangement using an appropriate ALK test; and
3. Patient has an ECOG performance score of 0-2.

Renewal application - only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:
Both:
1. No evidence of progressive disease according to RECIST criteria; and
2. The patient is benefitting from and tolerating treatment.

resolved to apply the following restrictions to alectinib in Part II of Section H of the Pharmaceutical Schedule, from 1 December 2019, as follows:

Restriction
Initiation
Re-assessment required after 6 months
All of the following:
1. Patient has locally advanced, or metastatic, unresectable, non-small cell lung cancer; and
2. There is documentation confirming that the patient has an ALK tyrosine kinase gene rearrangement using an appropriate ALK test; and
3. Patient has an ECOG performance score of 0-2.

Continuation
Re-assessment required after 6 months
Both:
1. No evidence of progressive disease according to RECIST criteria; and
2. The patient is benefitting from and tolerating treatment.

noted a confidential rebate would apply to Alecensa that would reduce the net price to the Funder.

noted Alecensa would have protection from delisting and subsidy reduction until 30 November 2022.

Trastuzumab emtansine

resolved to list trastuzumab emtansine in the Oncology Agents and Immunosuppressants Therapeutic Group (Immunosuppressants – Monoclonal Antibodies subgroup) in Section B of the Pharmaceutical Schedule, from 1 December 2019, as follows (ex-manufacturer, excluding GST):

Chemical	Formulation	Brand	Pack size	Price and subsidy
Trastuzumab emtansine	Inj 100 mg vial	Kadcyla	1	$2,320.00
Trastuzumab emtansine	Inj 160 mg vial	Kadcyla	1	$3,712.00
Trastuzumab emtansine	Inj 1 mg for ECP	Baxter	1 mg	$23.20

resolved to apply PCT-only – Specialist to trastuzumab emtansine in Section B of the Pharmaceutical Schedule from 1 December 2019.

resolved to apply the following Special Authority to trastuzumab emtansine in Section B of the Pharmaceutical Schedule from 1 December 2019:

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

1. Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2. Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
3. Either
   3.1. The patient has received prior therapy for metastatic disease*; or
   3.2. The patient developed disease recurrence during, or within six months of completing adjuvant therapy*; and
4. Patient has a good performance status (ECOG 0-1); and
5. Either:
   5.1. Patient does not have symptomatic brain metastases; or
   5.2. Patient has brain metastases and has received prior local CNS therapy; and
6. Treatment to be discontinued at disease progression.

Renewal – only from a relevant specialist or medical practitioner or on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:
Both:
1. The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine; and
2. Treatment to be discontinued at disease progression.

*Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

resolved to list trastuzumab emtansine in the Oncology Agents and Immunosuppressants Therapeutic Group (Immunosuppressants – Monoclonal Antibodies subgroup) in Part II of Section H of the Pharmaceutical Schedule, from 1 December 2019, as follows (ex-manufacturer, excluding GST):

Chemical	Formulation	Brand	Pack size	Price
Trastuzumab emtansine	Inj 100 mg vial	Kadcyla	1	$2,320.00
Trastuzumab emtansine	Inj 160 mg vial	Kadcyla	1	$3,712.00

resolved to apply the following restrictions to trastuzumab emtansine in Part II of Section H of the Pharmaceutical Schedule, from 1 December 2019, as follows:

Initiation
Re-assessment required after 6 months
All of the following:
1. Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2. Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
3. Either
   3.1. The patient has received prior therapy for metastatic disease*; or
   3.2. The patient developed disease recurrence during, or within six months of completing adjuvant therapy*; and
4. Patient has a good performance status (ECOG 0-1); and
5. Either:
   5.1. Patient does not have symptomatic brain metastases; or
   5.2. Patient has brain metastases and has received prior local CNS therapy; and
6. Treatment to be discontinued at disease progression.

Continuation
Re-assessment required after 6 months
Both:

1. The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine; and
2. Treatment to be discontinued at disease progression.

*Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

noted a confidential rebate would apply to Kadcyla that would reduce the net price to the Funder.

noted Kadcyla would have protection from delisting and subsidy reduction until 30 November 2022.

Ocrelizumab

resolved to list ocrelizumab in the Nervous System Therapeutic Group (Multiple Sclerosis Treatments subgroup) of Section B and Part II of Section H of the Pharmaceutical Schedule, from 1 December 2019, as follows (ex-manufacturer, excluding GST):

Chemical	Formulation	Brand	Pack size	Price and subsidy
Ocrelizumab	Inj 30 mg per ml, 10 ml vial	Ocrevus	1	$9,346.00

resolved to apply the following restriction to ocrelizumab in Section B of the Pharmaceutical Schedule from 1 December 2019:

Special Authority approved by the Multiple Sclerosis Treatment Committee
Notes: Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below).
Application details may be obtained from PHARMAC's website http://www.pharmac.govt.nz or:
The coordinator Phone: 04 460 4990
Multiple Sclerosis Treatment Assessment Committee Facsimile: 04 916 7571
PHARMAC PO Box 10 254 Email: mstaccoordinator@pharmac.govt.nz
Wellington

Completed application forms must be sent to the coordinator for MSTAC and will be considered by MSTAC at the next practicable opportunity.
Notification of MSTAC's decision will be sent to the patient, the applying clinician and the patient's GP (if specified).

Entry Criteria
1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
2) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
3) patients must have:
   a) EDSS score 0 - 4.0 and:
   - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the past 24 months; and
   - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
     i) a gadolinium enhancing lesion; or
     ii) a Diffusion Weighted Imaging positive lesion; or
     iii) a T2 lesion with associated local swelling; or
     iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
     v) new T2 lesions compared with a previous MR scan; and

4) A significant relapse must:
   a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
   b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
   c) last at least one week;
   d) start at least one month after the onset of a previous relapse;
   e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point;
   f) be distinguishable from the effects of general fatigue; and
   g) not be associated with a fever (T> 37.5°C); and
5) applications must be made by the patient's neurologist or general physician; and
6) patients must have no previous history of lack of response to ocrelizumab; and
7) patients must have not previously had intolerance to ocrelizumab; and
8) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria
Any of the following:
1) Confirmed progression of disability that is sustained for six months. Progression of disability is defined as progress by any of the following EDSS points:
   a) from starting at EDSS 0 increasing to (i.e. stopping on reaching) EDSS 3.0; or
   b) 1.0 to 3.0; or
   c) 1.5 to 3.5; or
   d) 2.0 to 4.0; or
   e) 2.5 to 4.5; or
   f) 3.0 to 4.5; or
   g) 3.5 to 4.5; or
   h) 4.0 to 4.5.
2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment) (see note); or
3) intolerance to ocrelizumab; or
4) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Switching between natalizumab, fingolimod, dimethyl fumarate, teriflunomide and ocrelizumab is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate. Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

resolved to amend the note in the Special Authority criteria for the Multiple Sclerosis Treatments natalizumab, fingolimod, dimethyl fumarate and teriflunomide in Section B of the Pharmaceutical Schedule from 1 December 2019 as follows (additions in bold, deletions in strikethrough):

Switching between natalizumab, fingolimod, dimethyl fumarate**,** ~~and~~ teriflunomide **and ocrelizumab** is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate.

Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

resolved to apply the following restriction to ocrelizumab in Part II of Section H of the Pharmaceutical Schedule, from 1 December 2019, as follows:

Restriction
Initiation
Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).

noted a confidential rebate would apply to Ocrevus that would reduce the net price to the Funder.

noted Ocrevus would have protection from delisting and subsidy reduction until 30 November 2022.

Pirfenidone

resolved to list a new presentation of pirfenidone in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 December 2019 as follows (ex-manufacturer, excluding GST):

Chemical	Formulation	Brand	Pack size	Price and subsidy
Pirfenidone	Tab 801 mg	Esbriet	90	$3,645.00

resolved to amend the Special Authority criteria for pirfenidone in Section B of the Pharmaceutical Schedule from 1 December 2019 as follows (additions in bold deletions in strikethrough);

Initial application – (idiopathic pulmonary fibrosis) only from a respiratory physician. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:
1. Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist; and
2. Forced vital capacity is between 50% and ~~80~~ **90**% predicted; and
3. Pirfenidone is to be discontinued at disease progression (See Note); and
4. Pirfenidone is not to be used in combination with subsidised nintedanib; and
5. Any of the following:
   5.1. The patient has not previously received treatment with nintedanib; or
   5.2. Patient has previously received nintedanib, but discontinued nintedanib within 12 weeks due to intolerance; or
   5.3. Patient has previously received nintedanib, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with nintedanib).

Renewal application – (idiopathic pulmonary fibrosis) only from a respiratory physician. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:
1. Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
2. Pirfenidone is not be used in combination with subsidised nintedanib; and
3. Pirfenidone is to be discontinued at disease progression (See Note).

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

resolved to amend the restrictions to pirfenidone in Part II of Section H of the Pharmaceutical Schedule from 1 December 2019 as follows (additions in bold deletions in strikethrough);

Initiation - idiopathic pulmonary fibrosis
Respiratory specialist

Re-assessment required after 12 months
All of the following:

1. Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist; and
2. Forced vital capacity is between 50% and ~~80~~ **90**% predicted; and
3. Pirfenidone is to be discontinued at disease progression (See Note); and
4. Pirfenidone is not to be used in combination with subsidised nintedanib; and
5. Any of the following:
   5.1. The patient has not previously received treatment with nintedanib; or
   5.2. Patient has previously received nintedanib, but discontinued nintedanib within 12 weeks due to intolerance; or
   5.3. Patient has previously received nintedanib, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with nintedanib).

Continuation - idiopathic pulmonary fibrosis
Respiratory specialist
Re-assessment required after 12 months
All of the following:

1. Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
2. Pirfenidone is not be used in combination with subsidised nintedanib; and
3. Pirfenidone is to be discontinued at disease progression (See Note).

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

noted a confidential rebate would apply to Esbriet (both the currently listed 276 mg capsule and the new 801 mg tablet presentation) that would reduce the net price to the Funder.

noted Esbriet would have protection from delisting and subsidy reduction until 28 February 2021.

noted that wastage applies to the 267 mg capsules presentation due to the initial dose titration phase, but it is not proposed to apply wastage to pirfenidone (Esbriet) tab 801 mg as this would be dispensed to patients on stable doses.

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

9.3 Medical Devices Transaction and Investment Report

noted the contents of this paper.

10. Strategic Planning and Policy

10.1 Submissions Summary – Fairer Access to Medical Devices

noted the Summary of Submissions on *Fairer Access to Medical Devices* will be released following the Board meeting.

Jane Wallace, Acting Board Secretary left the meeting

12.00pm – 12.45pm - lunch

Steph Tims, Acting Board Secretary joined the meeting

10.2 Board Strategy next steps update (includes Strategy Action Plan Dashboard) / Update on refresh of PHARMAC Strategy

noted the contents of this paper.

10.3 Final Draft Annual Report

noted the Audit and Forecast Committee have reviewed the Annual Report for the year ended 30 June 2019 at its September meeting and recommend to the Board for approval; and

noted Audit NZ's final management report to the Board;

resolved to approve the recommendation from the Audit and Forecast Committee to approve the Annual Report for the year ended 30 June 2019; and

resolved that the Board Chair and the Audit and Forecast Committee Chair sign the Annual Report, Statement of Responsibility and the Letter of Representation for the year ended 30 June 2019;

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

10.4 Update on Early Access to Medicines

noted that PHARMAC has been asked to contribute to the Ministry of Health's advice to the Minister of Health on options for increasing access to new cancer medicines; and

noted the options analysis work that PHARMAC staff have undertaken to date.

10.5 Health and Disability System Review Interim Report

note the contents of this paper.

11. Regular Reports and Noting Papers

11.1 Communications Report

noted the content of the Communications Report covering August 2019.

11.2 Legal Report

noted the legal report.

11.3 Legislative Compliance Report

noted that the legislative compliance survey is one of several mechanisms in place to ensure legal compliance and, based on the information obtained as a result of the survey, it appears that PHARMAC has a high level of compliance with its key legislative requirements; and

noted that this round of the survey was the second to be conducted following a comprehensive review of the questions and allocations. We took the opportunity to 'fine tune' the changes that were made based on experience and feedback from the last survey.

11.4 Travel Report – HTAi Meeting, Cologne

noted the international travel report on the HTAi conference.

11.5 Prioritisation Report

noted the prioritisation report.

11.6 Schedule of Ministerial Expectations 2018/19

noted the contents of this paper.

11.7 Risk Report

noted the contents of this report.

11.8 Expenditure Report

noted the contents of this paper.

noted that a fulsome CPB forecast will be finalised by PHARMAC staff in early October (following consideration by the Audit and Forecast Committee of a Forecast Assumptions paper at its September 2019 meeting);

noted that a Budget Management Options paper, setting out management's proposed approach to managing the CPB and any recommended alterations to expenditure targets, will be submitted to the Board for consideration at its October 2019 meeting.

11.9 Summary of Decisions Made Under Delegated Authority – July and August 2019

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.

12. Interest Articles

13. General Business

Date of Next Meeting

The date for the next Board meeting is set for Thursday 24 October 2019 in Wellington, commencing with the Directors only from 10.30am, and attendees and relevant staff from 11.00am.

The meeting closed at 1:50pm.

Chair: Date: