MINUTES OF THE PHARMACEUTICAL MANAGEMENT AGENCY (PHARMAC)

BOARD MEETING OCTOBER 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
Lizzy Cohen	Board Secretary

Geraldine MacGibbon, Sarah Beri, Rachel Read, Rachel Watt, Craig Butler, Andrew Oliver, Andrew Davies, Andrew Park, Angela Cathro and Jannel Fisher (PHARMAC staff) attended for relevant items.

In order to ensure quorum for papers requiring a decision, papers were not considered in the order presented on the meeting agenda and the minutes reflect this.

1. Directors' Only Discussion

1.4 Board Governance and Reporting

noted the contents of this paper to support Board discussion.

2. Apologies

3. Record of Previous Board and Committee Meetings

3.1 Minutes of September 2019 Board Meeting

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

Nicole and Ross Lawrenson **(carried)**

3.2 Minutes of September Audit and Forecast Committee Meeting

noted the minutes of the September 2019 Audit and Forecast Committee meeting.

3.3 Consumer Advisory Committee (CAC) Recommendations – September 2019

noted the recommendations of the Consumer Advisory Committee and the proposed/completed actions by PHARMAC staff.

3.4 Summary of August 2019 PTAC Meeting Minutes

noted the following summary of the record of the Pharmacology and Therapeutics Advisory Committee (PTAC) meeting held on 22 and 23 August 2019; and

noted the minutes for the PTAC meeting on 22 and 23 August 2019 were signed off by the Chair on 9 October 2019 and will be published on the PHARMAC website once applicants have been given the opportunity to review them and provide feedback on any aspects that they consider should be withheld in accordance with the Official Information Act.

3.5 Board Health and Safety Committee Recommendations

noted the verbal update from the Committee Chair; and

resolved to a biannual report from the Committee to the Board; and

resolved to recommend to the Board that the Committee Terms of Reference are updated to include reference to the biannual committee report to the Board.

Ross Lawrenson and Nicole Anderson **(carried)**

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 State Services Commissioners work to update legislation and noted the impact on the role of Crown Entities; and

noted feedback from Director-General of Health to the Board Chair expressing his appreciation of PHARMAC's support particularly during measles outbreak.

6.2 Correspondence

noted the correspondence report.

7. Chief Executive's Report

noted the Chief Executive's Report.

Discussed the information in the report on recent brand changes. In future consider sending updates to DHB CMOs, COOs, CEs to distribute to key DHB staff.

8. Key Items

8.1 Renewal of Appointments of Pharmacology and Therapeutics Advisory Committee (PTAC) Members

resolved to recommend to the Director-General of Health that Stephen Munn, MBChB, FRACS, FACS, be reappointed for a second term on PTAC;

resolved to recommend to the Director-General of Health that Tim Stokes, MA, MBChB, MPH, PhD, FRCP, FRCGP, FRNZCGP be reappointed for a second term on PTAC;

resolved to recommend to the Director-General of Health that Matthew Strother, MD (USA), FRACP be reappointed for a second term on PTAC,

noted that the above members have fulfilled the required performance reviews and are eligible to serve a further term on PTAC; and

noted that after considering the Board Chair's and PHARMAC Board's advice, the Director-General will determine if the members are to be reappointed.

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

8.2 Pharmaceutical Budget Management Update

noted the contents of this paper**.**

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

8.3 Preliminary Budget Bid 2020/21

noted the preliminary budget bid for 2020/21.

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

Dr Ken Clarke Ken left the meeting 12.55pm.

8.4 Update on proposal to trial a cancer medicines early access mechanism

noted the progress of the work exploring a cancer medicines early access pilot.

1.18pm Ross Lawrenson left the meeting

8.5 Risk in the Supply Chain Update

noted the contents of this paper; and

noted that an update report will be provided to the Board in March 2020.

9.3 Proposal to fund venetoclax and rituximab for chronic lymphocytic leukaemia

resolved to approve the amendments to the Pharmaceutical Schedule relating to venetoclax and rituximab;

resolved to approve the 21 August 2019 agreement with AbbVie Limited;

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

resolved to list venetoclax tablets in the Oncology Agents and Immunosuppressants Therapeutic Group (Chemotherapeutic agents - Other Cytotoxic Agents) 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***
Venetoclax	Tab 10 mg	Venclexta	14 OP	$95.78
Venetoclax	Tab 50 mg	Venclexta	7 OP	$239.44
Venetoclax	Tab 100 mg	Venclexta	120	$8,209.41
Venetoclax	Tab 14 x 10 mg, 7 x 50 mg, 21 x 100 mg	Venclexta	42 OP	$1,771.86

resolved to apply the wastage rule to venetoclax (Venclexta) tab 100 mg in Section B of the Pharmaceutical Schedule from 1 December 2019

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

Special Authority for Subsidy – Retail Pharmacy – Specialist

Initial application - (relapsed/refractory chronic lymphocytic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 7 months for applications meeting the following criteria:
All of the following:

1. Patient has chronic lymphocytic leukaemia requiring treatment; and
2. Patient has received at least one prior therapy for chronic lymphocytic leukaemia; and
3. Patient has not previously received funded venetoclax; and
4. The patient's disease has relapsed within 36 months of previous treatment; and
5. Venetoclax to be used in combination with six 28-day cycles of rituximab commencing after the 5-week dose titration schedule with venetoclax; and
6. Patient has an ECOG performance status of 0-2.

Renewal - (relapsed/refractory chronic lymphocytic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1. Treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment; and

2. Venetoclax is to be discontinued after a maximum of 24 months of treatment following the titration schedule unless earlier discontinuation is required due to disease progression or unacceptable toxicity.

Initial application - (previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*) only from a relevant specialist 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 previously untreated chronic lymphocytic leukaemia; and
2. There is documentation confirming that patient has 17p deletion by FISH testing or TP53 mutation by sequencing; and
3. Patient has an ECOG performance status of 0-2.

Renewal - (previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where the treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL)* and B-cell prolymphocytic leukaemia (B-PLL)*. Indications marked with * are Unapproved indications.

resolved to apply the following restriction criteria to venetoclax in Part II of Section H of the Pharmaceutical Schedule from 1 December 2019:

Initiation - relapsed/refractory chronic lymphocytic leukaemia
Haematologist.
Re-assessment required after 7 months
All of the following:
1. Patient has chronic lymphocytic leukaemia requiring treatment; and
2. Patient has received at least one prior therapy for chronic lymphocytic leukaemia; and
3. Patient has not previously received funded venetoclax; and
4. The patient's disease has relapsed within 36 months of previous treatment; and
5. Venetoclax to be used in combination with six 28-day cycles of rituximab commencing after the 5-week dose titration schedule with venetoclax; and
6. Patient has an ECOG performance status of 0-2.

Continuation - relapsed/refractory chronic lymphocytic leukaemia
Haematologist.
Re-assessment required after 6 months
Both:
1. Treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment; and
2. Venetoclax is to be discontinued after a maximum of 24 months of treatment following the titration schedule unless earlier discontinuation is required due to disease progression or unacceptable toxicity.

Initiation - previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*
Haematologist.
Re-assessment required after 6 months
All of the following:
1. Patient has previously untreated chronic lymphocytic leukaemia; and
2. There is documentation confirming that patient has 17p deletion by FISH testing or TP53 mutation by sequencing; and
3. Patient has an ECOG performance status of 0-2.

Continuation - previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*
Haematologist.
Re-assessment required after 6 months
The treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL)* and B-cell prolymphocytic leukaemia (B-PLL)*. Indications marked with * are unapproved indications.

resolved to amend the Special Authority criteria for rituximab in Section B of the Pharmaceutical Schedule from 1 December 2019 as follows (additions in bold deletions in strikethrough) (amended criteria only showed below):

Special Authority for Subsidy

Initial application — (Chronic lymphocytic leukaemia) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1. The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment; and
2. **Either:**
   2.**1** The patient is rituximab treatment naive; ~~and~~ **or**
      2.1.1. ~~3~~ Either:
         2.1.1.1. ~~3.1~~ The patient is chemotherapy treatment naive; or
         2.1.1.2. ~~3.2~~ Both:
            2.1.1.2.1. ~~3.2.1~~ The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and
            2.1.1.2.2. ~~3.2.2~~ The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; ~~and~~ **or**
   2.2. The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; and
3. ~~5~~ The patient has good performance status; and
4. **Either:**
   4.1. The patient does not have chromosome 17p deletion CLL; ~~and~~ **or**
   4.2. Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and
5. ~~6~~ Rituximab to be administered in combination with fludarabine and cyclophosphamide**,** ~~or~~ bendamustine **or venetoclax** for a maximum of 6 treatment cycles; and
6. ~~7~~ It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration)**,** ~~or~~ bendamustine **or venetoclax**.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to < 2.

Renewal — (Chronic lymphocytic leukaemia) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

1. **Either:**
   1.1. The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; or
   1.2. All of the following:
      1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and
      1.2.2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment; and
      1.2.3 The patient does not have chromosome 17p deletion CLL; and
      1.2.4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and

2 ~~5~~ Rituximab to be administered in combination with fludarabine and cyclophosphamide**,** ~~or~~ bendamustine **or venetoclax** for a maximum of 6 treatment cycles.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

resolved to amend the restriction criteria for rituximab in Part II of Section H of the Pharmaceutical Schedule from 1 December 2019 as follows (additions in bold deletions in strikethrough) (amended criteria only showed below):

Restricted
Initiation – Chronic lymphocytic leukaemia

Re-assessment required after 12 months
All of the following:
1 The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment; and
2 Either:
2.**1** The patient is rituximab treatment naive; ~~and~~ **or**
2.1.1 ~~3~~ Either:
2.1.1.1 ~~3.1~~ The patient is chemotherapy treatment naive; or
2.1.1.2 ~~3.2~~ Both:
2.1.1.2.1 ~~3.2.1~~ The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and
2.1.1.2.2 ~~3.2.2~~ The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; ~~and~~ **or**
2.2 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; and
3 ~~5~~ The patient has good performance status; and
4 Either:
4.1 The patient does not have chromosome 17p deletion CLL; ~~and~~ **or**
4.2 Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and
5 ~~6~~ Rituximab to be administered in combination with fludarabine and cyclophosphamide**,** ~~or~~ bendamustine **or venetoclax** for a maximum of 6 treatment cycles; and
6 ~~7~~ It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration)**,** ~~or~~ bendamustine **or venetoclax**.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to < 2.

Continuation – Chronic lymphocytic leukaemia
Re-assessment required after 12 months
All of the following:
Both:
2. Either:
2.1. The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; or
2.2. All of the following:
1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and
1.2.2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment; and
1.2.3 The patient does not have chromosome 17p deletion CLL; and
1.2.4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and
2 ~~5~~ Rituximab to be administered in combination with fludarabine and cyclophosphamide**,** ~~or~~ bendamustine **or venetoclax** for a maximum of 6 treatment cycles.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

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

Dr Ken Clark arrived at 1.31pm

8.6 Summary of Vaccine Management Activity

noted this report.

10.2 Update on the review of the Consumer Advisory Committee

noted the findings from the recent independent review of the Consumer Advisory Committee;

noted that some of the recommendations to enhance current arrangements will be implemented straight away; and

noted further work is required to analyse other recommended options for change before final decisions can be made.

Nicole Anderson left the meeting at 1.50pm

11.1 Communications Report

noted the content of the Communications Report covering September 2019.

9. Schedule and Funding

9.1 Medical Devices Transaction and Investment Report

noted the contents of this paper.

9.2 Pharmaceutical Transaction and Investment Report

noted the contents of this paper.

9.4 Named Patient Pharmaceutical Assessment Update

noted the Named Patient Pharmaceutical Assessment activities since the previous update to the Board in September 2018.

10. Strategic Planning and Policy

10.1 Te Whaioranga Strategy Refresh

noted the contents of this paper.

11. Regular Reports and Noting Papers

11.2 Risk Report and Register

noted the updated risk register.

noted need to add risk related to reputation.

11.3 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 Friday 29 November 2019 in Wellington, commencing with the Directors Only from 9.00am, and attendees and relevant staff from 9.30am.

The meeting closed at 2.30pm.

Chair: Date: