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 Monday 24 February at 2.00pm and Tuesday 25 February 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 (Via Teams)
Dr Diana Siew (PhD)	Board member (Via Teams on 24 February)
Dr Margaret Wilsher (MD, FRACP, FRACMA)	Board member

Apologies

Robyn Manuel	Board Observer, CAC Chair

Board Observers

Rhiannon Braund	Board Observer, PTAC Representative
Lucy Elwood	Board Observer, CAC Representative

Guests

Debbie Francis	Item 4 on 24 February
Hon David Seymour, Associate Minister of Health	Item 3 on 25 February
John Brinsley-Pirie, Office of Hon David Seymour	Item 3 on 25 February
Amanda Smith, Office of Hon David Seymour	Item 3 on 25 February
Dame Kerry Prendergast	Item 5 on 25 February

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
Jacqui Webber	Board Secretary (Minute taker)

Attendees joined the meeting to present relevant papers: Ben Campbell-Macdonald, Saar Cohen-Rohan.

24 February 2025

Welcome and Opening of Meeting

The Chair welcomed everyone and opened the meeting at 2.00pm with a karakia. The Chair acknowledged apologies from Robyn Manuel and welcomed Lucy Elwood and Rhiannon Braund.

1. Update on Societal Perspective, including Pilot

This paper provided an update on the societal perspective workstream, including results from a pilot study.

Staff attended the meeting and presented on the subject.

The Board:

noted the contents of this paper, and the intention to advance the societal perspective workstream through consultation and engagement with sector stakeholders, including suppliers and consumer groups. This work will contribute to the update of Pharmac's health economics guidelines

noted that further internal work is required to socialise and test the use of a societal perspective for budget bid purposes.

2. Plan for the comprehensive review of expert advice

This paper provided the Board with an outline of the comprehensive review of expert advice, signalled at the November Board meeting.

The Board:

noted the briefing document

noted the key elements of the review approach

endorsed the plan for the comprehensive review of expert advice.

Action: Provide a further update to the May Board meeting, following the Consumer Engagement Report and include this feedback.

3. Medical Device Review

This paper provided the Board with an update on the independent review of the Medical Devices Programme.

The Board:

noted and discussed the draft independent report prepared for the Ministry of Health; and noted Pharmac feedback to the Ministry of Health, on this draft report.

Action: [redacted]

4. Pharmac Culture Review

Debbie Francis joined the meeting to discuss this report.

This paper provided the Board with the Final Report prepared by Debbie Francis, on the recent Pharmac Culture Review.

Some key messages:

- The process is not yet complete and the Board has commissioned a piece of work on priorities and action plan from the Senior Leadership Team, to be discussed at the next Board meeting.
- The Board needs to consider this report alongside other external reviews underway.
- The Board will provide a copy of the report to the Associate Minister of Health for his consideration, in due time.
- The Board intends to proactively release the executive summary of the report, once the process has been completed.

The Board:

noted and discussed the report from Debbie Francis, in confidence.

Action: Priorities and Action Plan to be taken to March Board meeting.

The meeting closed at 5.00pm.

25 February 2025

Welcome and Opening of Meeting

The Chair welcomed everyone and opened the meeting at 9.00am. The Chair acknowledged apologies from Robyn Manuel.

The Chair noted that the order of some items had changed, which had an impact on numbering of papers.

1. Chief Executive's Report

1.1 Chief Executive's Report

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

- Budget 2025 – still waiting to hear the decision on this.

- Progress on medicines budget uplift –really good progress has been made. Not far off meeting the target the Government set.
- Obesity medicines – PTAC have just reconsidered options and identified issues. The Board queried whether we should consider Pharmac taking a lead in this space.
- Supply issues –a paper will come to the next Board meeting on potential issues around the US and their tariffs, medicines from China and possible geopolitical issues.
- Estradiol patches – we would like to have gone out with a consult this week, but we are still in consultation with suppliers. A note will go out today to update impacted parties.
- The Novavax settlement agreement was signed by the Chief Executive and Chair yesterday, so funding will be released to the Crown shortly.

The Board:

noted the Chief Executive's report for February 2025

noted the Senior Leadership Team Engagement Calendar

noted the financials for January 2025, as presented to the Finance, Audit & Risk Committee.

Action: Paper to March Board meeting on Supply Issues and impacts of US tariffs and potential geopolitical issues.

1.2 Legal Report – Legally Privileged

[redacted]

2. Chair's Report

2.1 Chair's Verbal Update

The Chair noted that comments she had to add, were being covered in existing items.

2.2 Minutes of Board meetings

The Board:

resolved to adopt the minutes of the meetings held on 29 November 2024, 28 January and 3 February 2025, subject to minor amendments.

2.3 Interest Register

The Board:

noted the interest register and Peter Bramley will advise of an update separately.

3. Guest – Hon David Seymour

The Minister joined the meeting for a discussion with the Board and management which was held in confidence.

The Minister thanked everyone for the work we do and acknowledged all the work that had been done against the LoE.

[redacted]

4. Key Items

4.2 Final Audit Report to the Board for YE 30 June 2024

The Board:

noted Audit NZ issued an unmodified audit opinion regarding the Annual Report 2023/24

noted the Board Chair and the Finance, Audit and Risk Committee Chair signed the Letter of Representation and the Statement of Responsibility, as had been agreed by the Board

noted the Audit NZ Audit Director attended the December 2024 Finance, Audit and Risk Committee meeting held on the 29 November 2024 and advised the Committee:

- the audit process was smoother this year due to not being the first year of the Health Sector changes
- the audit process went well from their perspective; and
- there was nothing of concern to raise.

noted the final Report from Audit NZ to the Board on its 2023/2024 audit of Pharmac.

4.3 Consumer Advisory Committee (CAC) Terms of Reference (TOR) Update

This paper sought Board agreement to approve the updated TOR for the CAC.

The update are technical changes in line with the Act and will be potentially reviewed following discussions around the publication of the consumer engagement report.

The Board:

noted the current CAC Terms of Reference are due to be updated

noted the current CAC Terms of Reference does not reflect current legislation

approved the updated CAC Terms of Reference.

Action: Section 4 – Māori are our priority populate …. and section 5 is different – these need to be aligned.

4.4 2024/25 Quarter Two Performance Report

This paper provided the Quarter Two report for 2024/25. The report provided a summary of progress against our strategic intentions, initiatives and measures set out in our Statement of Performance Expectations (SPE) and the Letter of Expectations for 2024/25.

The Board:

discussed and **approved** the 2024/25 quarter two performance report

noted that following Board approval of the quarterly performance report, it will be provided to the Associate Minister of Health.

5. Guest – Dame Kerry Prendergast

Consumer Engagement Workshop Report

Dame Kerry Prendergast joined the meeting for this paper and presented the independent Consumer Engagement Workshop Report to the Board.

Pharmac's Board commissioned Dame Kerry Prendergast to facilitate two Consumer Engagement workshops and to then prepare an independent report for the Board, summarising feedback and suggesting next steps. The purpose/aim of the workshops was for a reset.

Consumer advocates at the workshops identified a number of areas where it was perceived that Pharmac needs to improve their interactions with consumers, to ensure they are respectful and meaningful, and that consumer voices are valued and included throughout our work. These areas included:

- better decision-making processes
- faster and more efficient decision-making processes
- meaningful and respectful engagement
- effective and transparent communications.

There was a strong consensus that Pharmac is a long way from where it needs to be – there is a big gap between trust and respect.

Pharmac is grateful to the workshop participants who shared their insights and experiences of working with Pharmac.

It was agreed that a workplan is needed with clear deliverables and a Board sponsored reference group, to work in partnership with Pharmac. We need to be smart about how we engage to make a positive shift.

It was confirmed that we have a communications plan in place and the Board plans to proactively release the full report as part of its commitment to being a transparent organisation. It will be published on Pharmac's website on Monday 10 March and a media release will be sent out. The Board Chair will be our spokesperson.

Kerry Prendergast confirmed she has handed the report over to Pharmac and will not respond to queries.

We are now working through the next steps, but want to emphasise our commitment to strengthening Pharmac's relationships with consumers. There will be further opportunities for the wider consumer advocacy community to be involved as this work develops.

The Board:

noted and **discussed** the Consumer Engagement Workshop report.

6. Schedule and Funding

6.2 Prioritisation Report

This report described prioritisation activity since the last report presented to the Board at its October 2024 meeting. It also updated the Board on the progress of selected items from the following prioritisation lists:

- the full *Options for Investment* list as of 27 November 2024
- the impact on health outcomes for those with the highest health need.

The Board:

noted the prioritisation activity undertaken by Pharmac staff since September 2024 and the progress of selected items from Pharmac's prioritisation list.

Action: provide schedule of Prioritisation meeting dates for Board members to attend a meeting.

Add to strategic agenda – take board through process/journey for making it to the OFI list. 'What happens prior to the prioritisation meeting'.

6.3 Medicines Budget Management Report

The purpose of this paper was to update the Board on Pharmac staff's plans to manage the Medicines Budget. It aimed to enable a wider discussion by the Board regarding planned activities to manage expenditure in 2024/25 and in the out-years.

The Board:

noted the medicines budget [redacted]

noted the portfolio of recent, current and planned investments underway, as well as those on hold.

6.4 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:

resolved to delegate decision-making to the Chief Executive for a proposal that falls within the Board's financial delegations. This is to enable the decision to be made at the earliest available opportunity, to meet proposed timeframes, enable faster access to medicines for patients, and/or to support implementation of the proposals (both from a health sector perspective and for suppliers who need time to build up sufficient stock). This proposal is to fund insulin degludec with insulin aspart (brand name Ryzodeg) for type I and II diabetes mellitus.

noted that if, following consultation, the above proposal was considered to be contentious we would take it to the Board for a decision

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

noted that we are considering changes to the consultation process for the annual tender and will update the Board as this work progresses

noted the summary of decisions made under Delegated Authority during December 2024 and January 2025.

6.5 Proposal to fund treatments for cancer and infections, and to change the funded brand of palbociclib

This paper sought a decision from the Board on a proposal to fund treatments for cancer and infections and to change the funded brand of palbociclib. The proposal would result in listing four new medicines on the Pharmaceutical Schedule and reduce the net price of a currently funded medicine through immediate price reduction and by changing the funded brand at a later date.

The Board:

Inotuzumab ozogamicin

resolve to list inotuzumab ozogamicin (Besponsa) in the Oncology Agents and Immunosuppressants Therapeutic group, Monoclonal Antibodies therapeutic subgroup in Section B of the Pharmaceutical Schedule from 1 April 2025 as follows:

Chemical	Formulation	Brand	Pack size	Proposed price and subsidy
Inotuzumab ozogamicin	Inj 1 mg vial	Besponsa	1	$14,457.00
Inotuzumab ozogamicin	Inj 1 mg for ECP	Baxter	1 mg	$14,457.00

resolve to apply the following Special Authority to inotuzumab ozogamicin in Section B of the Pharmaceutical Schedule from 1 April 2025 as follows:

> Special Authority for Subsidy
> Initial application – only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for patients meeting the following criteria:
> All of the following:

1. Patient has relapsed or refractory CD22-positive B-cell acute lymphoblastic leukaemia/lymphoma, including minimal residual disease; and
2. Patient has ECOG performance status of 0-2; and
3. Either:
   3.1. Both:
      3.1.1. Patient has Philadelphia chromosome positive B-Cell ALL; and
      3.1.2. Patient has previously received a tyrosine kinase inhibitor; or
   3.2. Patient has received one prior line of treatment involving intensive chemotherapy; and
4. Treatment is to be administered for a maximum of 3 cycles.

Renewal – only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for patients meeting the following criteria:
All of the following:
1. Patient is not proceeding to a stem cell transplant; and
2. Either:
   2.1 Patient has experienced complete disease response; or
   2.2 Patient has experienced complete remission with incomplete haematological recovery; and
3. Treatment with inotuzumab ozogamicin is to cease after a total duration of 6 cycles.

resolve to apply PCT only rule to inotuzumab ozogamicin in Section B of the Pharmaceutical Schedule from 1 April 2025;

resolve to list inotuzumab ozogamicin (Besponsa) in the Oncology Agents and Immunosuppressants Therapeutic group, Monoclonal Antibodies therapeutic subgroup in Part II of Section H of the Pharmaceutical Schedule from 1 April 2025 as follows:

Chemical	Formulation	Brand	Pack size	Proposed price
Inotuzumab ozogamicin	Inj 1 mg vial	Besponsa	1	$14,457.00

resolve to apply the following Hospital Indication Restriction to inotuzumab ozogamicin in Part II of Section H of the Pharmaceutical Schedule from 1 April 2025 as follows:

Restricted
Initiation
Re-assessment required after 4 months
All of the following:
1. Patient has relapsed or refractory CD22-positive B-cell acute lymphoblastic leukaemia/lymphoma, including minimal residual disease; and
2. Patient has ECOG performance status of 0-2; and
3. Either:
   3.1. Both:
      3.1.1. Patient has Philadelphia chromosome positive B-Cell ALL; and
      3.1.2. Patient has previously received a tyrosine kinase inhibitor; or
   3.2. Patient has received one prior line of treatment involving intensive chemotherapy; and
4. Treatment is to be administered for a maximum of 3 cycles.

Continuation
Re-assessment required after 4 months
1. Patient is not proceeding to a stem cell transplant; and
2. Either:
   2.1 Patient has experienced complete disease response; or
   2.2 Patient has experienced complete remission with incomplete haematological recovery; and
3. Treatment with inotuzumab ozogamicin is to cease after a total duration of 6 cycles.

note that a confidential rebate would apply to inotuzumab ozogamicin (Besponsa) that would reduce the net price

note that inotuzumab ozogamicin (Besponsa) would have subsidy and delisting protection until 30 September 2028

Crizotinib

resolve to list crizotinib (Xalkori) in the Oncology Agents and Immunosuppressants Therapeutic group, Protein-Tyrosine Kinase Inhibitors therapeutic subgroup in Section B and Part II of Section H of the of the Pharmaceutical Schedule from 1 April 2025 as follows:

Chemical	Formulation	Brand	Pack size	Proposed price and subsidy
Crizotinib	Cap 200 mg	Xalkori	60	$7,250.00
Crizotinib	Cap 250 mg	Xalkori	60	$7,250.00

resolve to apply the following Special Authority to crizotinib (Xalkori) in Section B of the Pharmaceutical Schedule from 1 April 2025 as follows:

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 locally advanced or metastatic, unresectable, non-squamous non-small cell lung cancer; and
2. There is documentation confirming that the patient has a ROS1 rearrangement using an appropriate ROS1 test; and
3. Patient has ECOG performance score of 0-3; and
4. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal - from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
Both:
1. Response to treatment has been determined by comparable radiological assessment following the most recent treatment period; and
2. No evidence of disease progression.

resolve to apply the following Hospital Indication Restriction to crizotinib (Xalkori) in Part II of Section H of the Pharmaceutical Schedule from 1 April 2025 as follows:

Restricted
Initiation
Re-assessment required after 6 months
All of the following:
1. Patient has locally advanced or metastatic, unresectable, non-squamous non-small cell lung cancer; and
2. There is documentation confirming that the patient has a ROS1 rearrangement using an appropriate ROS1 test; and
3. Patient has ECOG performance score of 0-3; and
4. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Continuation
Re-assessment required after 6 months
Both:
1. Response to treatment has been determined by comparable radiological assessment following the most recent treatment period; and
2. No evidence of disease progression.

note that a confidential rebate would apply to crizotinib (Xallkori) that would reduce the net price

note that crizotinib (Xallkori) would have subsidy and delisting protection until 30 September 2028.

Ceftazidime with avibactam

resolve to list ceftazidime with avibactam (Zavicefta) in the Infections Therapeutic group, Cephalosporins and Cephamycins - 3rd Generation therapeutic subgroup in Part II of Section H of the Pharmaceutical Schedule from 1 April 2025, as follows:

Chemical	Formulation	Brand	Pack size	Proposed price
Ceftazidime with avibactam	Inj ceftazidime 2,000 mg with avibactam 500 mg, vial	Zavicefta	10	$2,250.00

resolve to apply the following Hospital Indication Restriction to ceftazidime with avibactam (Zavicefta) in Part II of Section H of the Pharmaceutical Schedule from 1 April 2025 as follows

Restricted
Initiation
Both

1. Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital; and
2. Either:
   2.1. Proven infection with a carbapenem-resistant micro-organism, based on microbiology report; or
   2.2. Probable infection with a carbapenem-resistant micro-organism, based on assessment by a clinical microbiologist or infectious disease specialist.

note that ceftazidime with avibactam (Zavicefta) would have subsidy and delisting protection until 30 September 2028.

Axitinib

resolve to list axitinib (Inlyta) in the Oncology Agents and Immunosuppressants Therapeutic group, Protein-Tyrosine Kinase Inhibitors therapeutic subgroup in Section B and Part II of Section H of the of the Pharmaceutical Schedule from 1 April 2025 as follows:

Chemical	Formulation	Brand	Pack size	Proposed price and subsidy
Axitinib	Tab 1 mg	Inlyta	28	$536.40
Axitinib	Tab 5 mg	Inlyta	28	$2,682.00

resolve to apply wastage rule to axitinib (Inlyta) tab 1 mg and tab 5 mg from 1 April 2025 in Section B of the Pharmaceutical Schedule

resolve to apply the following Special Authority to axitinib in Section B of the Pharmaceutical Schedule from 1 April 2025 as follows:

Special Authority for Subsidy
Initial application - from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

1. The patient has metastatic renal cell carcinoma; and
2. The disease is of predominant clear cell histology; and
3. The patient has documented disease progression following one previous line of treatment; and
4. The patient has ECOG performance status of 0-2.

Renewal – from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression.

resolve to apply the following Hospital Indication Restriction to axitinib in Part II of Section H of the Pharmaceutical Schedule from 1 April 2025 as follows:

Restricted
Initiation
Re-assessment required after 4 months
All of the following:

1. The patient has metastatic renal cell carcinoma; and
2. The disease is of predominant clear cell histology; and
3. The patient has documented disease progression following one previous line of treatment; and
4. The patient has ECOG performance status of 0-2.

Continuation
Re-assessment required after 4 months
No evidence of disease progression.

note that a confidential rebate would apply to axitinib that would reduce the net price

note that axitinib would have subsidy and delisting protection until 30 September 2028.

Palbociclib

resolve to list palbociclib (Palbociclib Pfizer) in the Oncology Agents and Immunosuppressants Therapeutic group, Protein-Tyrosine Kinase Inhibitors therapeutic subgroup in Section B and Part II of Section H of the of the Pharmaceutical Schedule from 1 July 2025 as follows:

Chemical	Formulation	Brand	Pack size	Proposed price and subsidy
Palbociclib	Tab 75 mg	Palbociclib Pfizer	21	$1,200.00
Palbociclib	Tab 100 mg	Palbociclib Pfizer	21	$1,200.00
Palbociclib	Tab 125 mg	Palbociclib Pfizer	21	$1,200.00

note the Special Authority, Hospital Indication Restriction and Wastage rules that currently apply to palbociclib continue to apply to the Palbociclib Pfizer brand.

note that a confidential rebate would apply to Palbociclib Pfizer that would reduce the net price

note that Palbociclib Pfizer would have subsidy and delisting protection until 30 November 2028.

note that the confidential rebate that applies to palbociclib (Ibrance) would increase from 1 April 2025.

resolve to delist palbociclib (Ibrance) from Section B and Part II of Section H of the Pharmaceutical Schedule from 1 December 2025 as follows:

Chemical and presentation	Supplier	Brand
Palbociclib tab 75 mg	Pfizer	Ibrance
Palbociclib tab 100 mg	Pfizer	Ibrance
Palbociclib tab 125 mg	Pfizer	Ibrance

Pembrolizumab and atezolizumab

resolve to amend the Special Authority criteria for pembrolizumab in Section B of the Pharmaceutical Schedule from 1 April 2026 as follows (only amended criteria shown, additions in bold):

Special Authority for Subsidy
Initial application — (non-small cell lung cancer first-line monotherapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

1. Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
2. Patient has not had chemotherapy for their disease in the palliative setting; and
3. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
4. For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR, **ROS-1** or ALK tyrosine kinase unless not possible to ascertain; and
5. Pembrolizumab to be used as monotherapy; and
6. Either:
    - 6.1. There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 50% as determined by a validated test unless not possible to ascertain; or
    - 6.2. Both:
        - 6.2.1. There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 1% as determined by a validated test unless not possible to ascertain; and
        - 6.2.2. Chemotherapy is determined to be not in the best interest of the patient based on clinician assessment; and
7. Patient has an ECOG 0-2; and
8. Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
9. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Initial application — (non-small cell lung cancer first-line combination therapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

1. Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
2. Patient has not had chemotherapy for their disease in the palliative setting; and
3. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
4. For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR, **ROS-1** or ALK tyrosine kinase unless not possible to ascertain; and
5. Pembrolizumab to be used in combination with platinum-based chemotherapy; and
6. Patient has an ECOG 0-2; and

7. Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
8. Baseline measurement of overall tumour burden is documented clinically and radiologically.

resolve to amend the Hospital Indication Restriction criteria for pembrolizumab in Part II of Section H of the Pharmaceutical Schedule from 1 April 2026 as follows (only amended criteria shown, additions in bold and deletions in strikethrough):

Restricted
Initiation - non-small cell lung cancer first-line monotherapy
Medical oncologist ~~or any relevant practitioner on the recommendation of a medical oncologist~~
Re-assessment required after 4 months
All of the following:
1. Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
2. Patient has not had chemotherapy for their disease in the palliative setting; and
3. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
4. For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR**, ROS-1** or ALK tyrosine kinase unless not possible to ascertain; and
5. Pembrolizumab to be used as monotherapy; and
6. Either:
    6.1. There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 50% as determined by a validated test unless not possible to ascertain; or
    6.2. Both:
        6.2.1. There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 1% as determined by a validated test unless not possible to ascertain; and
        6.2.2. Chemotherapy is determined to be not in the best interest of the patient based on clinician assessment; and
7. Patient has an ECOG 0-2; and
8. Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
9. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Initiation - non-small cell lung cancer first-line combination therapy
Medical oncologist ~~or any relevant practitioner on the recommendation of a medical oncologist~~
Re-assessment required after 4 months
All of the following:
1. Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
2. Patient has not had chemotherapy for their disease in the palliative setting; and
3. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
4. For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR**, ROS-1** or ALK tyrosine kinase unless not possible to ascertain; and
5. Pembrolizumab to be used in combination with platinum-based chemotherapy; and
6. Patient has an ECOG 0-2; and
7. Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
8. Baseline measurement of overall tumour burden is documented clinically and radiologically.

resolve to amend the Special Authority criteria for atezolizumab in Section B of the Pharmaceutical Schedule from 1 April 2026 as follows (only amended criteria shown, additions in bold):

Special Authority for Subsidy
Initial application **-** (non-small cell lung cancer second line monotherapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:
1. Patient has locally advanced or metastatic non-small cell lung cancer; and
2. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
3. For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR**, ROS-1** or ALK tyrosine kinase unless not possible to ascertain; and
4. Patient has an ECOG 0-2; and

5. Patient has documented disease progression following treatment with at least two cycles of platinum-based chemotherapy; and
6. Atezolizumab is to be used as monotherapy at a dose of 1200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
7. Baseline measurement of overall tumour burden is documented clinically and radiologically.

resolve to amend the Hospital Indication Restriction criteria for atezolizumab in Part II of Section H of the Pharmaceutical Schedule from 1 April 2026 as follows (only amended criteria shown, additions in bold and deletions in strikethrough):

Restricted
Initiation - – non-small cell lung cancer second line monotherapy
Medical oncologist ~~or any relevant practitioner on the recommendation of a medical oncologist~~
Re-assessment required after 4 months
All of the following:
1. Patient has locally advanced or metastatic non-small cell lung cancer; and
2. Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
3. For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR**, ROS-1** or ALK tyrosine kinase unless not possible to ascertain; and
4. Patient has an ECOG 0-2; and
5. Patient has documented disease progression following treatment with at least two cycles of platinum-based chemotherapy; and
6. Atezolizumab is to be used as monotherapy at a dose of 1200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
7. Baseline measurement of overall tumour burden is documented clinically and radiologically.

Continuation – non-small cell lung cancer second line monotherapy
Medical oncologist ~~or any relevant practitioner on the recommendation of a medical oncologist~~
Re-assessment required after 4 months
All of the following:
1 Any of the following:
1.1 Patient's disease has had a complete response to treatment; or
1.2 Patient's disease has had a partial response to treatment; or
1.3 Patient has stable disease; and
2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
3 No evidence of disease progression; and
4 The treatment remains clinically appropriate and patient is benefitting from treatment; and
5 Atezolizumab to be used at a maximum dose of 1200 mg every three weeks (or equivalent); and
6 Treatment with atezolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Ursodeoxycholic acid

resolve to add the following Special Authority criteria to ursodeoxycholic acid in Section B of the Pharmaceutical Schedule from 1 April 2025 as follows (new criteria only shown in bold):

Special Authority for Subsidy
Initial application - (prevention of sinusoidal obstruction syndrome) from any relevant practitioner. Approvals valid for 6 months for applications where the patient has leukaemia/lymphoma and requires prophylaxis for medications/therapies with a high risk of sinusoidal obstruction syndrome.

resolve to amend the Hospital Indication Restriction criteria for ursodeoxycholic acid in Part II of Section H of the Pharmaceutical Schedule from 1 April 2025 as follows (deletions in ~~strikethrough~~, additions in bold) (amended criteria only shown):

Restricted
Initiation – prevention of sinusoidal obstruction syndrome
Limited to 6 months treatment

Both:

1. **The patient is enrolled in the Children's Oncology Group AALL1732 trial; and**
2. **The patient has leukaemia/lymphoma and requires prophylaxis for medications/therapies with a high risk of Sinusoidal obstruction syndrome.**

resolved to amend Special Authority criteria for pembrolizumab and atezolizumab from 1 April 2026 to limit access to only those people without a *ROS1* mutation (in addition to EGFR and ALK mutations)

noted the 12 December 2024 provisional agreement included amendments to the net price of palbociclib (Ibrance) from 1 April 2025

resolved to approve the 12 December 2024 provisional listing agreement with Pfizer New Zealand Limited (Pfizer) for Besponsa, Xalkori, Zavicefta, Inlyta, Ibrance and Palbociclib Pfizer

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

[redacted]

6.6 Medical Devices Transaction and Investment Report

This paper provided the Board with an update on progress with medical devices national contracting activity. It also included some 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 November, December and January by the Director, Medical Devices.

7. Strategy and Policy

7.2 Medical Devices Programme Update

This paper provided the Board with an update on progress of the Medical Device Programme and the focus for delivery over the coming months.

The Board:

noted the update on progress with the Medical Device Programme

noted that the Programme aims to achieve by 30 June 2025 a comprehensive list that represents the medical devices hospitals are using. A public consultation on this is scheduled for release in February 2025

noted that the Programme is working to have the systems and settings in place to be able to move to more controlled list management settings ('close the list') by the end of 2025

noted that there is a lack of funding certainty for the Medical Device Programme from the beginning of the 2025/2026 financial year. If this is not secured, the Programme is unlikely to deliver the desired benefits within an acceptable timeframe.

8. Regular Reporting

8.2 Communications and Governance Report

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

The Board:

noted that 14 of the 31 action items recommended by the Chief Ombudsman to improve our OIA processes have been fully implemented and six have been partially implemented

noted that a proactive release policy is being developed to support increased transparency of Pharmac's work and decision making

noted the latest iSentia media analysis shows progress in increasing Pharmac's voice in media coverage with greater use of key messages and spokesperson cut-through

noted that patient resources about supply issues are being added to our website to support community pharmacists.

9. Record of Previous Minutes of Committee Meetings

9.2 Minutes of Finance, Audit & Risk Committee Meeting

The Board:

noted and **endorsed** the minutes of the Audit & Risk Committee meeting held on 29 November 2024, subject to minor edits.

9.3 Summary of November 2024 Consumer Advisory Committee (CAC) Meetings

The CAC representative spoke to the paper and confirmed the Deputy Chair has recently resigned for family reasons. This makes the Committee light on Pacific representation. The Board Chair confirmed her attendance at the next CAC Committee meeting.

The Board:

noted the minutes from the November CAC meeting

noted the summary of key issues across the meeting.

10. Governance Matters

10.2 Board and Committee Member Terms and Attendance Record

The Board:

noted the Board and Committee member terms

noted the 2025 Meeting Attendance Register.

10.3 Board Correspondence

The Board:

noted the correspondence sent / received for the prior month.

In addition to the correspondence noted in this paper, the Board noted that a large volume of emails have been received recently by the Chair and some staff, on funding for daratumumab.

10.4 Board Actions

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

10.5 Matters Arising

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

10.6 Board Annual Agenda for 2025

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

10.7 Glossary of Terms and Abbreviations

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

11. General Business

- **Future Māori Engagement**

Talia Anderson-Town and Trevor Simpson attended and presented at the Te Manawa Taki – IMPB board meeting in Hamilton on 21 February where six iwi Māori partnership boards were represented (there are 15 partnership boards around NZ). It was an opportunity to engage with iwi and discuss future engagement. They discussed Pharmac's purpose and provided background to what we can and can't do. It was a great interactive session and a really positive environment. Community Health Plans will be published soon and we will be able to work with these. They advised they have baseline funding until 2027. They are very keen to engage further with us.

The meeting closed at 1.24pm with a karakia.

Date of Next Meeting: 25 March 2025

Approved *25 March 2025*

Paula Bennett, Chair Date