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MINUTES OF THE PHARMACEUTICAL MANAGEMENT AGENCY (PHARMAC)

BOARD MEETING OCTOBER 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))	Chair
Claudia Wyss ((BHB, MBChB, MBA Harvard))	Deputy Chair (by zoom)
Talia Anderson-Town (BBS, PG Dip Professional Accounting, CA, CPP)	Board member
Anthony Jordan (BHB, MBChB, FRACP)	Board member (by zoom)
Diana Siew (PhD)	Board member

Board Observers

Peter Bramley	Board Observer, Te Whatu Ora representative
Lisa Lawrence	Board Observer, CAC Chair
Jane Thomas	Board Observer, PTAC Chair (by zoom)

Pharmac staff in attendance

Sarah Fitt	Chief Executive
Michael Johnson	Director, Strategic Initiatives
Peter Alsop	Director, Engagement & Implementation
Kathryn McInteer	Director, Finance and Corporate
Trevor Simpson	Director, Māori
David Hughes	Chief Medical Officer
Andrew Davies	Acting Director of Operations
Carol Morris	Board Secretary

Attendees joined the meeting to present relevant papers: Ben Campbell-Macdonald (zoom), Geraldine MacGibbon, Ashton Rounthwaite, Ishani Noble, Jared Solloway, Andrew Oliver, Joshua Cronin-Lampe, Logan Heyes, Danae Staples-Moon, Brent McPherson, Sandy Bhawan, Jannel Fisher, Davina Carpenter and Yazmin Juned.

1. Directors-only Discussion

It was noted that Diana Siew and Anthony Jordan will be apologies for the November Board meeting (to be held 2 December).

1.1 Glossary of Terms

1.2 Board Actions

The Board **noted** the Board Actions.

1.3 Board Annual Agenda 2022

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

1.4 Board and Committee Member Terms

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

1.5 Chief Executive Review

The Board **noted** the Chief Executive Review.

2. Apologies

Lisa Williams, Director of Operations.

3. Record of Previous Board and Committee Meetings

3.1 Minutes of Board Meeting held 30 September 2022

The Board **resolved** to adopt the minutes of the 30 September 2022 meeting as being a true and correct record.

Diana Siew and Talia Anderson-Town **Carried**

3.2 Minutes of Audit and Risk Committee Meeting of 30 September 2022

The Board **resolved** the Audit and Risk Committee minutes of the 30 September 2022 meeting.

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

3.3 Summary of Health and Safety Committee meeting

The Committee Chair provided a verbal update to the Board on the October Health and Safety Committee meeting. It was noted that good progress has been made in developing the quarterly work plan and we are high performing in some activities. The Committee is comfortable with the quarterly Health and Safety metrics.

3.4 Notes from Board Strategy meeting of 29 September 2022

The Board **noted** the Board Strategy meeting notes of 29 September 2022.

4. Interests Register

The Board:

noted the interests register.

noted any decisions by the Chair to manage actual or potential conflicts of interest.

5. Matters Arising

The Board **noted** the matters arising and actions progressed.

- Pae ora discussions to be held in future meetings.
- In relation to offsite board meetings, it was decided that travel to Board meetings contributes to carbon footprint and therefore the Board proposes to bring attendees to Wellington rather than the Board travel offsite.

6. Chair's Report

6.1 Verbal Report

A verbal update was provided by the Board Chair.

The Board chair:

- Advised that the Chair of Medicine New Zealand is changing
- Response for final review has been extended to 14 November
- Meeting with Board Chair of Te Aka Whai Ora did not take place and is currently being rescheduled
- Ongoing discussions around sourcing vaccine and treatment for monkeypox
- Various correspondence has been received in relation to the myeloma medicines funding campaign and are being replied to
- Liz Zhu, former Board observer whose term expired in September, will feature in an Institute of Directors' article about her time as an observer on the Pharmac Board.

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.
- A new Māori Directorate has been formed with Trevor Simpson being appointed to fill the new Kaituruki Māori - Director Māori position. This is a positive step in lifting our capacity across the organisation and meeting te Tiriti o Waitangi obligations.
- The Kaituruki Māori met with Te Aka Whai Ora for initial conversations with key people in the organisation.
- The Chief Executive and Director of Strategic Initiatives met with Chief Executive of Te Whatu Ora, Margie Apia to discuss implications of their strategy direction in relation to Pharmac. The key theme of the meeting was the health plan and agency priorities and ensuring that we are aligned. It was acknowledged we are all working towards Pae Ora.

External Guest Speaker for October 2022 Board meeting

Theme: Medical Devices

A panel of external stakeholders was organised to share thoughts with Pharmac Board members and to give them the opportunity to hear different perspectives from stakeholders about what medical devices mean to them. The panel discussion provided a range of viewpoints and each member gave a five-minute talk about what was important to them about medical devices.

The Chair thanked the group for an interesting and useful session.

7.2 Financial Report

The Board **noted** the September 2022 Financial report and appendices.

8. Key items

8.1 Prioritisation Report

This paper describes prioritisation activity since the last report presented to the Board at its July 2022 meeting. It also updates the Board on the progress of selected items from the following prioritisation lists:

- the top 10 proposals on the *Options for Investment* list
- proposals with a high PTAC priority on the *Options for Investment* or *Under Assessment* lists
- proposals with a high PTAC or Specialist Advisory Committee priority on the *Under-Assessment* list.

The Board **noted** the prioritisation activity undertaken by Pharmac staff since July 2022 and the progress of selected items from Pharmac's prioritisation list.

Since the report, there have been 15 new proposals prioritised and nine updated in the options for investments list and proposals.

8.2 Pharmaceutical Budget Management Report

This paper provided an update the Board on the pharmaceutical budget, including the October 2022 expenditure forecast and COVID-19 related expenditure. It enabled a wider discussion by the Board regarding planned activities to manage expenditure in 2022/23 and in the out-years. The update on COVID-19 costs incurred and any associated risks was also noted by the Board.

8.3 Pharmaceutical Transaction Report

This paper provided 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.

The Board:

resolved to delegate decision-making for a Named Patient Pharmaceutical Assessment (NPPA) to the Chief Executive due to urgency.

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

noted that the expenditure update that is usually provided in this paper is addressed in the separate budget management options paper (referred to in Board agenda)

Anthony Jordan and Claudia Wyss **Carried**

8.4 Proposal to fund PCV13, pneumococcal vaccine CPB Management Report

Diana Siew left the meeting for item 8.4.

This paper sought a decision from the Board on a significant pharmaceutical investment transaction that would widen access to an existing listing and end sole supply status for another existing treatment, to meet clinical needs.

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

resolved to amend the restrictions applying to the listing of pneumococcal (PCV13) conjugate vaccine in Section I of the Pharmaceutical Schedule from 1 December 2022 (additions in bold, deletions strikethrough):

Any of the following:

1. **A course of three doses for previously unvaccinated children up to the age of 59 months inclusive; or**
2. Two doses are funded for high-risk ~~children~~ individuals (over the age of 12 months and under 18 years) who have previously received two doses of the primary course of PCV10; or
3. Up to an additional four doses (as appropriate) are funded **for the (re)immunisation of** ~~for~~ high-risk children aged under 5 years ~~for (re-)immunisation of patients~~ with any of the following:
    a. on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
    b. ~~with~~ primary immune deficiencies; or
    c. ~~with~~ HIV infection; or
    d. ~~with~~ renal failure, or nephrotic syndrome; or
    e. who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
    f. ~~with~~ cochlear implants or intracranial shunts; or
    g. ~~with~~ cerebrospinal fluid leaks; or
    h. receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
    i. ~~with~~ chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
    j. pre-term infants, born before 28 weeks gestation; or
    k. ~~with~~ cardiac disease, with cyanosis or failure; or
    l. ~~with~~ diabetes; or
    m. ~~with~~ Down syndrome; or
    n. who are pre-or post-splenectomy, or with functional asplenia; or
4. Up to an additional four doses (as appropriate) are funded for the (re-)immunisation of ~~patients~~ **individuals** 5 years and over with HIV, ~~for patients~~ pre or post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post-solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, intracranial shunts, cerebrospinal fluid leaks or primary immunodeficiency; or
5. For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes

resolved to amend the restrictions applying to the listing of pneumococcal (PCV13) conjugate vaccine in Part II of Section H of the Pharmaceutical Schedule from 1 December 2022 (additions in bold, deletions strikethrough):

Restricted
Initiation – Primary course for previously unvaccinated individuals
Therapy limited to 3 doses

A primary course of three doses for previously unvaccinated children up to the age of 59 months inclusive.

Initiation – High risk children who have received PCV10
Therapy limited to 1 dose

Two doses are funded for high-risk ~~children~~ individuals (over the age of 12 months and under 18 years) who have previously received two doses of the primary course of PCV10.

Initiation – High risk children aged under 5 years
Therapy limited to 4 doses
Both:

1. Up to an additional four doses (as appropriate) are funded **for the (re)immunisation of** ~~for~~ high-risk children aged under 5 years ~~for (re-)immunisation of patients~~; and
2. Any of the following:
   - 2.1. on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
   - 2.2. ~~with~~ primary immune deficiencies; or
   - 2.3. ~~with~~ HIV infection; or
   - 2.4. ~~with~~ renal failure, or nephrotic syndrome; or
   - 2.5. ~~who~~ are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
   - 2.6. ~~with~~ cochlear implants or intracranial shunts; or
   - 2.7. ~~with~~ cerebrospinal fluid leaks; or
   - 2.8. receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
   - 2.9. ~~with~~ chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
   - 2.10. pre-term infants, born before 28 weeks gestation; or
   - 2.11. ~~with~~ cardiac disease, with cyanosis or failure; or
   - 2.12. ~~with~~ diabetes; or
   - 2.13. ~~with~~ Down syndrome; or
   - 2.14. who are pre-or post-splenectomy, or with functional asplenia.

Initiation – High risk adults and children 5 years and over
Therapy limited to 4 doses

Up to an additional four doses (as appropriate) are funded for the (re-)immunisation of ~~patients~~ **individuals** 5 years and over with HIV, ~~for patients~~ pre or post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post-solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, intracranial shunts, cerebrospinal fluid leaks or primary immunodeficiency.

Initiation – Testing for primary immunodeficiency diseases

For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Note: Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

resolved to end sole supply for pneumococcal (PCV10) conjugate vaccine (Synflorix) inj 1 mcg of pneumococcal polysaccharide serotypes 1, 5, 6B, 7F, 9V, 14 and 23F; 3 mcg of pneumococcal polysaccharide serotypes 4, 18C and 19F in 0.5 ml prefilled syringe in Section I of the Pharmaceutical Schedule from 30 November 2022.

resolved to end sole supply for pneumococcal (PCV10) conjugate vaccine (Synflorix) inj 1 mcg of pneumococcal polysaccharide serotypes 1, 5, 6B, 7F, 9V, 14 and 23F; 3 mcg of pneumococcal polysaccharide serotypes 4, 18C and 19F in 0.5 ml prefilled syringe in Part II of Section H of the Pharmaceutical Schedule from 30 November 2022.

resolved to approve the 21 September 2022 agreement with Pfizer New Zealand Limited for supply of pneumococcal (PCV13) conjugate vaccine (Prevenar 13).

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

noted that listing pneumococcal (PCV13) conjugate vaccine is considered necessary due to clinical risk and is strongly supported by clinical advice.

Claudia Wyss and Anthony Jordan **Carried**

Following the Board consideration of the proposal to widen access to PCV13 vaccine, the Board requested minor wording changes to the Special Authority criteria. On review, the titles of the Section H criteria were not aligned with the terminology used in the criteria itself in relation to 'children' and 'individuals'. This has since been amended and approved by the Chief Executive under delegated authority from the Board.

Diana Siew returned to the meeting.

8.5 Proposal to fund ibrutinib, paliperidone and risperidone

This paper was presented for Board decision on a significant pharmaceutical investment transaction that would result in new listings to meet clinical needs 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 ibrutinib (Imbruvica) and paliperidone palmitate (Invega Trinza) in the Pharmaceutical Schedule, as set out below

resolved to approve the amendments to the Pharmaceutical Schedule relating to paliperidone (Invega Sustenna) and risperidone (Risperdal Consta), as set out in below

resolved to approve the 7 September 2022 agreement with Janssen-Cilag Pty Ltd

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

Paliperidone three-monthly

resolved to list paliperidone palmitate in the Nervous Systems Therapeutic Group (Depot injections subgroup) in Section B of the Pharmaceutical Schedule from 1 December 2022 as follows:

Chemical	**Presentation**	**Brand**	**Pack Size**	**Price and subsidy** (ex-man., ex. GST)
Paliperidone palmitate	Inj 175 mg syringe	Invega Trinza	1	$815.85
Paliperidone palmitate	Inj 263 mg syringe	Invega Trinza	1	$1,072.26
Paliperidone palmitate	Inj 350 mg syringe	Invega Trinza	1	$1,305.36
Paliperidone palmitate	Inj 525 mg syringe	Invega Trinza	1	$1,305.36

resolved to list paliperidone palmitate in Section B of the Pharmaceutical Schedule subject to the following restrictions from 1 December 2022:

Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Both:
1 The patient has schizophrenia; and

2 The patient has had an initial Special Authority approval for paliperidone once-monthly depot injection.

Renewal from any relevant practitioner. Approvals valid for 12 months where the initiation of paliperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection.

Resolved to list paliperidone palmitate in the Nervous Systems Therapeutic Group (Depot injections subgroup) in Part II of Section H of the Pharmaceutical Schedule from 1 December 2022 as follows:

Chemical	Presentation	Brand	Pack Size	Price and subsidy (ex-man., ex. GST)
Paliperidone palmitate	Inj 175 mg syringe	Invega Trinza	1	$815.85
Paliperidone palmitate	Inj 263 mg syringe	Invega Trinza	1	$1,072.26
Paliperidone palmitate	Inj 350 mg syringe	Invega Trinza	1	$1,305.36
Paliperidone palmitate	Inj 525 mg syringe	Invega Trinza	1	$1,305.36

resolved to list paliperidone palmitate in Part II of Section H of the Pharmaceutical Schedule subject to the following restrictions from 1 December 2022:

Restricted
Initiation
Re-assessment required after 12 months
Both:
1 The patient has schizophrenia; and
2 The patient has had an initial Special Authority approval for paliperidone once-monthly depot injection.

Continuation
Re-assessment required after 12 months
The initiation of paliperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection.

noted a confidential rebate would apply to Invega Trinza that would reduce the net price to the Funder

noted Invega Trinza would have protection from delisting and subsidy reduction until 30 November 2025.

Ibrutinib

resolved to list ibrutinib (Imbruvica) in the Oncology Agents and Immunosuppressants Therapeutic Group (Other Cytotoxic Agents subgroup) in Section B of the Pharmaceutical Schedule from 1 December 2022 as follows:

Chemical	Presentation	Brand	Pack Size	Price and subsidy (ex-man., ex. GST)
Ibrutinib	Tab 140 mg	Imbruvica	30	$3,217.00

Ibrutinib	Tab 420 mg	Imbruvica	30	$9,652.00

resolved to list ibrutinib in Section B of the Pharmaceutical Schedule subject to the following restrictions from 1 December 2022:

Special Authority for Subsidy
Initial application – (chronic lymphocytic leukaemia (CLL)) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1 Patient has chronic lymphocytic leukaemia (CLL) requiring therapy; and
2 Patient has not previously received funded ibrutinib; and
3 Ibrutinib is to be used as monotherapy; and
4 Any of the following:
- 4.1 Both:
  - 4.1.1 There is documentation confirming that patient has 17p deletion or TP53 mutation; and
  - 4.1.2 Patient has experienced intolerable side effects with venetoclax monotherapy; or
- 4.2 All of the following:
  - 4.2.1 Patient has received at least one prior immunochemotherapy for CLL; and
  - 4.2.2 Patient's CLL has relapsed within 36 months of previous treatment; and
  - 4.2.3 Patient has experienced intolerable side effects with venetoclax in combination with rituximab regimen; or
- 4.3 Patient's CLL is refractory to or has relapsed within 36 months of a venetoclax regimen.

Renewal – (chronic lymphocytic leukaemia (CLL)) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Both:
1 No evidence of clinical disease progression; and
2 The treatment remains appropriate and the patient is benefitting from 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 list ibrutinib (Imbruvica) in the Oncology Agents and Immunosuppressants Therapeutic Group (Other Cytotoxic Agents subgroup) in Part II of Section H of the Pharmaceutical Schedule from 1 December 2022 as follows:

Chemical	**Presentation**	**Brand**	**Pack Size**	**Price and subsidy** (ex-man., ex. GST)
Ibrutinib	Tab 140 mg	Imbruvica	30	$3,217.00
Ibrutinib	Tab 420 mg	Imbruvica	30	$9,652.00

resolved to list ibrutinib in Part II of Section H of the Pharmaceutical Schedule subject to the following restrictions from 1 December 2022:

Restricted
Initiation – chronic lymphocytic leukaemia (CLL)
Re-assessment required after 6 months
All of the following:
1 Patient has chronic lymphocytic leukaemia (CLL) requiring therapy; and
2 Patient has not previously received funded ibrutinib; and
3 Ibrutinib is to be used as monotherapy; and
4 Any of the following:
- 4.1 Both:
  - 4.1.1 There is documentation confirming that patient has 17p deletion or TP53 mutation; and

4.1.2 Patient has experienced intolerable side effects with venetoclax monotherapy; or

4.2 All of the following:

4.2.1 Patient has received at least one prior immunochemotherapy for CLL; and

4.2.2 Patient's CLL has relapsed within 36 months of previous treatment; and

4.2.3 Patient has experienced intolerable side effects with venetoclax in combination with rituximab regimen; or

4.3 Patient's CLL is refractory to or has relapsed within 36 months of a venetoclax regimen.

Continuation – chronic lymphocytic leukaemia (CLL)
Re-assessment required after 12 months
Both:

1. No evidence of clinical disease progression; and
2. The treatment remains appropriate and the patient is benefitting from treatment.

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

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

noted Imbruvica would have protection from delisting and subsidy reduction until 30 November 2025.

Paliperidone one-monthly

resolved to maintain the current price and subsidy for paliperidone in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 December 2022 as follows (ex-manufacturer, excluding GST)

Chemical	Presentation	Brand	Pack size	Current price and subsidy
Paliperidone	Inj 25 mg syringe	Invega Sustenna	1	$194.25
Paliperidone	Inj 50 mg syringe	Invega Sustenna	1	$271.95
Paliperidone	Inj 75 mg syringe	Invega Sustenna	1	$357.42
Paliperidone	Inj 100 mg syringe	Invega Sustenna	1	$435.12
Paliperidone	Inj 150 mg syringe	Invega Sustenna	1	$435.12

noted a new confidential rebate would apply to Invega Sustenna that would further reduce the net price to the Funder

noted there would be no changes to the current Special Authority criteria or hospital restrictions for paliperidone (Invega Sustenna)

noted Invega Sustenna would have protection from delisting and subsidy reduction until 30 November 2025.

Risperidone

resolved to maintain the current price and subsidy for risperidone in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 December 2022 as follows (ex-manufacturer, excluding GST)

Chemical	Presentation	Brand	Pack size	Current price and subsidy
Paliperidone	Inj 25 mg vial	Risperdal Consta	1	$135.98
Paliperidone	Inj 37.5 mg vial	Risperdal Consta	1	$178.71
Paliperidone	Inj 50 mg vial	Risperdal Consta	1	$217.56

noted a new confidential rebate would apply to Risperdal Consta that would further reduce the net price to the Funder

noted there would be no changes to the current Special Authority criteria or hospital restrictions for risperidone (Risperdal Consta)

noted Risperdal Consta would have protection from delisting and subsidy reduction until 30 November 2025.

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

8.6 Proposal to fund vedlizumab, brentuximab and icatibant

This paper was presented for Board decision on a significant pharmaceutical transaction that would result in new listings 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 vedolizumab (Entyvio) and brentuximab vedotin (Adcetris) in the Pharmaceutical Schedule, as set out below

resolved to approve the amendments to the Pharmaceutical Schedule relating to icatibant (Firazyr) as set out below

resolved to approve the 14 September 2022 agreement with Takeda New Zealand Limited (Takeda)

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

Vedolizumab

resolved to list vedolizumab (Entyvio) in the Oncology Agents and Immunosuppressants therapeutic group and Monoclonal Antibodies subgroup in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 February 2023 as follows:

Chemical	Presentation	Brand	Pack Size	Price and subsidy (ex-man., ex. GST)
Vedolizumab	Inj 300 mg vial	Entyvio	1	$3,313.00

resolved to apply the following Special Authority criteria to vedolizumab in Section B of the Pharmaceutical Schedule from 1 February 2023 as follows:

Special Authority for Subsidy

Initial application – (Crohn's disease – adults) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Patient has active Crohn's disease; and
2. Either;
   - 2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
   - 2.2 Any of the following:
     - 2.2.1 Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10; or
     - 2.2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
     - 2.2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
     - 2.2.4 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
3. Any of the following:
   - 3.1.1 Patient has tried but had experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
   - 3.1.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
   - 3.1.3 Immunomodulators and corticosteroids are contraindicated; and
4. Surgery (or further surgery) is considered to be clinically inappropriate.

Renewal – (Crohn's disease – adults) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1. Any of the following:
   - 1.1 CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated on biologic therapy; or
   - 1.2 CDAI score is 150 or less, or HBI is 4 or less; or
   - 1.3 The patient has demonstrated an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed; and
2. Vedolizumab to administered at a dose no greater than 300 mg every 8 weeks.

Initial application – (Crohn's disease – children*) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:
1. Paediatric patient has active Crohn's disease; and
2. Either:

2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
2.2 Either:
Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or
2.3 Patient has extensive small intestine disease; and
3. Any of the following:
3.1 Patient has tried but had experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
3.3 Immunomodulators and corticosteroids are contraindicated; and
4. Surgery (or further surgery) is considered to be clinically inappropriate.

Note: Indication marked with * is an unapproved indication

Renewal – (Crohn's disease – children*) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:
1. Any of the following:
1.1 PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy; or
1.2 PCDAI score is 15 or less; or
1.3 The patient has demonstrated an adequate response to treatment, but CDAI score cannot be assessed; and
2. Vedolizumab to administered at a dose no greater than 300 mg every 8 weeks.

Note: Indication marked with * is an unapproved indication

Initial application – (ulcerative colitis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:
1. Patient has histologically confirmed ulcerative colitis; and
2. Either:
2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
2.2 Either:
2.3 Patient has a SCCAI score is greater than or equal to 4; or
2.4 Patient's PUCAI score is greater than or equal to 65*; and
3 Any of the following:
3.1 Patient has tried but had experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
3.3 Immunomodulators and corticosteroids are contraindicated); and
4 Surgery (or further surgery) is considered clinically inappropriate.

Note: Indication marked with * is an unapproved indication

Renewal – (ulcerative colitis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:
1. Either
1.1 The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy; or

1.2 The PUCAI score has reduced by 30 points or more from the PUCAI score since initiation on biologic therapy*; and

2. Vedolizumab will be used at a dose no greater than 300 mg intravenously every 8 weeks.

Note: Indication marked with * is an unapproved indication

resolved to apply the following restrictions to vedolizumab in Part II of Section H of the Pharmaceutical Schedule from 1 February 2023 as follows:

Restriction
Initiation - Crohn's disease – Adults
Reassessment required after 6 months
Prerequisites

All of the following:
1. Patient has active Crohn's disease; and
2. Either:
   2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
   2.2 Any of the following:
      2.2.1 Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10; or
      2.2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
      2.2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
      2.2.4 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
3. Any of the following:
   3.1 Patient has tried but had experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
   3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
   3.3 Immunomodulators and corticosteroids are contraindicated; and
4. Surgery (or further surgery) is considered to be clinically inappropriate.

Continuation - Crohn's disease - adults
Reassessment required after 6 months

Both:
1. Any of the following:
   1.1 CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated on biologic therapy; or
   1.2 CDAI score is 150 or less, or HBI is 4 or less; or
   1.3 The patient has demonstrated an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed; and
2. Vedolizumab to administered at a dose no greater than 300 mg every 8 weeks.

Initiation - Crohn's disease – children*
Reassessment required after 6 months

All of the following:
1. Paediatric patient has active Crohn's disease; and
2. Either:
   2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
   2.2 Either:
      2.2.1 Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or
      2.2.2 Patient has extensive small intestine disease; and
3. Any of the following:

3.1 Patient has tried but had experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
3.3 Immunomodulators and corticosteroids are contraindicated); and
4. Surgery (or further surgery) is considered to be clinically inappropriate.

Note: Indication marked with * is an unapproved indication

Continuation - Crohn's disease – children*
Reassessment required after 6 months
Prerequisites

Both:
1. Any of the following:
1.1 PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy; or
1.2 PCDAI score is 15 or less; or
1.3 The patient has demonstrated an adequate response to treatment, but CDAI score cannot be assessed; and
2. Vedolizumab to administered at a dose no greater than 300 mg every 8 weeks.

Note: Indication marked with * is an unapproved indication

Initiation – ulcerative colitis
Reassessment required after 6 months

All of the following:
1. Patient has histologically confirmed ulcerative colitis; and
2. Either:
2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
2.2 Either:
2.2.1 Patient has a SCCAI score is greater than or equal to 4; or
2.2.2 Patient's PUCAI score is greater than or equal to 65*; and
3. Any of the following:
3.1 Patient has tried but had experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
3.3 Immunomodulators and corticosteroids are contraindicated; and
4. Surgery (or further surgery) is considered clinically inappropriate.

Note: Indication marked with * is an unapproved indication

Continuation – ulcerative colitis
Reassessment required after 6 months

Both:
1. Either
1.1 The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy; or
1.2 The PUCAI score has reduced by 30 points or more from the PUCAI score since initiation on biologic therapy*; and
2. Vedolizumab will be used at a dose no greater than 300 mg intravenously every 8 weeks.

Note: Indication marked with * is an unapproved indication

resolved to apply PCT only to vedolizumab in Section B of the Pharmaceutical Schedule from 1 February 2023

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

noted Entyvio would have protection from delisting and subsidy reduction until 31 January 2026.

Brentuximab vedotin

resolved to list brentuximab vedotin (Adcetris) in the Oncology Agents and Immunosuppressants therapeutic group, monoclonal antibodies subgroup in Section B and Part II of Section H of the Pharmaceutical Schedule as soon as practicable following Medsafe approval, as follows:

Chemical	Presentation	Brand	Pack Size	Price and subsidy (ex-man., ex. GST)
Brentuximab vedotin	Inj 50 mg vial	Adcetris	1	$5,275.18

resolved to apply the following Special Authority criteria to brentuximab vedotin in Section B of the Pharmaceutical Schedule as soon as practicable following Medsafe approval as follows:

Initial application - (relapsed/refractory Hodgkin lymphoma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Either:
    1.1. Both:
        1.1.1. Patient has relapsed/refractory CD30-positive Hodgkin lymphoma after two or more lines of chemotherapy; and
        1.1.2. Patient is ineligible for autologous stem cell transplant; or
    1.2. Both:
        1.2.1. Patient has relapsed/refractory CD30-positive Hodgkin lymphoma; and
        1.2.2. Patient has previously undergone autologous stem cell transplant; and
2. Patient has not previously received funded brentuximab vedotin; and
3. Response to brentuximab vedotin treatment is to be reviewed after a maximum of 6 treatment cycles; and
4. Brentuximab vedotin to be administered at doses no greater than 1.8 mg/kg every 3 weeks.

Renewal - (relapsed/refractory Hodgkin lymphoma) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:
All of the following:
1. Patient has achieved a partial or complete response to brentuximab vedotin after 6 treatment cycles; and
2. Treatment remains clinically appropriate and the patient is benefitting from treatment and treatment is being tolerated; and
3. Patient is to receive a maximum of 16 total cycles of brentuximab vedotin treatment.

Initial application - (anaplastic large cell lymphoma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Patient has relapsed/refractory CD30-positive systemic anaplastic large cell lymphoma; and
2. Patient has an ECOG performance status of 0-1; and
3. Patient has not previously received brentuximab vedotin; and
4. Response to brentuximab vedotin treatment is to be reviewed after a maximum of 6 treatment cycles; and
5. Brentuximab vedotin to be administered at doses no greater than 1.8 mg/kg every 3 weeks.

Renewal - (anaplastic large cell lymphoma) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:
1. Patient has achieved a partial or complete response to brentuximab vedotin after 6 treatment cycles; and
2. Treatment remains clinically appropriate and the patient is benefitting from treatment and treatment is being tolerated; and
3. Patient is to receive a maximum of 16 total cycles of brentuximab vedotin treatment

resolved to apply the following restrictions to brentuximab vedotin in Part II of Section H of the Pharmaceutical Schedule as soon as practicable following Medsafe approval as follows:

Restriction
Initiation - relapsed/refractory Hodgkin lymphoma
Reassessment required after 6 months
All of the following:
1. Either:
    1.1. Both:
        1.1.1. Patient has relapsed/refractory CD30-positive Hodgkin lymphoma after two or more lines of chemotherapy; and
        1.1.2. Patient is ineligible for autologous stem cell transplant; or
    1.2. Both:
        1.2.1. Patient has relapsed/refractory CD30-positive Hodgkin lymphoma; and
        1.2.2. Patient has previously undergone autologous stem cell transplant; and
2. Patient has not previously received funded brentuximab vedotin; and
3. Response to brentuximab vedotin treatment is to be reviewed after a maximum of 6 treatment cycles; and
4. Brentuximab vedotin to be administered at doses no greater than 1.8 mg/kg every 3 weeks.

Continuation - relapsed/refractory Hodgkin lymphoma
Reassessment required after 9 months
All of the following:
1. Patient has achieved a partial or complete response to brentuximab vedotin after 6 treatment cycles; and
2. Treatment remains clinically appropriate and the patient is benefitting from treatment and treatment is being tolerated; and
3. Patient is to receive a maximum of 16 total cycles of brentuximab vedotin treatment.

Initiation - anaplastic large cell lymphoma
Reassessment required after 9 months

All of the following:
1. Patient has relapsed/refractory CD30-positive systemic anaplastic large cell lymphoma; and
2. Patient has an ECOG performance status of 0-1; and
3. Patient has not previously received brentuximab vedotin; and
4. Response to brentuximab vedotin treatment is to be reviewed after a maximum of 6 treatment cycles; and
5. Brentuximab vedotin to be administered at doses no greater than 1.8 mg/kg every 3 weeks.

Continuation – anaplastic large cell lymphoma
Reassessment required after 9 months
All of the following:
1. Patient has achieved a partial or complete response to brentuximab vedotin after 6 treatment cycles; and
2. Treatment remains clinically appropriate and the patient is benefitting from treatment and treatment is being tolerated; and
3. Patient is to receive a maximum of 16 total cycles of brentuximab vedotin treatment

resolved to apply PCT only to brentuximab vedotin in Section B of the Pharmaceutical Schedule at a date to be determined

resolved to establish a pathway under our Exceptional Circumstances Framework to consider applications for funded access to brentuximab vedotin prescribed and used in accordance with Section 29 of the Medicines Act 1981 for patients who consent to treatment and meet eligibility criteria, from 1 December 2022 until brentuximab vedotin is listed on the Pharmaceutical Schedule

noted that a confidential rebate would apply to Adcetris from 1 December 2022 that would reduce the net price to the Funder

noted that brentuximab vedotin would have protection from delisting and subsidy reduction until 30 November 2025

noted that brentuximab vedotin is not Medsafe approved and would be listed in the Schedule as soon as reasonably practicable following Medsafe approval.

Icatibant

resolved to maintain the current price and subsidy for icatibant (Firazyr) in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 December 2022 as follows (ex-manufacturer, excluding GST)

Chemical	Presentation	Brand	Pack size	Current price and subsidy
Icatibant	Inj 10 mg per ml, 3 ml prefilled syringe	Firazyr	1	$2,668.00

noted that a new confidential rebate would apply to Firazyr that would further reduce the net price to the Funder from 1 December 2022

noted there would be no changes to the current Special Authority criteria or hospital restrictions for Firazyr

noted that Firazyr would have protection from delisting and subsidy reduction until 30 November 2024.

Diana Siew and Talia Anderson-Town **Carried**

8.7 Medical Devices Transaction Report

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

8.8 Summary of Decisions made under Delegated Authority for September 2022

The Board **noted** the summary of decisions made under Delegated Authority during September 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 Medical Devices Programme Update

This paper provided the Board with an update on our Medical Devices Programme and further detail of the proposed timeline and approach planned for delivery by the Investment Management Project component of this programme.

The Board:

noted progress of the programme to deliver on its medical devices strategic priority

noted the proposed approach for moving to the next stage of the Medical Device Programme, Investment Management (Fairer Access), and the identified issues and risks of this approach

noted the timeframe for moving to the Investment Management stage is heavily resource dependant

noted that more regular updates on progress with the Investment Management Project will be provided to the Board

noted that a focus for the Programme over the next few months is to build relationships with Te Whatu Ora and discuss roles and responsibilities with respect to medical devices; with a view to formalising a partnership at the organisational level.

9.2 Exceptional Circumstances Update

The Board were provided an annual update on Pharmac's management of applications under the Exceptional Circumstances framework for 2021/22, highlighting any particular areas where there have been changes in outcomes or approach since the last report.

The Board **noted** the update on activities under the Exceptional Circumstances framework, including an update on Named Patient Pharmaceutical Assessments, since the previous update to the Board in November 2021.

9.3 Research Activity update

The Board **noted** the annual update on Pharmac's research commitment and activities.

9.4 Report-back on Health Technology Association International (HTAi) Conference

In March 2022, the Board approved attendance of the Manager Pharmaceutical Assessment at the 2022 annual conference of Health Technology Assessment International (HTAi) in Utrecht, Netherlands. This paper summarised the highlights and observations from the Manager Pharmaceutical Assessment's attendance at the meeting.

10. Strategic Planning and Policy

10.1 2022/23 Q1 Performance Report

This paper provided the Board with a summary of the progress of our strategic initiatives from the Statement of Performance Expectations 2022/23 (SPE), which includes Pharmac Review response initiatives.

The Board **noted** Pharmac's Quarter One Performance Report

10.2 Disabilities Update

This paper identifies the first steps we will take to better meet the needs and interests of tangata whaikaha (disabled people) and confirms the commencement of an initial 'discovery' piece of work identifying what tangata whaikaha need from Te Pātaka Whaioranga Pharmac. It also described the scope and objectives of a two-phased approach.

The Board:

noted that this paper provides assurance that we are progressing this important aspect of our work, including responding to the Pharmac review

noted the intended approach for building a strong disability focus into Te Pātaka Whaioranga Pharmac's work

noted that the paper is for information only, for awareness about planned work, and no decisions are required at this stage.

11.0 Regular Reporting

11.1 Communications Report

This paper summarised communications and engagement activity for September 2022 and the impact of our work.

The Board:

noted that the eight proactive media releases and pitches in September resulted in a large amount of positive coverage including positive comments from patient advocacy groups

noted our proactive and transparent approach to media management with meetings in Auckland with several key reporters

noted our media sentiment score has increased to 0.5 this quarter and that our key messages and spokespeople are included in more media coverage than other government agencies

noted our social media sentiment score has increased to 0.4 this quarter and our social media engagement has also increased.

11.2 Q1 Risk Register

The full risk register, which has been considered by the Audit and Risk Committee was provided to the Board. The purpose of the risk management programme, and this paper summarising its status, was to identify potential problems before they occur, or, in the case of mitigation or improvement opportunities, to ensure that positive action steps are taken.

The Board**:**

noted the risk register provides a summary of current and ongoing risks of relevance to the Board for the first quarter

noted that the quarter one risk register will be included in the quarterly report to the Minister of Health following the October Board meeting.

11.3 Legal Report

The purpose of this paper was for Pharmac's legal team to provide a legal oversight of all contracts, and supports decision making processes as required, including for those matters that come before the Board. The legal report provided 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.

The Board **noted** the legal report which provides an update on key legal issues.

12. Interest Articles

The Board **noted** the interest articles.

13. General Business

To consider a third member for the Health and Safety Committee in early 2023.

The meeting closed at 2.45pm with a karakia.

Date of Next Meeting

The date for the next Board meeting is set for Friday, 2 December 2022.

Chair: _____ Date: _____
Steve Maharey