PHARMAC
TE PĀTAKA WHAIORANGA

Version for Public Release
Some information may have been redacted for reasons including confidentiality

Pharmaceutical Management Agency (Pharmac)
Minutes of the Board Meeting held on 28 March 2024 at 9.30am
At Pharmac Offices, Level 9, 40 Mercer Street, Wellington and via Teams

Present:

Board members

Dr Peter Bramley (BSc (Hon), LL.B, PhD)	Acting Chair
Talia Anderson-Town (BBS, PG Dip Professional Accounting, CA, CPP)	Board member
Dr Anthony Jordan (BHB, MBChB, FRACP)	Board member
Dr Diana Siew (PhD)	Board member
Dr Margaret Wilsher (MD, FRACP, FRACMA)	Board member

Apologies

Board Observers

Dr Jane Thomas	Board Observer, CAC Chair (via Teams after lunch)
Robyn Manuel	Board Observer, CAC Chair (via Teams)

Pharmac staff in attendance

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

Attendees joined the meeting to present relevant papers: Graham Durston, Ishani Noble, Logan Heyes, Ben Graham, Imani Kerr, Matt McKenzie, Gillian Anderson, Paul Denham, Tyson Edwards, Danae Staples-Moon, Ben Campbell-McDonald, Caroline De Luca, Ryan Perica, Brent McPherson, Robyn Harris, Cushla Managh, and Oliver Whitehead.

1. Director-only Discussion

The meeting commenced at 9.30 am for Board only time, with the full meeting commencing at 10.22am.

During Director only time, the Board met with Brenda Ratcliff of MindMeld to discuss the culture change work programme.

2. Governance and Information matters

2.1 Glossary of Terms

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

2.2 Board Actions

The Board **noted** the Actions.

2.3 Board Annual Agenda 2024

The Board **noted** the Annual Agenda for 2024.

2.4 Board and Committee Member Terms

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

2.5 Apologies

There were no apologies for this meeting.

2.6 Interests Register

The Board **noted** the Interests Register.

3. Record of Previous Meetings

3.1 Minutes of Previous Board Meetings

The Board **resolved** to adopt the minutes of the meetings held on 23 February 2024 and 7 March 2024, as being a true and correct record of the meetings held on:

3.2 Audit & Risk Committee Recommendations

The Chair of the Audit & Risk Committee provided a verbal update to the Board on that morning's meeting, noting that Stephen Usher, Audit Director, Audit NZ also attended the meeting. This year's audit and the performance reporting were the primary topics discussed. Financial delegations and the Board expenses reporting were also covered off. The Chair noted it was a productive meeting.

3.3 Summary of CAC Meeting

This paper informed the Board of advice received from the Consumer Advisory Committee at the meeting held on 14 February 2024.

The Board:

received the minutes from the February 2024 Consumer Advisory Committee meeting; and

noted the summary of key issues across the meeting.

The CAC Chair noted that there will be some vacancies on the Committee shortly for three members and two members will be attending HTAi in Spain in June 2024. They are waiting on the letter of expectations to understand some of the needs going forward.

4. Matters Arising

The Board **noted** the matters arising.

5. Chair's Report

5.1 Verbal Update from the Chair

The Chair provided a verbal update to the Board on recent activities. Comments included:

- Noted there is a lot of uncertainty at present and we need to be mindful of cost cutting measures and head count decreases across ministries.
- New Chair will likely be in place in four weeks – possibly be at May Board meeting.

[redacted]

- Will likely have clarity around budget by May.
- The Chair acknowledged the work that the Government Services team are doing.

5.2 Correspondence

The Board **noted** the correspondence report.

6. CE Report

6.1 Chief Executive's Report

The Board **noted** the Chief Executive's Report.

The CE spoke to her report and noted:

- Following the last Board meeting, Minister Seymour visited the Pharmac offices and met with several staff. He is planning a return visit to meet with the devices directorate, at the end of May.

[redacted]

- The Board suggested inviting Simon Medcalf, MOH, to attend a Board meeting – possibly after the new Chair has started.

[redacted]

6.2 Financial Update

The purpose of this paper was to update the Board on the pharmaceutical budget expenditure, associated risks, and our approach to managing the CPB, to update the Board on COVID-19 expenditure and forecasting, and to provide the Board with an overview of financials for February 2024.

The Board commented on the Dashboard and suggested adding dates and the 'as at [date]' – needs to be broken out a bit more – it is too high level at present. Use of colours needs to be consistent for the likes of revenue, expenditure, etc.

The Board:

Combined Pharmaceutical Budget

noted that the Combined Pharmaceutical Expenditure Budget (CPB) for 2023/24 is $1.738 billion [redacted]

[redacted]

[redacted]

February 2024 financial results

[redacted]

noted that following discussions with the Ministry monitoring unit we have included Legal Risk Fund activity in this report for the first time.

Action Staff to discuss dashboard ideas and improving the presentation of numbers, offline with Audit & Risk Committee Chair.

7. Key Items

7.1 Pharmaceuticals 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 Combined Pharmaceutical Budget (CPB), including an update on vaccines, COVID-19 treatments, 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 on a proposal for price increases [redacted] to the Chief Executive;

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

noted the summary of decisions made under Delegated Authority during February 2024.

7.2 GlaxoSmithKline multiproduct proposal

The proposal outlined in this paper has not been dealt with by the Chief Executive under delegated authority because the estimated Financial Impact (NPV) of this proposal is [redacted] of the Pharmaceutical Budget.

The Financial Impact (NPV) is calculated on the basis of [redacted] and the forecast demand, taking into account any effect of the change /decision on that demand, versus the status quo.

Key comments included:

[redacted]

It was noted that Anthony Jordan would abstain from voting due to a conflict.

The Board:

resolved to approve the listing of niraparib (Zejula) capsules on the Pharmaceutical Schedule as set out

resolved to approve the listing of fluticasone furoate with umeclidinium and vilanterol inhaler (Trelegy Ellipta) on the Pharmaceutical Schedule as set out

resolved to approve the listing of dolutegravir with lamivudine tablets (Dovato) on the Pharmaceutical Schedule as set out

resolved to approve the amendment of the mepolizumab (Nucala) pre-filled pen Special Authority/Hospital indication restriction on the Pharmaceutical Schedule as set out

resolved to approve the amendment of the recombinant varicella zoster virus vaccine (Shingrix) restrictions on the Pharmaceutical Schedule as set out

resolved to approve the 12 February 2024 Provisional Multiproduct Listing Agreement with GlaxoSmithKline New Zealand (GSK)

resolved to approve the 15 February 2024 Provisional Letter of Agreement regarding PCV10 vaccine (Synflorix) sole supply with GlaxoSmithKline New Zealand (GSK)

resolved to approve the 15 February 2024 Provisional Letter of Amendment to Shingrix and Bexsero Agreement with GlaxoSmithKline New Zealand (GSK)

resolved to approve the 12 February 2024 Provisional Letter of Agreement regarding Lamotrigine (Lamictal) supply with GlaxoSmithKline New Zealand (GSK)

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

Niraparib

resolved to list niraparib (Zejula) cap 100 mg in the Oncology Agents and Immunosuppressants Therapeutic group, Other Cytotoxic Agents therapeutic subgroup in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 May 2024 as follows:

Chemical	Brand	Presentation	Pack size	Proposed price and subsidy
Niraparib	Zejula	Cap 100 mg	56	$8,929.84
Niraparib	Zejula	Cap 100 mg	84	$13,393.50

resolved to list niraparib in Section B of the Pharmaceutical Schedule subject to the following Special Authority criteria from 1 May 2024:

Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:
1. Patient has advanced high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2. Patient has received at least one line** of treatment with platinum-based chemotherapy; and
3. Patient has experienced a partial or complete response to the preceding treatment with platinum-based chemotherapy; and
4. Patient has not previously received funded treatment with a PARP inhibitor; and
5. Either:
   5.1. Treatment will be commenced within 12 weeks of the patient's last dose of the preceding platinum-based regimen; or
   5.2. Patient commenced treatment with niraparib prior to 1 May 2024; and
6. Treatment to be administered as maintenance treatment; and
7. Treatment not to be administered in combination with other chemotherapy.

Renewal from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:
1. No evidence of progressive disease; and
2. Treatment to be administered as maintenance treatment; and
3. Treatment not to be administered in combination with other chemotherapy; and
4. Either
   4.1. Treatment with niraparib to cease after a total duration of 36 months from commencement; or
   4.2. Treatment with niraparib is being used in the second-line or later maintenance setting.

Notes:
** "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component.*
***A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.*

resolved to apply wastage claimable to niraparib in Section B of the Pharmaceutical Schedule from 1 May 2024

resolved to list niraparib in Part II of Section H of the Pharmaceutical Schedule subject to the following hospital indication restriction from 1 May 2024:

Restricted
Initiation
Reassessment required after 6 months
All of the following:
1. Patient has advanced high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2. Patient has received at least one line** of treatment with platinum-based chemotherapy; and
3. Patient has experienced a partial or complete response to the preceding treatment with platinum-based chemotherapy; and
4. Patient has not previously received funded treatment with a PARP inhibitor; and
5. Either:
   5.1. Treatment will be commenced within 12 weeks of the patient's last dose of the preceding platinum-based regimen; or
   5.2. Patient commenced treatment with niraparib prior to 1 May 2024; and
6. Treatment to be administered as maintenance treatment; and
7. Treatment not to be administered in combination with other chemotherapy.

Continuation
Reassessment required after 6 months
All of the following:
1. No evidence of progressive disease; and
2. Treatment to be administered as maintenance treatment; and
3. Treatment not to be administered in combination with other chemotherapy; and
4. Either
   4.1. Treatment with niraparib to cease after a total duration of 36 months from commencement; or
   4.2. Treatment with niraparib is being used in the second-line or later maintenance setting.

Notes:
** "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component.*
***A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.*

[redacted]

[redacted]

Fluticasone furoate with umeclidinium and vilanterol

resolved to create a new TG3 heading titled Inhaled Corticosteroid with Long-Acting Muscarinic Antagonist and Beta Agonist under the Anticholinergic Agents TG2 heading in the Respiratory System and Allergies therapeutic group in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 May 2024;

resolved to list fluticasone furoate with umeclidinium and vilanterol (Trelegy Ellipta) in the Inhaled Corticosteroid with Long-Acting Muscarinic Antagonist and Beta Agonist subtherapeutic group of the Respiratory System and Allergies Therapeutic group in Section B of the Pharmaceutical Schedule from 1 May 2024 as follows:

Chemical	Brand	Presentation	Pack size	Proposed price and subsidy
Fluticasone furoate with umeclidinium and vilanterol	Trelegy Ellipta	Powder for inhalation fluticasone furoate 100 mcg with umeclidinium 62.5 mcg and vilanterol 25 mcg	30 dose OP	$104.24

resolved to list fluticasone furoate with umeclidinium and vilanterol (Trelegy Ellipta) in the Inhaled Corticosteroid with Long-Acting Muscarinic Antagonist and Beta Agonist subtherapeutic group of the Respiratory System and Allergies Therapeutic group in Part II of Section H of the Pharmaceutical Schedule from 1 May 2024 as follows:

Chemical	Brand	Presentation	Pack size	Proposed price
Fluticasone furoate with umeclidinium and vilanterol	Trelegy Ellipta	Powder for inhalation fluticasone furoate 100 mcg with umeclidinium 62.5 mcg and vilanterol 25 mcg	30 dose	$104.24

resolved to list fluticasone furoate with umeclidinium and vilanterol in Section B of the Pharmaceutical Schedule subject to the following Special Authority criteria from 1 May 2024:

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
All of the following
1. Patient has a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible; and
2. Either:
   2.1. Both:
      2.1.1. Patient is currently receiving an inhaled corticosteroid with long acting beta-2 agonist (ICS/LABA), long acting muscarinic antagonist with long acting beta-2 agonist (LAMA/LABA); and
      2.1.2. Any of the following:
         Clinical criteria:
         2.1.2.1. Patient has a COPD Assessment Test (CAT) score greater than 10; or
         2.1.2.2. Patient has had 2 or more exacerbations in the previous 12 months; or
         2.1.2.3. Patient has had one exacerbation requiring hospitalisation in the previous 12 months; or

2.1.2.4. Patient has had an eosinophil count greater than or equal to 0.3 x 10^9 cells/L in the previous 12 months; or

2.2. Patient is currently receiving multiple inhaler triple therapy (inhaled corticosteroid with long acting muscarinic antagonist and long acting beta-2 agonist – ICS/LAMA/LABA) and met at least one of the clinical criteria above prior to commencing multiple inhaler triple therapy.

resolved to list fluticasone furoate with umeclidinium and vilanterol in Part II of Section H of the Pharmaceutical Schedule subject to the following hospital indication restriction from 1 May 2024:

Restricted
Initiation
All of the following
1. Patient has a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible; and
2. Either:
   2.1. Both:
      2.1.1. Patient is currently receiving an inhaled corticosteroid with long acting beta-2 agonist (ICS/LABA), long acting muscarinic antagonist with long acting beta-2 agonist (LAMA/LABA); and
      2.1.2. Any of the following:
      Clinical criteria:
      2.1.2.1. Patient has a COPD Assessment Test (CAT) score greater than 10; or
      2.1.2.2. Patient has had 2 or more exacerbations in the previous 12 months; or
      2.1.2.3. Patient has had one exacerbation requiring hospitalisation in the previous 12 months; or
      2.1.2.4. Patient has had an eosinophil count greater than or equal to 0.3 x 10^9 cells/L in the previous 12 months; or

   2.2. Patient is currently receiving multiple inhaler triple therapy (inhaled corticosteroid with long acting muscarinic antagonist and long acting beta-2 agonist – ICS/LAMA/LABA) and met at least one of the clinical criteria above prior to commencing multiple inhaler triple therapy.

[redacted]

[redacted]

Dolutegravir with lamivudine

resolved to list dolutegravir with lamivudine (Dovato) in the Infections - Agents for Systemic Use Therapeutic **group**, Antiretrovirals – Strand Transfer Inhibitors therapeutic subgroup in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 May 2024 as follows:

Chemical	Brand	Presentation	Pack size	Proposed price and subsidy
Dolutegravir with lamivudine	Dovato	Tablet 50 mg with lamivudine 300 mg	30	$1,090.00

noted dolutegravir with lamivudine listed in Section B of the Pharmaceutical Schedule will be subject to the Antiretrovirals Special Authority criteria (SA2139)

noted dolutegravir with lamivudine listed in Part II of Section H of the Pharmaceutical Schedule will be subject to the Antiretrovirals Hospital Indication Restriction criteria (RS1901)

noted that the criteria for Dovato would be the same as that of dolutegravir

[redacted]

[redacted]

Recombinant varicella zoster virus vaccine

resolved to amend the restriction for Recombinant varicella zoster virus vaccine (Shingrix) Inj 50 mcg per 0.5 ml vial in Section I of the Pharmaceutical Schedule from 1 July 2024 as follows (additions in **bold**, deletions in ~~strikethrough~~):

a) **VARICELLA ZOSTER VACCINE [SHINGLES VACCINE]**Only on a prescription
b) No patient co-payment payable
c)

A. Funded for patients meeting the following criteria:

~~1. Two doses for all people aged 65 years~~

Either:

1. **Two doses for all people aged 65 years, or**
2. **Two doses for people 18 years of age or older with any of the following:**
   - **a. pre- and post-haematopoietic stem cell transplant or cellular therapy; or**
   - **b. pre- or post-solid organ transplant; or**
   - **c. haematological malignancies; or**
   - **d. people living with poorly controlled HIV infection; or**
   - **e. planned or receiving disease modifying anti-rheumatic drugs (DMARDs) for polymyalgia rheumatica, systemic lupus erythematosus or rheumatoid arthritis; or**
   - **f. end stage kidney disease (CKD 4 or 5); or**
   - **g. primary immunodeficiency**

B. Contractors will be entitled to claim payment from the Funder for the supply of Varicella zoster vaccine (Shingles vaccine) to patients eligible under the above criteria pursuant to their contract with Te Whatu Ora Health New Zealand for subsidised immunisation, and they may only do so in respect of the Varicella zoster vaccine [Shingles vaccine] listed in the Pharmaceutical Schedule.

C. Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

[redacted]

[redacted]

Mepolizumab

resolved to amend the Special Authority criteria in Section B of the Pharmaceutical Schedule from 1 May 2024 to include the following indication for mepolizumab as follows (new criteria shown only):

Initial application – (eosinophilic granulomatosis with polyangiitis) from any relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 The patient has eosinophilic granulomatosis with polyangiitis; and

2 The patient has trialled and not received adequate benefit from at least one of the following: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate, or rituximab for at least three months (unless contraindicated to all); and

3 Either:

- 3.1 The patient has trialled prednisone for a minimum of three months and is unable to maintain disease control at doses below 7.5 mg per day; or
- 3.2 Corticosteroids are contraindicated.

Renewal application – (eosinophilic granulomatosis with polyangiitis) from any relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months where patient has no evidence of clinical disease progression.

resolved to amend the hospital indication restriction criteria in Part II of Section H of the Pharmaceutical Schedule from 1 May 2024 to include the following indication for mepolizumab as follows (new criteria shown only):

Restricted
Initiation – Eosinophilic granulomatosis with polyangiitis
Re-assessment required after 12 months
All of the following:
1 The patient has eosinophilic granulomatosis with polyangiitis; and
2 The patient has trialled and not received adequate benefit from at least one of the following: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate, or rituximab for at least three months (unless contraindicated to all); and
3 Either:
3.1 The patient has trialled prednisone for a minimum of three months and is unable to maintain disease control at doses below 7.5 mg per day; or
3.2 Corticosteroids are contraindicated.

[redacted]

[redacted]

Dolutegravir

noted that dolutegravir (Tivicay) would remain listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 May 2024

[redacted]

[redacted]

Umeclidinium with vilanterol

noted that Anoro Ellipta would remain listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 May 2024

[redacted]

[redacted]

Lamotrigine

noted that lamotrigine (Lamictal) Tab dispersible 2 mg and Tab dispersible 5 mg would remain listed from 1 May 2024

noted that lamotrigine (Lamictal) Tab dispersible 25 mg, Tab dispersible 50 mg and Tab dispersible 100 mg strengths are funded via Pharmac's exceptional circumstances framework

[redacted]

7.3 Dasatinib tender decision

This paper sought a decision from the Board on awarding Principal Supply Status for dasatinib tablets, resulting from Pharmac's Annual Invitation to Tender. This would involve a change of the funded brand. Dasatinib is used to treat two types of leukaemia.

The Board:

resolved to accept the tender from Teva Pharmaceuticals for its brand (Dasatinib-Teva) to be the Principal Supply Status brand for dasatinib tab 20 mg, 50 mg and 70 mg in the Community and Health New Zealand hospitals, as set out

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

noted that this decision would result in a brand change

noted that this decision will be publicly notified once approved by the Board.

resolved to accept the tender from Teva Pharmaceuticals for its brand (Dasatinib -Teva) to be the Principal Supply brand of the Community Pharmaceutical dasatinib tab 20 mg, 50 mg and 70 mg, with a 5% alternative brand allowance (ABA) from 1 March 2025 until 30 June 2027 in Section B of the Pharmaceutical Schedule

resolved to list Teva's brand of dasatinib tab 20 mg, 50 mg and 70 mg in the Oncology Agents and Immunosuppressants therapeutic group in Section B of the Pharmaceutical Schedule from 1 October 2024 as follows:

Chemical and Presentation	**Brand**	**Pack Size**	**Current Price and Subsidy (ex-man., ex. GST)**	**New Price and Subsidy** (ex-man., ex. GST)
Dasatinib Tab 20 mg	Dasatinib-Teva	60	$3,774.06	$132.88
Dasatinib Tab 50 mg	Dasatinib-Teva	60	$6,214.20	$304.13
Dasatinib Tab 70 mg	Dasatinib-Teva	60	$7,692.58	$415.75

resolved to delist the following product from Section B of the Pharmaceutical Schedule on 1 March 2025:

Chemical and presentation	**Supplier**	**Brand**
Dasatinib Tab 20 mg	BMS	Sprycel
Dasatinib Tab 50 mg	BMS	Sprycel
Dasatinib Tab 70 mg	BMS	Sprycel

resolved to accept the tender from Teva Pharmaceuticals for its brand (Dasatinib-Teva) to be the Principal Supply brand of the Hospital Pharmaceutical dasatinib tab 20 mg, 50 mg and 70 mg, with a DV limit of 5% from 1 March 2025 until 30 June 2027;

resolved to list Teva's brand of dasatinib tab 20 mg, 50 mg and 70 mg in the Oncology Agents and Immunosuppressants therapeutic group in Part II of Section H of the Pharmaceutical Schedule from 1 October 2024 as follows:

Chemical and Presentation	**Brand**	**Pack Size**	**Current Price (ex-man., ex. GST)**	**New Price** (ex-man., ex. GST)
Dasatinib Tab 20 mg	Dasatinib-Teva	60	$3,774.06	$132.88

Dasatinib Tab 50 mg	Dasatinib-Teva	60	$6,214.20	$304.13
Dasatinib Tab 70 mg	Dasatinib-Teva	60	$7,692.58	$415.75

resolved to delist the following product from Part II of Section H of the Pharmaceutical Schedule on 1 March 2025:

Chemical and presentation	Supplier	Brand
Dasatinib Tab 20 mg	BMS	Sprycel
Dasatinib Tab 50 mg	BMS	Sprycel
Dasatinib Tab 70 mg	BMS	Sprycel

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

resolved to list on 1 March 2025 and delist on 1 June 2025 in the Oncology Agents and Immunosuppressants therapeutic group of Section B of the Pharmaceutical Schedule the following brand switch fee:

Chemical and presentation	Brand	Pack Size	Subsidy and price (ex-man., ex. GST)
Pharmacy Services, Brand switch fee (BSF)	BSF Dasatinib-Teva	1 fee	$4.50
May only be claimed once per patient			

resolved to add a note to the following presentations of chemical name as listed in Section B of the Pharmaceutical Schedule from 1 March 2025 until 31 May 2025 as follows (changes in bold):

DASATINIB- Brand Switch Fee payable

Dasatinib Tab 20 mg	$132.88	60	√ **Dasatinib-Teva**
Dasatinib Tab 50 mg	$304.13	60	√ **Dasatinib-Teva**
Dasatinib Tab 70 mg	$415.75	60	√ **Dasatinib-Teva**

resolved to amend the Special Authority criteria applying to dasatinib tab 20 mg, 50 mg and 70 mg in Section B of the Pharmaceutical Schedule from 1 October 2024 as follows (additions in bold and deletions in strikethrough):

Special Authority for Subsidy

Initial application only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

Any of the following:

1 ~~Both~~:

~~1.1~~ The patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis or accelerated phase; **or** ~~and~~
~~1.2 Maximum dose of 140 mg/day; or~~

2 ~~Both~~:

~~2.1~~ The patient has a diagnosis of Philadelphia chromosome-positive acute lymphoid leukaemia (Ph+ ALL); **or** ~~and~~
~~2.2 Maximum dose of 140 mg/day; or~~

3 **Both** ~~All of the following~~:

3.1 The patient has a diagnosis of CML in chronic phase; and
~~3.2 Maximum dose of 100 mg/day; and~~
3.2 ~~3.3~~ Any of the following:

3.2.1 ~~3.3.1~~ Patient has documented treatment failure* with imatinib; or
3.2.2 ~~3.3.2~~ Patient has experienced treatment-limiting toxicity with imatinib precluding further treatment with imatinib; or
3.2.3 ~~3.3.3~~ Patient has high-risk chronic-phase CML defined by the Sokal or EURO scoring system**.**~~; or~~
~~3.3.4 Patients is enrolled in the KISS study** and requires dasatinib treatment according to the study protocol.~~

Renewal only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:
Both ~~All of the following~~:
1 Lack of treatment failure while on dasatinib*; and
2 Dasatinib treatment remains appropriate and the patient is benefiting from treatment.~~; and~~
~~3 Maximum dasatinib dose of 140 mg/day for accelerated or blast phase CML and Ph+ ALL, and 100 mg/day for chronic phase CML.~~

Note: *treatment failure for CML as defined by Leukaemia Net Guidelines~~. **Kinase-Inhibition Study with Sprycel Start-up~~ https://www.cancertrialsnz.ac.nz/kiss/

resolved to amend the Hospital Indication Restriction criteria of dasatinib tab 20 mg, 50 mg and 70 mg in Part II of Section H of the Pharmaceutical Schedule from 1 October 2024 as follows (changes in strikethrough):

Initiation
Haematologist or any relevant practitioner on the recommendation of a haematologist
Re-assessment required after 6 months
Any of the following:

1 ~~Both:~~

~~1.1~~ The patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis or accelerated phase; **or**~~ and~~
~~1.2 Maximum dose of 140 mg/day; or~~

2 ~~Both:~~

~~2.1~~ The patient has a diagnosis of Philadelphia chromosome-positive acute lymphoid leukaemia (Ph+ ALL); **or**~~ and~~
~~2.2 Maximum dose of 140 mg/day; or~~

3 All of the following:

3.1 The patient has a diagnosis of CML in chronic phase; and
~~3.2 Maximum dose of 100 mg/day; and~~
3.2 ~~3.3~~ Any of the following:

3.2.1 ~~3.3.1~~ Patient has documented treatment failure* with imatinib; or
3.2.2 ~~3.3.2~~ Patient has experienced treatment-limiting toxicity with imatinib precluding further treatment with imatinib; or
3.2.3 ~~3.3.3~~ Patient has high-risk chronic-phase CML defined by the Sokal or EURO scoring system**.**~~; or~~

~~3.3.4 Patients is enrolled in the KISS study** and requires dasatinib treatment according to the study protocol.~~

Continuation
Haematologist or any relevant practitioner on the recommendation of a haematologist
Re-assessment required after 6 months
Both ~~All of the following~~:

1 Lack of treatment failure while on dasatinib*; and
2 Dasatinib treatment remains appropriate and the patient is benefiting from treatment~~; and~~
~~3 Maximum dasatinib dose of 140 mg/day for accelerated or blast phase CML and Ph+ ALL, and 100 mg/day for chronic phase CML.~~

Note: *treatment failure for CML as defined by Leukaemia Net Guidelines~~. **Kinase-Inhibition Study with Sprycel Start-up https://www.cancertrialsnz.ac.nz/kiss/~~

7.4 Supply Chain Risk Mitigation and Management Update

This paper is a six-monthly update to the Board on Pharmac's supply chain risk mitigation and management.

The Board:

noted that a continuous improvement and wānanga approach continues to be used for how Pharmac manages and mitigates risks in the supply chain

noted the tūhono with other government agencies Pharmac engages with in relation to supply chain management

noted hospital medical device supply chain risk management is included within this report.

7.5 Medical Devices Transaction and Investment Report

This paper provided a monthly update to the Board on progress with medical devices national contracting activity.

Key comments noted:

- We have met with ACC since the last Board meeting and they are keen to engage with us.

[redacted]

- The Board queried what our policy is on purchasing locally so that we aren't shipping large pieces of kit around the world. Management responded that environmental impact is one of our considerations.

The Board:

noted the update on progress with medical devices national contracting activity

noted the summary of decisions made under Delegated Authority during February by the Director, Medical Devices.

8. Strategic Planning and Policy

8.1 Medical Devices Programme Update

This paper provided the Board with an update on progress of the Medical Device Programme and the work underway to consolidate and scale up operational activity to deliver additional value for the sector.

The Board:

noted the update on progress with the Medical Device Programme

noted the status and progress of the four workstreams that are being progressed concurrently to deliver a coherent and functional approach to managing the hospital medical devices list

noted that the next Programme update to the Board will be at the May meeting. [redacted]

8.2 Update on 'Enhanced Assessment and Decision Making' strategic priority

This paper updated the Board on progress and next steps for the 'Enhanced Assessment and Decision Making' strategic priority.

The Board:

noted that enhanced assessment and decision making is one of our strategic priorities in our 2023/24 – 2026/27 Statement of Intent

noted the three key areas of focus over the next three years:

1. enhance how we assess and make funding decisions, to make our processes more timely and transparent, better coordinated with sector partners, and centred around health equity and other Pae Ora health sector principles
2. strengthen the voice of the New Zealand public in our considerations
3. ensure people benefit from funding decisions we make

noted the next steps for the year ahead.

Action: Provide feedback to the Board on the right sizing work which is underway.

8.3 Engagement Strategy Implementation plan

The purpose of this paper was to provide for the Board's information, the first version of the engagement strategy implementation plan.

The Board:

noted the engagement strategy implementation plan

noted short-term activities are predominantly focussed on setting the foundations for more meaningful and empathetic engagement by building internal capability.

Action: Add Stakeholder engagement map alongside implementation plan for future papers.

8.4 Draft Statement of Performance Expectations 2024/2025

This paper presented Pharmac's draft 2024/25 Statement of Performance Expectations (SPE). The Board considered the draft and provided feedback prior to a revised draft version being prepared for consideration by the Associate Minister of Health (Pharmac) and other stakeholders.

The draft SPE is less well advanced at this time, as we have not yet received the annual Ministerial Letter of Expectations. [redacted]

The Board:

noted that the 2024/25 annual Ministerial Letter of Expectations has not yet been received

[redacted]

noted the early draft of the 2024/25 Statement of Performance Expectations

noted further development of initiatives, performance measures and financial information, will take place during April and early May

noted that a final 2024/25 Statement of Performance Expectations will be discussed and agreed by the Board at its May Board meeting.

[redacted]

9. Regular Reporting

9.1 Risk Exception Report

The full risk register and quarter three report were considered by the Audit and Risk Committee at its March 2023 meeting. For Board meetings in the intervening months, an exceptions report updates the Board on the items on the risk register that have materially changed.

The Board:

noted that this exception risk report summarises current and ongoing risks of relevance to the Board for March 2024.

9.2 Implementation Update

This paper provided an update on key implementation work that has occurred over the last three months within the Equity and Engagement Directorate.

The Board:

noted the contract with Matui to support the responsible use of medicines in primary care ends on 30 June 2024

noted the steps that are being taken to transition our responsible use work to a new approach which will focus on collaborating with a range of stakeholders

noted the utilisation of feedback from the Responsible Use Advisory Group (RUAG) and the Consumer Advisory Committee (CAC) to advise implementation activities

noted the implementation activities completed to support supply issues and Pharmac's transactional decisions

noted the process improvement activities that are being progressed within our implementation work.

9.3 Communications and Government Services report

This paper summarised communications and government services activity for February 2024 and the impact of our work.

The Board:

noted that we are committed to our proactive media approach and issued five media releases in February

noted that Pharmac's 2023 Year in Review publication was sent to stakeholders in early March and is available on our website

noted that we continue to grow traffic to our website, in particular the medicine notices which detail supply issues, discontinuations, and brand changes

noted that the volume of Official Information Act and Correspondence requests is increasing which is impacting on our timeliness

noted that Pharmac has identified enhancements to the complaints process which will be implemented this year.

Action: Media Summary and summary of themes that are topical – can this be shared with Board on a regular basis.

10. Interest Articles

The Board **noted** the interest articles.

11. General Business

A Board member queried what our take on AI is in relation to reducing some of our workload – use to simplify some of the information we put out. Management responded that it is a Government policy that AI is not used. However, we are still getting information on this.

The meeting closed at 2.15pm with a karakia.

Date of Next Meeting

The date for the next Board meeting is set for 30 April 2024.

Approved *30 April 2024*

Dr Peter Bramley, Acting Chair Date