PHARMAC
TE PĀTAKA WHAIORANGA

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Some information may have been redacted for reasons including confidentiality

Pharmaceutical Management Agency (Pharmac)

Minutes of the Board Meeting

Held on Tuesday 25 March 2025 at 9.00am

At Pharmac, Wellington

Present:

Board members

Paula Bennett	Chair
Dr Peter Bramley (BSc (Hon), LL.B, PhD)	Deputy Chair
Talia Anderson-Town (BBS, PG Dip Professional Accounting, CA, CPP)	Board member
Anna Adams	Board member
Lucy Elwood	Board member
Dr Margaret Wilsher (MD, FRACP, FRACMA)	Board member

Apologies Nil

Board Observers

Rhiannon Braund	Board Observer, PTAC Representative
Robyn Manuel	Board Observer, CAC Chair

Guests

Chris James	Medsafe

Pharmac staff in attendance

Sarah Fitt	Chief Executive
Catherine Epps	Director, Medical Devices
Michael Johnson	Director, Strategy, Policy & Performance and Acting Director, Corporate Services
Geraldine MacGibbon	Director, Pharmaceuticals
Nicola Ngawati	Director, Equity & Engagement
David Hughes	Director, Advice and Assessment/CMO
Trevor Simpson	
Jacqui Webber	Board Secretary (Minute taker)

Attendees joined the meeting to present relevant papers: Saar Cohen-Ronen, Rose Simpson, Natalie James, Robyn Harris.

The meeting commenced with a mihi whakatau to welcome two new Board members - Anna Adams and Lucy Elwood. Following the mihi whakatau, the Board carried out a floor walk for Health & Safety purposes.

1. Directors Only time

The Board held *Board Only* discussions, prior to formally commencing the meeting.

Welcome and Opening of Meeting

Following Directors only time, the Chair welcomed everyone and formally opened the meeting at 9.30am with a karakia. The Chair welcomed Lucy Elwood and Anna Adams to the Board.

The Chair welcomed Chris James to the meeting.

2. Guest – Chris James

Chris James, Group Manager of Medsafe, joined the meeting to discuss hot topics with the Board. The Board enjoyed an interactive and informative session.

3. Chair's Report

3.1 Chair's Verbal Update

The Chair provided an update on recent activities.

The Chair noted that:

- recently met with Minister Seymour and Minister Brown – they were good, positive interactions. The Ministers would like Pharmac to put their best foot forward on proposed savings.
- Acting Chief Executive, Brendan Boyle, would be joining the Board for lunch and the recruitment process is underway for a permanent replacement Chief Executive.
- Crown entities reference group – the Chair will be a member.

The Chair took the opportunity to acknowledge that it was Sarah Fitt's last meeting and noted the considerable impact she has had on the organisation. Sarah would be missed, and the Board wished her well in her future endeavours.

3.2 Minutes of Board meetings

The Board **resolved** to adopt the minutes of the meetings held on 3 February and 24/25 February 2025, subject to minor amendments.

3.3 Interest Register

The Board **noted** the interest register.

4. Chief Executive's Report

4.1 Chief Executive's Report

The Chief Executive took the report as read and added further updates as follows:

- oestradiol patches – a no surprises notice is being sent to the Minister today
- Societal impacts – team are working on this for the Minister for Monday's meeting – a copy will be provided to the Board
- Daratumumab – have met with Jansen and patient groups.

The Board:

- **noted** the Chief Executive's report for March 2025
- **noted** the Senior Leadership Team Engagement Calendar
- **noted** the financials for February 2025, as presented to the Finance, Audit & Risk Committee.

Action: Societal Impacts briefing for the Minister – copy to the Board.

4.2 Legal Report – Legally Privileged

This paper provided an update for the Board on current hot topics.

The Board:

- **noted** the legal update
- **noted** potential risks as highlighted.

5. Key Items

5.1 External Reviews and initial thoughts on Pharmac Response

This paper provided an update on the work to date, following receipt of the external review reports. Staff presented to the Board on Pharmac's commitment to change and reset.

The Board:

- **noted** and considered the findings of the Workplace Culture Review and Consumer Workshop reports at its February meetings
- **discussed** and considered the presentation from the Senior Leadership Team on how Pharmac might respond to the findings of both reviews.

5.2 Update on Rule 8.1b of the Pharmaceutical Schedule

This paper provided an update on the work to date, following the review of rule 8.1b of the Pharmaceutical Schedule.

The Board:

- **noted** that rule 8.1b allows for exceptions to Pharmac's usual process for the assessment and funding of medicines

- **noted** that following public consultation**,** an announcement was made in March 2024 that rule 8.1b would remain, supplemented with improved, robust oversight codesigned with clinicians and patient groups. Three objectives were announced:

    1. improve governance and oversight of the decisions made under rule 8.1b

    2. collaborate with clinicians to design a way to manage new and emerging therapies to ensure financial sustainability

    3. consider options in Pharmac's current budget to improve access to treatment for adolescent and young adults with a paediatric type cancer regardless of where they are treated

- **noted** the progress made in relation to the three objectives

- **discussed** the considerations regarding equitable access for adolescent and young adults with a paediatric type cancer and next steps for this

- **noted** that in retaining Rule 8.1b, there remains a fiscal risk to the medicines budget.

Action: A further update to be provided to the Board in June.

5.3 Supply Chain Risk Mitigation and Management Update

This paper provided the Board with a six-monthly update on Pharmac's supply chain risk mitigation and management for medicines and medical devices.

The Board:

- **noted** that Pharmac applies a continuous improvement and wānanga approach to the management and mitigation of supply chain risks

- **noted** the cross-government collaboration Pharmac engages in to strengthen supply chain resilience

- **noted** that Pharmac has recently signed a Memorandum of Understanding with the Ministry of Business Innovation and Employment to begin investigation into modern slavery risks in our supply chain.

5.4 International Travel: HTAi Buenos Aires June 2025, and INAHTA 2025 Congress

The international travel plan provides the Board with estimated costs for international travel for two Pharmac staff members in June 2025. The Board was asked to consider this application due to the proposed budget being over $20,000.

The Board **delegated** this decision to the Chief Executive.

5.5 Quorum for Finance, Audit & Risk Committee

Previously, the Audit & Risk Committee and Health & Safety Committee had a quorum of two members, as the Committees at that time, consisted of two members each.

When the Committees were merged in 2024 to the Finance, Audit & Risk Committee, consideration was not given to the quorum. The Committee now recommend that the quorum be increased from two to three members, as the size of the Committee has increased to four members.

The Board:

- **agreed to pause** the decision on this paper, until such time as the membership of the Committee is confirmed
- **noted** that the Board Chair will serve in an ex officio capacity for FAR Committee meetings.

6. Schedule & Funding

6.1 Proposal to fund treatments for blood cancer, inflammatory bowel disease and atopic dermatitis

This paper sought a decision from the Board on a proposal to fund treatments for blood cancer, inflammatory bowel disease, atopic dermatitis and rheumatoid arthritis. The proposal would result in widened access to four medicines currently listed on the Pharmaceutical Schedule for six health conditions and reduce the net price of four medicines currently supplied by AbbVie.

The Board:

- **resolved** to approve the 23 December 2024 provisional agreement with AbbVie Limited for the supply of Rinvoq, Venclexta, Humira, and glecaprevir with pibrentasvir (Maviret)
- **noted** that extensive consultation on this proposal was undertaken and all responses have been carefully considered

Upadacitinib

- **resolved** to amend the presentation to upadacitinib (Rinvoq) tab 15 mg in the Oncology Agents and Immunosuppressants Therapeutic group, JAK inhibitors therapeutic subgroup in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 May 2025 at the following price and subsidy (ex-manufacturer, excluding GST) (changes in bold):

Chemical	Formulation	Brand	Pack size	Proposed price and subsidy
Upadacitinib	Tab **modified-release** 15 mg	Rinvoq	28	$1,271.00

- **resolved** to list upadacitinib (Rinvoq) tab modified-release 30 mg and 45 mg in the Oncology Agents and Immunosuppressants Therapeutic group, JAK inhibitors therapeutic subgroup in Section B and Part II of Section H of the of the Pharmaceutical Schedule from 1 May 2025 at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Formulation	Brand	Pack size	Proposed price and subsidy
Upadacitinib	Tab modified-release 30 mg	Rinvoq	28	$ 2,033.00
Upadacitinib	Tab modified-release 45 mg	Rinvoq	28	$ 3,049.00

- **resolved** to amend the following Special Authority for upadacitinib in Section B of the Pharmaceutical Schedule from 1 May 2025 as follows (additions in **bold**, deletions in ~~strikethrough~~):

Special Authority for Subsidy
Initial application – (rheumatoid arthritis (previously treated with adalimumab or etanercept)) ~~only from a rheumatologist or practitioner on the recommendation of a rheumatologist~~ **from any relevant practitioner**.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. The ~~patient~~ **individual** has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
2. Either:
   - 2.1. The ~~patient~~ **individual** has experienced intolerable side effects ~~from~~ **with** adalimumab and/or etanercept; or
   - 2.2. The ~~patient~~ **individual** has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
3. Either: **Any of the following:**
   - 3.1. **Rituximab is not clinically appropriate; or**
   - 3.2. ~~3.1~~ The ~~patient~~ **individual** is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or
   - 3.3. ~~3.2~~ Both:
     - 3.3.1. ~~3.2.1~~ The ~~patient~~ **individual** has been started on rituximab for rheumatoid arthritis in a Health NZ hospital; and
     - 3.3.2. ~~3.2.2~~ Either:
       - 3.3.2.1. ~~3.2.1.1~~ The ~~patient~~ **individual** has experienced intolerable side effects ~~from~~ **with** rituximab; or
       - 3.3.2.2. ~~3.2.1.2~~ At four months following the initial course of rituximab the ~~patient~~ **individual** has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis.

Renewal – (Rheumatoid arthritis) ~~only from a rheumatologist or Practitioner on the recommendation of a rheumatologist~~ **from any relevant practitioner**. Approvals valid for 6 months for applications meeting the following criteria:
Either:

1. Following 6 months' initial treatment, the ~~patient has~~ **individual has experienced** at least a 50% decrease in active joint count from baseline ~~and a clinically significant response to treatment in the opinion of the physician~~; or
2. On subsequent reapplications, the ~~patient demonstrates~~ **individual has experienced** at least a continuing 30% improvement in active joint count from baseline ~~and a clinically significant response to treatment in the opinion of the physician~~.

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

1. **Individual is currently on treatment with upadacitinib for atopic dermatitis and met all remaining criteria prior to commencing treatment; or**
2. **All of the following:**
   - **2.1. Individual has moderate to severe atopic dermatitis, severity as defined by an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 or a Dermatology Life Quality Index (DLQI) score of greater than or equal to 10; and**
   - **2.2. Individual has received insufficient benefit from topical therapy (including topical corticosteroids or topical calcineurin inhibitors) for a 28-day trial within the last 6 months, unless contraindicated to all; and**

2.3. Individual has trialled and received insufficient benefit from at least one systemic therapy for a minimum of three months (eg ciclosporin, azathioprine, methotrexate or mycophenolate mofetil), unless contraindicated to all; and
2.4. An EASI assessment or DLQI assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
2.5. The most recent EASI or DQLI assessment is no more than 1 month old at the time of application.

Renewal – (atopic dermatitis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Either:
1. **Individual has received a 75% or greater reduction in EASI score (EASI 75) as compared to baseline EASI prior to commencing upadacitinib; or**
2. **Individual has received a DLQI improvement of 4 or more as compared to baseline DLQI prior to commencing upadacitinib.**

Initial application – (Crohn's disease – adult) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
Either:
1. **Individual is currently on treatment with upadacitinib for Crohn's disease and met all remaining criteria prior to commencing treatment; or**
2. **Both:**
   2.1. Individual has active Crohn's disease; and
   2.2. Either:
      2.2.1. Individual has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
      2.2.2. Both:
         2.2.2.1. Individual meets the initiation criteria for prior biologic therapies for Crohn's disease; and
         2.2.2.2. Other biologic therapies for Crohn's disease are contraindicated.

Renewal – (Crohn's disease – adult) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Any of the following
1. **CDAI score has reduced by 100 points from the CDAI score when the individual was initiated on biologic therapy; or**
2. **HBI score has reduced by 3 points from when individual was initiated on biologic therapy; or**
3. **CDAI score is 150 or less; or**
4. **HBI score is 4 or less; or**
5. **The individual has experienced an adequate response to treatment, but CDAI score cannot be assessed.**

Initial application – (Crohn's disease – children*) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
Either
1. **Individual is currently on treatment with upadacitinib for Crohn's disease and met all remaining criteria prior to commencing treatment; or**
2. **Both:**
   2.1. Child has active Crohn's disease; and
   2.2. Either:
      2.2.1. Child has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
      2.2.2. Both:
         2.2.2.1. Child meets the initiation criteria for prior biologic therapies for Crohn's disease; and
         2.2.2.2. Other biologic therapies for Crohn's disease are contraindicated.

Renewal – (Crohn's disease – children*) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Any of the following:
1. **PCDAI score has reduced by 10 points from when the child was initiated on treatment; or**
2. **PCDAI score is 15 or less; or**
3. **The child has experienced an adequate response to treatment, but PCDAI score cannot be assessed.**

Note: Indications marked with * are unapproved indications.

Initial application — (ulcerative colitis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria.
Either:
1. **Individual is currently on treatment with upadacitinib for ulcerative colitis and met all remaining criteria prior to commencing treatment; or**
2. **Both:**
   - **2.1. Individual has active ulcerative colitis; and**
   - **2.2. Either:**
     - **2.2.1. Individual has had an initial approval for prior biologic therapy for ulcerative colitis and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or**
     - **2.2.2. Both:**
       - **2.2.2.1. Individual meets the initiation criteria for prior biologic therapies for ulcerative colitis; and**
       - **2.2.2.2. Other biologic therapies for ulcerative colitis are contraindicated.**

Renewal – (ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria
Either:
1. **The SCCAI score has reduced by 2 points or more from the SCCAI score when the individual was initiated on treatment; or**
2. **PUCAI score has reduced by 10 points or more from the PUCAI score when the individual was initiated on treatment.**

- **resolved** to amend the Hospital Indication Restriction for upadacitinib in Part II of Section H of the Pharmaceutical Schedule from 1 May 2025 as follows (additions in **bold**, deletions in ~~strikethrough~~):

Restricted
Initiation – Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)
~~Rheumatologist~~
Limited to 6 months treatment
All of the following:
1. The ~~patient~~ **individual** has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
2. Either:
   - 2.1. The ~~patient~~ **individual** has experienced intolerable side effects ~~from~~ **with** adalimumab and/or etanercept; or
   - 2.2. The ~~patient~~ **individual** has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
3. E~~ither:~~ **Any of the following:**
   - **3.1. Rituximab is not clinically appropriate; or**
   - 3.2. ~~3.1~~ The ~~patient~~ **individual** is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or
   - 3.3. ~~3.2~~ Both:
     - 3.3.1. ~~3.2.1~~ The ~~patient~~ **individual** has been started on rituximab for rheumatoid arthritis in a Health NZ hospital ; and
     - 3.3.2. ~~3.2.2~~ Either:
       - 3.3.2.1. ~~3.2.1.1~~ The ~~patient~~ **individual** has experienced intolerable side effects ~~from~~ **with** rituximab; or
       - 3.3.2.2. ~~3.2.1.2~~ At four months following the initial course of rituximab the ~~patient~~ **individual** has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis.

Continuation – Rheumatoid Arthritis
~~Rheumatologist~~
Re-assessment required after 6 months
Either:
1. Following 6 months' initial treatment, the ~~patient has~~ **individual has experienced** at least a 50% decrease in active joint count from baseline ~~and a clinically significant response to treatment in the opinion of the physician~~; or
2. On subsequent reapplications, the ~~patient demonstrates~~ **individual has experienced** at least a continuing 30% improvement in active joint count from baseline ~~and a clinically significant response to treatment in the opinion of the physician~~.

Initiation – Atopic dermatitis
Re-assessment required after 6 months
Either:
1. **Individual is currently on treatment with upadacitinib for atopic dermatitis and met all remaining criteria prior to commencing treatment; or**
2. **All of the following:**
    2.1. **Individual has moderate to severe atopic dermatitis, severity as defined by an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 or a Dermatology Life Quality Index (DLQI) score of greater than or equal 10; and**
    2.2. **Individual has received insufficient benefit from topical therapy (including topical corticosteroids or topical calcineurin inhibitors) for a 28-day trial within the last 6 months, unless contraindicated to all; and**
    2.3. **Individual has trialled and received insufficient benefit from at least one systemic therapy for a minimum of three months (eg ciclosporin, azathioprine, methotrexate or mycophenolate mofetil), unless contraindicated to all; and**
    2.4. **An EASI assessment or DLQI assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and**
    2.5. **The most recent EASI or DQLI assessment is no more than 1 month old at the time of application.**

Continuation – Atopic dermatitis
Re-assessment required after 12 months
Either:
1. **Individual has received a 75% or greater reduction in EASI score (EASI 75) as compared to baseline EASI prior to commencing upadacitinib; or**
2. **Individual has received a DLQI improvement of 4 or more as compared to baseline DLQI prior to commencing upadacitinib.**

Initiation – Crohn's disease – adult
Re-assessment required after 6 months
Either:
1. **Individual is currently on treatment with upadacitinib for Crohn's disease and met all remaining criteria prior to commencing treatment; or**
2. **Both:**
    2.1. **Individual has active Crohn's disease; and**
    2.2. **Either:**
        2.2.1. **Individual has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or**
        2.2.2. **Both:**
            2.2.2.1. **Individual meets the initiation criteria for prior biologic therapies for Crohn's disease; and**
            2.2.2.2. **Other biologic therapies for Crohn's disease are contraindicated.**

Continuation – Crohn's disease – adult
Re-assessment required after 2 years
Any of the following
1. **CDAI score has reduced by 100 points from the CDAI score when the individual was initiated on biologic therapy; or**
2. **HBI score has reduced by 3 points from when individual was initiated on biologic therapy; or**
3. **CDAI score is 150 or less; or**
4. **HBI score is 4 or less; or**
5. **The individual has experienced an adequate response to treatment, but CDAI score cannot be assessed.**

Initiation – Crohn's disease – children
Re-assessment required after 6 months
Either:
1. **Individual is currently on treatment with upadacitinib for Crohn's disease and met all remaining criteria prior to commencing treatment; or**
2. **Both:**
    2.1. **Child has active Crohn's disease; and**
    2.2. **Either:**
        2.2.1. **Child has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or**

2.2.2. Both:
2.2.2.1. Child meets the initiation criteria for prior biologic therapies for Crohn's disease; and
2.2.2.2. Other biologic therapies for Crohn's disease are contraindicated.

Continuation – Crohn's disease – children
Re-assessment required after 2 years
Any of the following:
1. **PCDAI score has reduced by 10 points from when the child was initiated on treatment; or**
2. **PCDAI score is 15 or less; or**
3. **The child has experienced an adequate response to treatment, but PCDAI score cannot be assessed.**

Note: Indications marked with * are unapproved indications.

Initiation – Ulcerative colitis
Re-assessment required after 6 months
Either:
1. **Individual is currently on treatment with upadacitinib for ulcerative colitis and met all remaining criteria prior to commencing treatment; or**
2. **Both:**
   2.1. Individual has active ulcerative colitis; and
   2.2. Either:
      2.2.1. Individual has had an initial approval for prior biologic therapy for ulcerative colitis and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
      2.2.2. Both:
         2.2.2.1. Individual meets the initiation criteria for prior biologic therapies for ulcerative colitis; and
         2.2.2.2. Other biologic therapies for ulcerative colitis are contraindicated.

Continuation – Ulcerative colitis
Re-assessment required after 2 years
Either:
1. The SCCAI score has reduced by 2 points or more from the SCCAI score when the individual was initiated on treatment; or
2. PUCAI score has reduced by 10 points or more from the PUCAI score when the individual was initiated on treatment.

Venetoclax

- **resolved** to apply the following Special Authority to venetoclax (Venclexta) in Section B of the Pharmaceutical Schedule from 1 May 2025 as follows (additions in **bold**, deletions in ~~strikethrough~~):

Special Authority for Subsidy
Initial application – (relapsed/refractory chronic lymphocytic leukaemia) ~~only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist~~ **from any relevant practitioner**.
Approvals valid for 7 months for applications meeting the following criteria:
All of the following:
1. **Individual** ~~Patient~~ has chronic lymphocytic leukaemia requiring treatment; and
2. **Individual** ~~Patient~~ has received at least one prior therapy for chronic lymphocytic leukaemia; and
3. **Individual** ~~Patient~~ has not previously received funded venetoclax; and
4. **The individual's** ~~Patient's~~ disease has relapsed ~~within 36 months of previous treatment~~; and
5. Venetoclax to be used in combination six 28-day cycles of rituximab commencing after the 5-week dose titration schedule with venetoclax; and
6. **Individual** ~~Patient~~ has ECOG performance status 0-2;

Renewal – (relapsed/refractory chronic lymphocytic leukaemia) ~~only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist~~ **from any relevant practitioner**. Approvals valid for 6 months for applications meeting the following criteria:
Both:
1. Treatment remains clinically appropriate and the **individual** ~~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~~ **from any relevant practitioner**. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. **Individual** ~~Patient~~ has previously untreated chronic lymphocytic leukaemia; and
2. There is documentation that the **individual** ~~patient~~ has the 17p deletion by FISH testing or TP53 mutation sequencing; and
3. **Individual** ~~Patient~~ has ECOG performance status 0-2.

Renewal – (relapsed/refractory chronic lymphocytic leukaemia) ~~only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist~~ **from any relevant practitioner**. 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.

Initial application – (previously untreated acute myeloid leukaemia) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
Either:
1. **The individual is currently on treatment with venetoclax and met all remaining special authority criteria prior to commencing treatment; or**
2. **All of the following:**
   - 2.1. **Individual has previously untreated acute myeloid leukaemia (see note a), according to World Health Organization (WHO) Classification; and**
   - 2.2. **Venetoclax not to be used in combination with standard intensive remission induction chemotherapy; and**
   - 2.3. **Venetoclax to be used in combination with azacitidine or low dose cytarabine.**

Renewal – (previously untreated acute myeloid leukaemia) from any relevant practitioner. Approvals valid for 6 months where there is no evidence of disease progression.

Notes:
a) 'Acute myeloid leukaemia' includes myeloid sarcoma*.
b) Indications marked with * are Unapproved indications.

- **resolved** to apply the following Hospital Indication Restriction to venetoclax (Venclexta) in Part II of Section H of the Pharmaceutical Schedule from 1 May 2025 as follows (additions in **bold**, deletions in ~~strikethrough~~):

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

Continuation – relapsed/refractory chronic lymphocytic leukaemia
~~Haematologist~~
Re-assessment required after 6 months

Both:
1. Treatment remains clinically appropriate and the **individual** ~~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. **Individual** ~~Patient~~ has previously untreated chronic lymphocytic leukaemia; and
2. There is documentation that the **individual** ~~patient~~ has the 17p deletion by FISH testing or TP53 mutation sequencing; and
3. **Individual** ~~Patient~~ has ECOG performance status 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.~~ **No evidence of disease progression**.
Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL)~~*~~ and B-cell prolymphocytic leukaemia (B-PLL)*. Indications marked with * are Unapproved indications.

Initiation – previously untreated acute myeloid leukaemia
Re-assessment required after 6 months
Either:
1. **The individual is currently on treatment with venetoclax and met all remaining special authority criteria prior to commencing treatment; or**
2. **All of the following:**
   - 2.1. **Individual has previously untreated acute myeloid leukaemia (see note a), according to World Health Organization (WHO) Classification; and**
   - 2.2. **Venetoclax not to be used in combination with standard intensive remission induction chemotherapy; and**
   - 2.3. **Venetoclax to be used in combination with azacitidine or low dose cytarabine.**

Continuation – previously untreated acute myeloid leukaemia
Re-assessment required after 6 months
No evidence of disease progression.

Notes:
a) 'Acute myeloid leukaemia' includes myeloid sarcoma*.
b) Indications marked with * are Unapproved indications.

Ibrutinib

- **resolved** to apply the following Special Authority to ibrutinib (Imbruvica) in Section B of the Pharmaceutical Schedule from 1 May 2025 as follows (additions in **bold**, deletions in ~~strikethrough~~):

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~~ **Individual** has chronic lymphocytic leukaemia (CLL) requiring therapy; and
2. ~~Patient~~ **Individual** 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~~ **the individual** has 17p deletion or TP53 mutation; and
     - 4.1.2. ~~Patient~~ **Individual** has experienced intolerable side effects with venetoclax monotherapy; or

4.2. All of the following:
4.2.1. ~~Patient~~ **Individual** has received at least one prior immunochemotherapy for CLL; and
4.2.2. ~~Patient~~ **Individual's** CLL has relapsed ~~within 36 months of previous treatment~~; and
4.2.3. ~~Patient~~ **Individual** has experienced intolerable side effects with venetoclax in combination with rituximab regimen; or
4.3. ~~Patient~~ **Individual's** CLL is refractory to or has relapsed ~~within 36 months of~~ **following** a venetoclax regimen.

Renewal – (chronic lymphocytic leukaemia (CLL)) from any relevant practitioner. Approvals valid for 12 months **where there is no evidence of disease progression.** ~~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 apply the following Hospital Indication Restriction to ibrutinib (Imbruvica) in Part II of Section H of the Pharmaceutical Schedule from 1 May 2025 as follows (additions in **bold**, deletions in ~~strikethrough~~):

Restricted
Initiation – chronic lymphocytic leukaemia (CLL)
Re-assessment required after 6 months
All of the following:
1. ~~Patient~~ **Individual** has chronic lymphocytic leukaemia (CLL) requiring therapy; and
2. ~~Patient~~ **Individual** 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~~ **the individual** has 17p deletion or TP53 mutation; and
4.1.2. ~~Patient~~ **Individual** has experienced intolerable side effects with venetoclax monotherapy; or
4.2. All of the following:
4.2.1. ~~Patient~~ **Individual** has received at least one prior immunochemotherapy for CLL; and
4.2.2. ~~Patient~~ **Individual's** CLL has relapsed ~~within 36 months of previous treatment~~; and
4.2.3. ~~Patient~~ **Individual** has experienced intolerable side effects with venetoclax in combination with rituximab regimen; or
4.3. ~~Patient~~ **Individual's** CLL is refractory to or has relapsed ~~within 36 months of~~ **following** 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.

Adalimumab (Humira)

- **resolved** to amend the price and subsidy for adalimumab (Humira - alternative brand) in the Oncology Agents and Immunosuppressants Therapeutic group, Monoclonal Antibodies therapeutic subgroup in Section B and Part II of Section H of the of the Pharmaceutical Schedule from 1 May 2025 as follows:

Chemical	Formulation	Brand	Pack size	Current price and Subsidy	Proposed price and subsidy
Adalimumab	Inj 40 mg per 0.4 ml prefilled syringe	Humira	2		$595.50

				$1,599.96	
Adalimumab	Inj 40 mg per 0.4 ml prefilled pen	HumiraPen	2	$1,599.96	$595.50
Adalimumab	Inj 20 mg per 0.2 ml prefilled pen	Humira	2	$1,599.96	$595.50

- **noted** that price support will be provided for wholesalers and pharmacies for the adalimumab (Humira) price and subsidy change on 1 May 2025

Azacitidine

- **resolved** to amend the following Special Authority to azacitidine (Azacitidine Dr Reddy's) in Section B of the Pharmaceutical Schedule from 1 May 2025 as follows (deletions in ~~strikethrough~~, additions in **bold**):

Special Authority for Subsidy
Initial application ~~only from a haematologist or medical practitioner on the recommendation of a haematologist~~ **any relevant practitioner**. Approvals valid for 12 months for applications meeting the following criteria:
~~All of the following~~ **Both**:
1. Any of the following:
   1.1. The ~~patient~~ **individual** has **intermediate or high risk MDS based on an internationally recognised scoring system** ~~International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome~~; or
   1.2. The ~~patient~~ **individual** has chronic myelomonocytic leukaemia (**based on an intermediate or high risk score from an internationally recognised scoring system or** 10%-29% marrow blasts without myeloproliferative disorder); or
   1.3. The ~~patient~~ **individual** has acute myeloid leukaemia ~~with 20-30% blasts and multi-lineage dysplasia,~~ according to World Health Organization (WHO) Classification; and
~~2. The patient has performance status (WHO/ECOG) grade 0-2; and~~
~~3.~~**2.** The ~~patient~~ **individual** has an estimated life expectancy of at least 3 months

Renewal only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 12 months ~~for applications meeting the following criteria:~~ **where there is no evidence of disease progression.**
~~Both:~~
~~1. No evidence of disease progression; and~~
~~2. The treatment remains appropriate and patient is benefitting from treatment.~~

resolve to amend the following Hospital Indication Restriction to azacitidine (Azacitidine Dr Reddy's)) in Part II of Section H of the Pharmaceutical Schedule from 1 May 2025 as follows (deletions in ~~strikethrough~~, additions in **bold**):

Restricted
Initiation
~~Haematologist~~
Re-assessment required after 12 months
~~All of the following~~ **Both**:
1. Any of the following:
   1.1. The ~~patient~~ **individual** has **intermediate or high risk MDS based on an internationally recognised scoring system** ~~International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome~~; or
   1.2. The ~~patient~~ **individual** has chronic myelomonocytic leukaemia (**based on an intermediate or high risk score from an internationally recognised scoring system or** 10%-29% marrow blasts without myeloproliferative disorder); or
   ~~1.3.~~ The ~~patient~~ **individual** has acute myeloid leukaemia ~~with 20-30% blasts and multi-lineage dysplasia,~~ according to World Health Organization (WHO) Classification; and
~~2. The patient has performance status (WHO/ECOG) grade 0-2; and~~
~~3.~~**2.** The ~~patient~~ **individual** has an estimated life expectancy of at least 3 months

Continuation
~~Haematologist or medical practitioner on the recommendation of a haematologist~~
Re-assessment required after 12 months
~~Both:~~
1. No evidence of disease progression~~; and~~
2. ~~The treatment remains appropriate and patient is benefitting from treatment~~.

6.2 Pharmaceutical transactions report

The purpose of this paper was to provide the Board with an advanced overview of current issues relating to pharmaceuticals funded through the medicines budget, current significant supply issues, the contentious, large or significant pharmaceutical transactions and investments that staff are currently progressing and an update on vaccines and COVID-19 treatments.

The Board:

- **noted** the update from Pharmac staff on the large and/or significant medicines transactions that are currently planned or in progress
- **noted** the update from Pharmac staff on work to change the consultation process for the annual tender
- **noted** the update from Pharmac staff on upcoming public consultations and decision notifications
- **noted** the summary of decisions made under Delegated Authority during February 2025.

6.3 Medical Devices Transaction and Investment Report

This paper updated the Board on progress with medical devices national contracting activity. It also included updates on some wider medical device programme activity.

The Board:

- **noted** the update on progress with medical devices national contracting activity
- **noted** the summary of decisions made under Delegated Authority during February 2025 by the Director, Medical Devices.

7. Strategy and Policy

7.1 Update on ‘Strategic management of the medicines budget’ strategic priority

This paper provided an update on work to deliver on the ‘Strategic management of the Medicines Budget’, which is one of our strategic priorities as outlined in Pharmac’s refreshed 2024/25 - 2027/28 Statement of Intent (SOI).

Collaboration and engagement are key factors in the work on Strategic management of the Medicines Budget. Enabling consumer involvement in the end-to-end funding process and ensuring alignment with the health sector, are key parts of our focus areas on this work.

The Board:

- **noted** that 'Strategic management of the medicines budget' is a strategic priority in Pharmac's 2024/25 – 2027/28 Statement of Intent
- **noted** the key areas of focus for this strategic priority in 2024/25, as outlined in the Statement of Performance Expectations, and plans for delivery in these areas
- **noted** that staff have made good progress in some areas, but in others, progress has been hindered by competing priorities and resource constraints
- **noted** that Pharmac continues to engage with Health NZ on a number of opportunities for improvement in the management of medicines.

8. Regular Reporting

8.1 Implementation half year update

This paper provided the Board with an update on key implementation activities from September 2024 to March 2025, within the Equity and Engagement Directorate.

The Board:

- **noted** the implementation activities completed to support supply issues and Pharmac's transactional decisions
- **noted** the work Pharmac are doing to support the responsible use of medicines and medical devices
- **noted** the utilisation of feedback from the Consumer Advisory Committee (CAC) and ongoing plans to strengthen and embed consumer input into Pharmac's implementation approach.

8.2 Communications and Government Services Report

This paper summarised communications and government services activity for the previous month.

The Board:

- **noted** that five media releases were distributed in February, as well as communications planning for the proactive release of organisational review reports and the announcement of the CE's resignation
- **noted** that 17 of the 31 action items recommended by the Chief Ombudsman to improve our OIA processes have been fully implemented and five have been partially implemented.

9. Record of Previous Minutes of Committee Meetings

9.1 Minutes of Finance, Audit & Risk Committee Meeting

The Board **noted** and **endorsed** the minutes of the Finance, Audit & Risk Committee meeting held on 21 February 2025, subject to minor edits.

9.2 Summary of February 2025 Consumer Advisory Committee (CAC) Meetings

This paper informed the Board of advice received from the Consumer Advisory Committee at the 12 February 2025 virtual meeting.

There are three vacancies at present and are keen to recruit as soon as possible.

The Board:

- **noted** the minutes from the February CAC meeting
- **noted** the summary of key issues across the meeting.

9.3 Summary of November 2024 PTAC advice and recommendations

This paper informed the Board of recommendations made and advice given by PTAC at its meeting held in-person on 14 and 15 November 2024**.**

Staff conveyed that they acknowledged and apologised for the delay in circulating this information.

The Board:

- **noted** the summary of the record of the Pharmacology and Therapeutics Advisory Committee (PTAC) meeting held on 14 and 15 November 2024.
- **noted** the November 2024 PTAC record has now been signed off by the previous PTAC Chair and is available on request.

10. Governance Matters

10.1 Board and Committee Member Terms and Attendance Record

The Board:

- **noted** the Board and Committee member terms
- **noted** the 2025 Meeting Attendance Register.

10.2 Board Correspondence

The Board **noted** the correspondence sent / received for the prior month.

10.3 Board Actions

The Board **noted** there were no new Board Actions.

10.4 Matters Arising

The Board **noted** the Matters Arising schedule.

10.5 Board Annual Agenda for 2025

The Board **noted** the Board Annual Agenda for 2025.

10.6 Glossary of Terms and Abbreviations

The Board **noted** the Glossary of Terms and Abbreviations.

4. General Business

There was no general business.

The meeting closed at 2.30pm with a karakia.

Date of Next Meeting: 29 April 2025 *virtual meeting*

Approved *April 2025*

Paula Bennett, Chair Date