PHARMAC
TE PĀTAKA WHAIORANGA

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Some information may have been redacted for reasons including confidentiality

Minutes of the Pharmaceutical Management Agency (Pharmac) Board Meeting held on 28 July 2023 at 9.00am

At Pharmac Offices, Level 9, 40 Mercer Street, Wellington and via Teams

Present:

Board members

Hon Steve Maharey ((MA (Hons), CNZM))	Chair
Dr Peter Bramley (BSc (Hon), LL.B, PhD)	Deputy Chair *via Teams*
Talia Anderson-Town (BBS, PG Dip Professional Accounting, CA, CPP)	Board member *via Teams*
Dr Anthony Jordan (BHB, MBChB, FRACP)	Board member
Dr Margaret Wilsher (MD, FRACP, FRACMA)	Board member

Apologies

Dr Diana Siew (PhD)	Board member

Board Observers

Lisa Lawrence	Board Observer, CAC Chair
Jane Thomas	Board Observer, PTAC Chair
Robyn Manuel	Board Observer, CAC Chair

Pharmac staff in attendance

Sarah Fitt	Chief Executive
Michael Johnson	Director, Strategic Initiatives
Geraldine MacGibbon	Acting Director, Pharmaceuticals
Kathryn McInteer	Director, Finance and Corporate
Trevor Simpson	Kaituruki Māori - Director Māori
Nicola Ngawati	Director, Equity & Engagement
David Hughes	Chief Medical Officer
Andrew Davies	Acting Director Devices
Jacqui Webber	Board Secretary

Attendees joined the meeting to present relevant papers: *Danae Staples-Moon, Graham Durston, Ishani Noble, Jannel Fisher, Jacqui Mettam, Brent McPherson, Andrew Oliver, Catherine Kingsbury, Logan Heyes, Chippy Compton, Sam Bright, Ben Campbell-MacDonald, Caroline de Luca and Davina Carpenter.*

1. Director-only Discussion

The meeting commenced at 9.00am with a Mihi Whakatau for new Board members, Dr Margaret Wilsher and Dr Peter Bramley and was followed by Board only time.

2. Governance and Information matters

2.1 Guest Speaker

James Le Fevre - Te Whatu Ora

James shared his insights from the robotic assisted orthopaedic surgery HTA collaborative project, including highlights, challenges and learnings. He also described

how the project may inform future national HTA processes and provided his perspective on the future of national HTA more broadly.

James's presentation was followed by a brief Q&A session.

Following the guest speaker, the Chair formally welcomed everyone to the meeting and acknowledged that it was Lisa Lawrence's last meeting (CAC Chair). The Chair also acknowledged the new CAC Chair, Robyn Manuel, who joined the Board meeting today as a guest.

2.2 Glossary of Terms

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

2.3 Board Actions

The Board noted the Board Actions.

2.4 Board Annual Agenda 2023

The Board **noted** the Annual Agenda 2023.

Action: It was suggested that an invite be extended to the Minister for the November Board meeting.

2.5 Board Annual Agenda 2024

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

The Board Secretary will liaise with the Board to confirm dates.

A discussion was had on the need to consider whether we have some meetings in Auckland/Regional.

2.6 Board and Committee Member Terms

The Board:

noted the Board and Committee Member terms; and

approved Margaret Wilsher being appointed to the Audit & Risk Committee.

2.7 Apologies

The Board **noted** apologies from Diana Siew.

3. Record of Previous Board and Committee Meetings

3.1 Minutes of Board Meeting held on 30 June 2023

The Board **resolved** to adopt the minutes of the 30 June 2023 meeting as being a true and correct record.

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

3.2 Health & Safety Committee Recommendations

The Chair of the Health & Safety Committee provided a verbal update to the Board and noted two items to be tabled:

- Health, Safety and Wellbeing Approach for 2023/2024
    - **agreed in principle** that a multi-faceted approach including international standards, a Maori perspective on health and our organisation values, will help us embed a more meaningful (and effective) framework to manage health, safety and wellbeing for our kaimahi.
- Next 90 days focus areas for first quarter of 2023/2024
    - **agreed in principle** that the focus areas for quarter one, are the items identified in the 2022/23 workplan that have yet to be completed.

Anthony Jordan and Steve Maharey **Carried**

3.3 Summary of CAC Meeting

This paper informed the Board of advice received from the Consumer Advisory Committee at the meeting held on 15 June 2023.

The Board:

received the minutes from the June Consumer Advisory Committee meeting; and

noted the summary of key issues across the meeting.

4. Interests Register

The Board **noted** the interests register.

5. Matters Arising

The Board **noted** there were no matters arising or actions to progress.

6. Chair's Report

6.1 Verbal Update from the Chair

The Chair provided a verbal update on recent activities.

6.2 Correspondence

The Board **noted** the correspondence report.

7. CE Report

7.1 Chief Executive's Report

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

[redacted]

[redacted]

HTAi Conference - Robyn asked that it be noted that she was supported to attend the conference HTAi.

7.2 Financial Report

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 June 2023.

The Board:

Combined Pharmaceutical Budget

noted that the National Pharmaceutical Purchasing appropriation for 2022/23 is $1,186 billion [redacted]

[redacted]

noted that a $21.8 million uplift to the CPB for 2023/24 has been approved to meet the anticipated increase in demand for prescription medicines arising from the Budget 2023 decision to remove the $5 co-payment from prescription medicines;

[redacted]

noted the 2023/24 CPB Forecast.

COVID-19-related CPB cost pressures

noted that the Government has separately provided $50 million for 2022/23 to meet COVID-19-related CPB cost pressures. [redacted]

[redacted]

[redacted]

[redacted]

June 2023 financial results

[redacted]

8. Key Items

8.1 Annual Review of PTAC, Specialist Advisory Committees and CAC Fees

This paper sought approval, consistent with the Cabinet Fees Framework, to increase the fees paid to members of PTAC, SACs and CAC.

The Board:

PTAC and SACs

agreed to increase the meeting day rate for both PTAC and SACs from $780 per day to $800 per day, with an equivalent hourly rate increase from $97.50 per hour to $100 per hour for preparation work (both being increases of 2.5%);

agreed that, in line with the revised fees framework, Committee members who are self-employed in primary care, may claim either the daily rate or the cost of locum cover when they attend meetings, whichever is the higher, to a maximum of $1,200 per day;

CAC

agreed to increase the CAC member meeting day rate from $286 per day to $295 per day and the CAC Chair meeting day rate from $407 per day to $419 per day (both being increases of 3%, the maximum increase the Board is permitted to make each year);

noted that the increase will help to close the gap between what CAC members are paid and what the Health Quality and Safety Commission pays its consumer members;

Other
noted that the annual budget impact for these changes is estimated to be around $20K, to be met within existing funding; and

noted that the Fees Framework requires fee increases to be reported to Te Kawa Mataaho/ Public Service Commission and the Crown Entities Act requires annual fees for Board Committee members to be reported in the annual report.

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

8.2 People and Capability Strategy Progress Report

This paper provided the Board with an overview of the People and Capability Strategy (Strategy) work programme that is led by the People and Capability team. The paper also provided an update on our areas of future focus.

It was also noted that the Collective negotiations reached agreement with PSA and that staff turnover has reduced.

The Board **noted** the work programme update for the people and capability strategy programme and the progress made since the last Board update in May 2023.

9. Strategic Planning and Policy

9.1 Pharmac 2022/23 Quarter Four Performance Report

This paper provided a summary of the progress of reporting commitments (initiatives and measures) as outlined in Pharmac's 2022/23 Statement of Performance Expectations (SPE). The next report will be aligned to the new strategic priorities and have a slightly different structure.

The Board:

noted the quarter four performance report;

noted that we continue to make good progress against the 30 commitments made in 2022/23 in response to the Pharmac Review; and

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

9.2 Health and Disability System Planning Update

In the last few months, Pharmac has connected with the cross-agency planning underway across the health and disability system. This has resulted in Pharmac's closer connection to the work underway on the development of the Pae Ora strategies, next Government Policy Statement on Health (GPS) and the next New Zealand Health Plan - Te Pae Tata.

This paper sought to inform the Board of progress of the cross-agency planning work underway as part of the next phase of the health and disability system reforms and Pharmac's involvement in this work.

The Board:

noted the progress of the joint agency planning work underway - and Pharmac's growing participation in this work; and

noted that an update will be provided to the Board on progress and preparations for Budget 2024, at its September 2023 meeting.

10. Schedule and Funding

10.1 Proposal for funding of various vaccines and a diagnostic agent through an RFP

This paper sought a decision from the Board on a significant procurement process that will result in new supply agreements to secure the supply of the funded vaccines for eligible people in the National Immunisation Schedule.

The paper outlined the process undertaken for the Various Vaccines and a Diagnostic Agent RFP. It provided an overview of the proposals received in response to the RFP and was supported by three supplementary papers, specifically:

- proposal for the supply of various vaccines with proposed changes to the funded brand or eligibility criteria, [redacted]
- proposal for the supply of various vaccines with no proposed changes to the funded brand or eligibility criteria;
- proposal for changing the funded brand of influenza vaccine.

The Board:

noted the contents of the paper;

noted the three supplementary papers that provide additional detail and analysis of the proposals relating to:

- vaccines with proposed changes to the brand or eligibility criteria
- vaccines with no proposed changes to the funded brand or eligibility criteria
- changing the funded brand of influenza vaccine **resolved** to approve the amendments to the Pharmaceutical Schedule listings relating to various vaccines and a diagnostic agent.
- *Appendix One Resolutions*

[redacted]

[redacted]

Bacillus Calmette-Guerin vaccine

resolved to accept the proposal from Seqirus New Zealand Ltd for its brand to be the Principal Supply Status brand of the Community Pharmaceutical Bacillus Calmette-Guerin vaccine (BCG Vaccine) inj Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated, vial with diluent from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from Seqirus New Zealand Ltd for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical Bacillus Calmette-Guerin vaccine (BCG Vaccine) inj Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated, vial with diluent with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

Diphtheria, tetanus and pertussis vaccine

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical diphtheria, tetanus and pertussis vaccine (Boostrix) inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg pertussis toxoid, 8 mcg pertussis filamentous haemagglutinin and 2.5 mcg pertactin in 0.5 ml prefilled syringe from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical diphtheria, tetanus and pertussis vaccine (Boostrix) inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg pertussis toxoid, 8 mcg pertussis filamentous haemagglutinin and 2.5 mcg pertactin in 0.5 ml prefilled syringe with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

resolved to amend the presentation description for diphtheria, tetanus and pertussis vaccine (Boostrix) inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg pertussis toxoid, 8 mcg pertussis filamentous haemagglutinin and 2.5 mcg pertactin in 0.5 ml

prefilled syringe in Section I and Part II of Section H of the Pharamceutical Schedule from 1 July 2024 as follows (additions in bold):

> DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE
> Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg pertussis toxoid, 8 mcg pertussis filamentous haemagglutinin and 2.5 mcg pertactin in 0.5 ml **prefilled** syringe

noted that accepting the above proposal would not result in a change to the eligibility criteria for diphtheria, tetanus and pertussis vaccine.

Diphtheria, tetanus, pertussis and polio vaccine

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical diphtheria, tetanus, pertussis and polio vaccine (Infanrix IPV) inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin and 80 D-antigen units poliomyelitis virus in 0.5 ml syringe from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical diphtheria, tetanus, pertussis and polio vaccine (Infanrix IPV) Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin and 80 D-antigen units poliomyelitis virus in 0.5 ml syringe with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type B vaccine

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type B vaccine (Infanrix-hexa) inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin, 80 D-AgU polio virus, 10 mcg hepatitis B antigen, 10 mcg H. influenzae type b with tetanus toxoid 20-40 mcg from 1 November 2024 until 30 June 2027;

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type B vaccine (Infanrix-hexa) Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin, 80 D-Ag U polio virus, 10 mcg hepatitis B surface antigen in 0.5 ml syringe with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

resolved to amend the presentation description for diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type B vaccine (Infanrix-hexa) inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin, 80 D-Ag U polio virus, 10 mcg hepatitis B surface antigen in 0.5 ml syringe in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 July 2024 as follows (changes in bold and strikethrough):

> DIPHTHERIA, TETANUS, PERTUSSIS, POLIO, HEPATITIS B AND HAEMOPHILUS INFLUENZAE TYPE B VACCINE
> Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin, 80 D-AgU polio virus, 10 mcg hepatitis B ~~surface~~ antigen, **10 mcg H. influenzae type b with tetanus toxoid 20-40 mcg** in 0.5 ml syringe

Hepatitis A Vaccine

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical hepatitis A vaccine (Havrix 1440) inj 1440 ELISA units in 1 ml syringe from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical hepatitis A vaccine (Havrix 1440) inj 1440 ELISA units in 1 ml syringe with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical hepatitis A vaccine (Havrix Junior) inj 720 ELISA units in 0.5 ml syringe from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical hepatitis A vaccine (Havrix Junior) Inj 720 ELISA units in 0.5 ml syringe with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

resolved to amend the brand name of hepatitis A vaccine (Havrix), inj 1440 ELISA units in 1 ml syringe in Section I and Part II of Section H of the Pharmaceutical Schedule as follows (changes in bold):

Chemical	Formulation	Brand	Pharmacode	Supplier
Hepatitis A vaccine	Inj 1440 ELISA units in 1 ml syringe	Havrix 1440	2061937	GSK

Hepatitis B vaccine

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical hepatitis B recombinant vaccine (Engerix-B) inj 20 mcg per 1 ml prefilled syringe from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical hepatitis B recombinant vaccine (Engerix-B) inj 20 mcg per 1 ml prefilled syringe with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical hepatitis B recombinant vaccine (Engerix-B) inj 10 mcg per 0.5 ml prefilled syringe from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical hepatitis B recombinant vaccine (Engerix-B) Inj 10 mcg per 0.5 ml prefilled syringe with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

Haemophilus influenzae type b vaccine

resolved to accept the proposal from Sanofi-Aventis Australia Pty Ltd for its brand to be the Principal Supply Status brand of the Community Pharmaceutical Haemophilus influenzae type b vaccine (Act-HIB) Inj 10 mcg vial with diluent syringe from 1 December 2024 to 30 June 2027;

resolved to accept the proposal from Sanofi-Aventis Australia Pty Ltd for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical Haemophilus influenzae type b vaccine (Act-HIB) Inj 10 mcg vial with diluent syringe with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

resolved to list Sanofi-Aventis Australia Pty Ltd's Haemophilus influenzae type B vaccine (Act-HIB) inj 10 mcg vial with diluent syringe in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 July 2024 as follows:

Chemical	Presentation	Brand	Pack size	Price
Haemophilus influenzae type B vaccine	Inj 10 mcg vial with diluent syringe	Act-HIB	1	$0.00

resolved to apply the following Indication restrictions to the inj 10 mcg vial with diluent syringe presentation of Haemophilus influenzae type b vaccine (Act-HIB) in Section I of the Pharmaceutical Schedule from 1 July 2024:

One dose for people meeting any of the following:

1) For primary vaccination in children; or

2) An additional dose (as appropriate) is funded for (re-)immunisation for patients post haematopoietic stem cell transplantation, or chemotherapy; functional asplenic; pre or post splenectomy; pre- or post solid organ transplant, pre or post cochlear implants, renal dialysis and other severely immunosuppressive regimens; or

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

resolved to apply the following indication restrictions to the inj 10 mcg vial with diluent syringe presentation of Haemophilus influenzae type b vaccine (Act-HIB) in Section H of the Pharmaceutical Schedule from 1 July 2024:

Restricted
Initiation
Therapy limited to 1 dose
Any of the following:

1. For primary vaccination in children; or
2. An additional dose (as appropriate) is funded for (re-)immunisation for patients post haematopoietic stem cell transplantation, or chemotherapy; functional asplenic; pre or post splenectomy; pre- or post solid organ transplant, pre- or post cochlear implants, renal dialysis and other severely immunosuppressive regimens; or
3. For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

resolved to delist the following brand and presentation of Haemophilus influenzae type b vaccine from Section I and Part II of Section H of the Pharmaceutical Schedule on 1 December 2024, as follows:

Chemical	Presentation	Brand	Pack size
Haemophilus influenzae type b vaccine	Haemophilus Influenzae type B polysaccharide 10 mcg conjugated to tetanus toxoid as carrier protein 20-40 mcg; prefilled syringe plus vial 0.5 ml	Hiberix	1

Measles, Mumps and Rubella vaccine

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical measles, mumps and rubella vaccine (Priorix) inj, measles virus 1,000 CCID50, mumps virus 5,012 CCID50, Rubella virus 1,000 CCID50; prefilled syringe/ampoule of diluent 0.5 ml from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical measles, mumps and rubella vaccine (Priorix) injection, measles virus 1,000 CCID50, mumps virus 5,012 CCID50, Rubella virus 1,000 CCID50; prefilled syringe/ampoule of diluent 0.5 ml with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

resolved to delist the following brand of measles, mumps and rubella vaccine from Section of the Pharmaceutical Schedule on 1 December 2024, as follows:

Chemical	Presentation	Brand	Pack size
Measles, mumps and rubella vaccine	Inj, measles virus 1,000 CCID50, mumps virus 5,012 CCID50, Rubella virus 1,000 CCID50; prefilled syringe/ampoule of diluent 0.5 ml	MMR	5

Meningococcal vaccine

resolved to accept the proposal from Sanofi-Aventis Australia Pty Ltd for its brand to be the Principal Supply Status brand of the Community Pharmaceutical Meningococcal (Groups A, C, Y, and W-135) conjugate vaccine (MenQuadfi) inj 10 mcg of each meningococcal polysaccharide conjugated to a total of approximately 55 mcg of tetanus toxoid carrier per 0.5 ml vial from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from Sanofi-Aventis Australia Pty Ltd for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical Meningococcal (Groups A, C, Y, and W-135) conjugate vaccine (MenQuadfi) inj 10 mcg of each meningococcal polysaccharide conjugated to a total of approximately 55 mcg of tetanus toxoid carrier per 0.5 ml vial with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

resolved to list Pfizer New Zealand Limited's brand of Meningococcal (Groups A, C, Y, and W-135) conjugate vaccine in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 July 2024 as follows:

Chemical	Presentation	Brand	Pack size	Price
Meningococcal (Groups A, C, Y, and W-135) conjugate vaccine	Inj 5 mcg of each meningococcal polysaccharide conjugated to a total of approximately 44 mcg of tetanus toxoid carrier per 0.5 ml vial	Nimenrix	1	$0.00

resolved to apply the following Indication restrictions to the inj 5 mcg of each meningococcal polysaccharide conjugated to a total of approximately 44 mcg of tetanus toxoid carrier per 0.5 ml vial presentation of Meningococcal (Groups A, C, Y, and W-135) conjugate vaccine (Nimenrix) in Section I of the Pharmaceutical Schedule from 1 July 2024:

Both:
1) The child is under 12 months of age; and
2) Any of the following:
   a. A maximum of three doses (dependant on age at first dose) for patients pre- and post- splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post- solid organ transplant; or
   b. A maximum of three doses (dependant on age at first dose) for close contacts of meningococcal cases of any group; or
   c. A maximum of three doses (dependant on age at first dose) for child who has previously had meningococcal disease of any group; or
   d. A maximum of three doses (dependant on age at first dose) for bone marrow transplant patients; or
   e. A maximum of three doses (dependant on age at first dose) for child pre- and post -immunosuppression*.

Note: infants from 6 weeks to less than 6 months of age require a 2+1 schedule, infants from 6 months to less than 12 months of age require a 1+1 schedule. Refer to the Immunisation Handbook for recommended booster schedules with meningococcal ACWY vaccine.
'Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

resolved to apply the following Indication restrictions to the inj 5 mcg of each meningococcal polysaccharide conjugated to a total of approximately 44 mcg of tetanus toxoid carrier per 0.5 ml vial presentation of Meningococcal (Groups A, C, Y, and W-135) conjugate vaccine (Nimenrix) in Part II of Section H of the Pharmaceutical Schedule from 1 July 2024:

Restricted
Initiation - Children under 12 months of age
Any of the following:
1. A maximum of three doses (dependant on age at first dose) for patients pre- and post - splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post- solid organ transplant; or

2. A maximum of three doses (dependant on age at first dose) for close contacts of meningococcal cases of any group; or
3. A maximum of three doses (dependant on age at first dose) for child who has previously had meningococcal disease of any group; or
4. A maximum of three doses (dependant on age at first dose) for bone marrow transplant patients; or
5. A maximum of three doses (dependant on age at first dose) for child pre- and post-immunosuppression*.

Note: infants from 6 weeks to less than 6 months of age require a 2+1 schedule, infants from 6 months to less than 12 months of age require a 1+1 schedule. Refer to the Immunisation Handbook for recommended booster schedules with meningococcal ACWY vaccine.

Note: infants from 6 weeks to less than 6 months of age require a 2+1 schedule, infants from 6 months to less than 12 months of age require a 1+1 schedule. Refer to the Immunisation Handbook for recommended booster schedules with meningococcal ACWY vaccine.

'Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

resolved to apply the Xpharm restriction to Meningococcal (Groups A, C, Y, and W-135) conjugate vaccine (Nimenrix) inj 5 mcg of each meningococcal polysaccharide conjugated to a total of approximately 44 mcg of tetanus toxoid carrier per 0.5 ml vial in Section I of the Pharmaceutical Schedule from 1 July 2024.

resolved to delist the following brand and presentation of meningococcal C conjugate vaccine from Section I and Part II of Section H of the Pharmaceutical Schedule on 1 December 2024, as follows:

Chemical	Presentation	Brand	Pack size
Meningococcal C conjugate vaccine	Inj 10 mcg in 0.5 ml syringe	Neisvac- C	1

noted the acceptance of the above proposal from Sanofi-Aventis Australia Pty Ltd would not result in widening of access of the Meningococcal (Groups A, C, Y, and W-135) conjugate vaccine, however this doesn't preclude widening of access at a future date.

Pneumococcal conjugate vaccine

resolved to accept the proposal from Pfizer New Zealand Limited for its brand to the Principal Supply Status brand of the Community Pharmaceutical Pneumococcal (PCV13) conjugate vaccine (Prevenar 13) inj 30.8 mcg of pneumococcal polysaccharide serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in 0.5ml syringe from 1 December 2024 to 30 June 2027;

resolved to accept the proposal from Pfizer New Zealand Limited for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical Pneumococcal (PCV13) conjugate vaccine (Prevenar 13) inj 30.8 mcg of pneumococcal polysaccharide serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in 0.5ml syringe with a 5% DV Limit, from 1 December 2024 to 30 June 2027;

[redacted]

Pneumococcal (PPV23) polysaccharide vaccine

resolved to accept the proposal from Merck Sharpe & Dohme (New Zealand) Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical pneumococcal (PPV23) polysaccharide vaccine (Pneumovax 23) inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each of 23 pneumococcal serotypes) from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from Merck Sharpe & Dohme (New Zealand) Limited for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical pneumococcal (PPV23) polysaccharide vaccine (Pneumovax 23) inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each of 23 pneumococcal serotypes) with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

Poliomyelitis vaccine

resolved to accept the proposal from Sanofi-Aventis Australia Pty Ltd for its brand to be the Principal Supply Status brand of the Community Pharmaceutical poliomyelitis vaccine (IPOL) inj 80D antigen units in 0.5 ml syringe from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from Sanofi-Aventis Australia Pty Ltd for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical poliomyelitis vaccine (IPOL) inj 80D antigen units in 0.5 ml syringe with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

Rotavirus oral vaccine

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical rotavirus oral vaccine (Rotarix) oral susp live attenuated human rotavirus 1,000,000 CCID50 per dose, prefilled oral applicator from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical rotavirus oral vaccine (Rotarix) oral susp live attenuated human rotavirus 1,000,000 CCID50 per dose, prefilled oral applicator with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

Tuberculin PPD [Mantoux] test

resolved to accept the proposal from Sanofi-Aventis Australia Pty Ltd for its brand to be the Principal Supply Status brand of the Community Pharmaceutical Tuberculin PPD [Mantoux] test (Tubersol) inj 5 TU per 0.1 ml, 1 ml vial from 1 December 2024 until 30 June 2027;

resolved to accept the proposal from Sanofi-Aventis Australia Pty Ltd for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical Tuberculin PPD [Mantoux] test (Tubersol) inj 5 TU per 0.1 ml, 1 ml vial with a 5% DV Limit, from 1 December 2024 until 30 June 2027;

Varicella Vaccine [Chickenpox vaccine]

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical Varicella Vaccine [Chickenpox vaccine] (Varilrix) inj 2000 PFU prefilled syringe plus vial from 1 December 2024 to 30 June 2027;

resolved to accept the proposal from GlaxoSmithKline NZ Limited for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical Varicella vaccine [Chickenpox vaccine] (Varilrix) inj 2000 PFU prefilled syringe plus vial with a 5% DV Limit, from 1 December 2024 to 30 June 2027;

resolved to list GlaxoSmithKline's Varicella vaccine [Chickenpox vaccine] (Varilirix) Inj 2000 PFU prefilled syringe plus vial in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 July 2024 as follows:

Chemical	Presentation	Brand	Pack size	Price
Varicella vaccine [Chickenpox vaccine]	Inj 2000 PFU prefilled syringe plus vial	Varilrix	1	$0.00
Varicella vaccine [Chickenpox vaccine]	Inj 2000 PFU prefilled syringe plus vial	Varilrix	10	$0.00

resolved to apply the following indication restrictions to the Inj 2000 PFU prefilled syringe plus vial presentation of Varicella Vaccine [Chickenpox vaccine] (Varilrix) in Section I of the Pharmaceutical Schedule from 1 July 2024:

Either:

1) Maximum of one dose for primary vaccination for either:
   a) Any infant born on or after 1 April 2016; or
   b) For previously unvaccinated children turning 11 years old on or after 1 July 2017, who have not previously had a
   c) varicella infection (chickenpox), or
2) Maximum of two doses for any of the following:
   a) Any of the following for non-immune patients:
      i) with chronic liver disease who may in future be candidates for transplantation; or
      ii) with deteriorating renal function before transplantation; or
      iii) prior to solid organ transplant; or
      iv) prior to any elective immunosuppression*; or
      v) for post exposure prophylaxis who are immune competent inpatients; or
   b) For patients at least 2 years after bone marrow transplantation, on advice of their specialist; or
   c) For patients at least 6 months after completion of chemotherapy, on advice of their specialist; or
   d) For HIV positive non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist; or
   e) For patients with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella; or
   f) For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella; or
   g) For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of

varicella.
* immunosuppression due to steroid or other immunosuppressive therapy must be for a treatment period of greater than 28 days

resolved to apply the following indication restrictions to the Inj 2000 PFU prefilled syringe plus vial presentation of Varicella Vaccine [Chickenpox vaccine] (Varilrix) in Part II of Section H of the Pharmaceutical Schedule from 1 July 2024:

Initiation - primary vaccinations
Therapy limited to 1 dose
Either:
1. Any infant born on or after 1 April 2016; or
2. For previously unvaccinated children turning 11 years old on or after 1 July 2017, who have not previously had a varicella infection (chickenpox).

Initiation - other conditions
Therapy limited to 2 doses
Any of the following:
1. Any of the following:

for non-immune patients:
1.1. With chronic liver disease who may in future be candidates for transplantation; or
1.2. With deteriorating renal function before transplantation; or
1.3. Prior to solid organ transplant; or
1.4. Prior to any elective immunosuppression*; or
1.5. For post exposure prophylaxis who are immune competent inpatients; or
2. For patients at least 2 years after bone marrow transplantation, on advice of their specialist; or
3. For patients at least 6 months after completion of chemotherapy, on advice of their specialist; or
4. For HIV positive patients non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist; or
5. For patients with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella; or
6. For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella; or
7. For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.

Note: * immunosuppression due to steroid or other immunosuppressive therapy must be for a treatment period of greater than 28 days

resolved to delist the following brands and presentations of Varicella vaccine [Chickenpox vaccine] from Section I and Part II of Section H of the Pharmaceutical Schedule on 1 December 2024, as follows:

Chemical	Presentation	Brand	Pack size
Varicella vaccine [Chickenpox vaccine]	Inj 1350 PFU prefilled syringe	Varivax	1
Varicella vaccine [Chickenpox vaccine]	Inj 1350 PFU prefilled syringe	Varivax	1

Influenza vaccine

resolved to accept the proposal from Viatris Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical Influenza vaccine (Influvac

Tetra) inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) from 1 February 2024 to 30 December 2026;

resolved to accept the proposal from Viatris Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical Influenza vaccine (Influvac Tetra) inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) from 1 February 2024 to 30 December 2026.

resolved to list Viatris Limited's influenza vaccine (Influvac Tetra) in Section I and Part II of Section H of the Pharmaceutical Schedule from 1 February 2024 as follows:

Chemical	Presentation	Brand	Pack size	Price
Influenza vaccine	Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)	Influvac Tetra (2024 formulation)	10	$120.00

resolved to apply the following indication restrictions to the inj 60 mcg in 0.5 ml syringe presentation of Influenza vaccine (Influvac Tetra) in Section I of the Pharmaceutical Schedule from 1 February 2024:

A. Influenza Vaccine is available each year for people who meet the following criteria, as set by Pharmac:
   a. all people 65 years of age and over; or
   b. people under 65 years of age who:
      i. have any of the following cardiovascular diseases:
      a. ischaemic heart disease, or
      b. congestive heart failure, or
      c. rheumatic heart disease, or
      d. congenital heart disease, or
      e. cerebro-vascular disease; or
      ii. have either of the following chronic respiratory diseases:
      a. asthma, if on a regular preventative therapy, or
      b. other chronic respiratory disease with impaired lung function; or
      Hi. have diabetes; or
      iv. have chronic renal disease; or
      v. have any cancer, excluding basal and squamous skin cancers if not invasive; or
      vi. have any of the following other conditions:
      a. autoimmune disease, or
      b. immune suppression or immune deficiency, or
      c. HIV, or
      d. transplant recipients, or
      e. neuromuscular and CNS diseases/disorders, or
      f. haemoglobinopathies, or
      g. are children on long term aspirin, or
      h. have a cochlear implant, or
      i. errors of metabolism at risk of major metabolic decompensation, or
      j. pre and post splenectomy, or
      k. Down syndrome, or
      vii. are pregnant; or
   c. children 4 years of age and under who have been hospitalised for respiratory illness or have a history of significant respiratory illness; or
   d. people under 65 years of age who:
      i. have any of the following serious mental health conditions:
      a. schizophrenia, or
      b. major depressive disorder, or

c. bipolar disorder, or
d. schizoaffective disorder, or
ii. are currently accessing secondary or tertiary mental health and addiction services.

Unless meeting the criteria set out above, the following conditions are excluded from funding:
a. asthma not requiring regular preventative therapy,
b. hypertension and/or dyslipidaemia without evidence of end-organ disease.

B. Contractors will be entitled to claim payment for the supply of influenza 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 influenza 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.

resolved to apply the following indication restrictions to the inj 60 mcg in 0.5 ml syringe presentation of Influenza vaccine (Influvac Tetra) in Part II of Section H of the Pharmaceutical Schedule from 1 February 2024:

Restricted
Initiation – People over 65
The patient is 65 years of age or over.

Initiation – cardiovascular disease
Any of the following:
1. Ischaemic heart disease; or
2. Congestive heart failure; or
3. Rheumatic heart disease; or
4. Congenital heart disease; or
5. Cerebro-vascular disease.

Note: hypertension and/or dyslipidaemia without evidence of end-organ disease is excluded from funding.

Initiation – chronic respiratory disease
Either:
1. 1 Asthma, if on a regular preventative therapy; or
2. 2 Other chronic respiratory disease with impaired lung function.

Note: asthma not requiring regular preventative therapy is excluded from funding.

Initiation – Other conditions
Either:
1. Any of the following:
   1.1. Diabetes; or
   1.2. chronic renal disease; or
   1.3. Any cancer, excluding basal and squamous skin cancers if not invasive; or
   1.4. Autoimmune disease; or
   1.5. Immune suppression or immune deficiency; or
   1.6. HIV; or
   1.7. Transplant recipient; or
   1.8. Neuromuscular and CNS diseases/ disorders; or
   1.9. Haemoglobinopathies; or
   1.10. Is a child on long term aspirin; or
   1.11. Has a cochlear implant; or
   1.12. Errors of metabolism at risk of major metabolic decompensation; or
   1.13. Pre and post splenectomy; or
   1.14. Down syndrome; or
   1.15. Is pregnant; or
   1.16. Is a child 4 years of age or under (inclusive) who has been hospitalised for respiratory illness or has a history of significant respiratory illness; or

2. Patients in a long-stay inpatient mental health care unit or who are compulsorily detained long-term in a forensic unit within a Public Hospital.

Initiation - Serious mental health conditions or addiction
Any of the following:
1. schizophrenia; or
2. major depressive disorder; or
3. bipolar disorder; or
4. schizoaffective disorder; or
5. person is currently accessing secondary or tertiary mental health and addiction services.

resolved to delist the following brands and presentations of Influenza vaccine from Section I and Part II of Section H of the Pharmaceutical Schedule on 1 February 2024, as follows:

Chemical	Presentation	Brand	Pack size
Influenza vaccine	Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)	Afluria Quad (2023 formulation)	10
Influenza vaccine	Inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine)	Afluria Quad Junior (2023 formulation)	1

[redacted]

noted the acceptance of the above proposal from Viatris Limited would not result in widening of access of the Influenza vaccine, however this doesn't preclude widening of access at a future date.

noted that the supply period for influenza vaccine may be extended to include the 2026 and 2027 influenza seasons.

noted that the bids for human papilloma virus (HPV) vaccine are unresolved and are subject to further discussions with suppliers; and

resolved that the consultation on the proposals was appropriate and no further consultation is required.

In consideration of this paper 10.1 and the supplementary papers 10.1a and 10.1b:

Resolutions from 10.1a:

noted the summary of information about the proposed changes to three vaccines; and

[redacted]

Resolutions from 10.1b:

noted the summary of information about the proposed supply of vaccines with no changes to funded brand or eligibility criteria.

resolved to approve the provisional agreement with GlaxoSmithKline NZ Limited dated 19 May 2023;

resolved to approve the provisional agreement with Merck Sharp & Dohme (New Zealand) Limited dated 25 May 2023;

resolved to approve the provisional agreement with Pfizer New Zealand Limited dated 15 May 2023 for supply of pneumococcal conjugate vaccine (Prevenar 13);

resolved to approve the provisional agreement with Pfizer New Zealand Limited dated 19 May 2023 for supply of meningococcal ACWY vaccine (Nimenrix);

resolved to approve the provisional agreement with Sanofi-Aventis Australia Pty Ltd dated 27 April 2023; and

resolved to approve the provisional agreement with Seqirus (NZ) Ltd dated 23 May 2023.

In consideration of this paper 10.1 and the supplementary paper 10.1c:

Resolutions from 10.1c:

noted the summary of information about the proposed supply of influenza vaccine for the 2024-2025 influenza seasons, with optional extensions for the 2026 and 2027 influenza seasons;

[redacted]

[redacted]

resolved to approve the provisional agreement with Viatris Limited dated 8 May 2023.

Margaret Wilsher and Talia Anderson-Town **Carried**

10.2 Proposal to widen access and award principal supply status for intravenous trastuzumab to Celltrion (Herzuma)

This paper requested a decision from the Board on a significant pharmaceutical transaction which would widen funded access to trastuzumab and release substantial funds to reinvest in other medicines.

The Board:

resolved to approve the changes to the Pharmaceutical Schedule:

Changes from 1 October 2023

resolved to amend the Special Authority criteria for trastuzumab in Section B of the Pharmaceutical Schedule from 1 October 2023 as follows (changes in bold and

~~strikethrough~~):

TRASTUZUMAB
Special Authority for Subsidy
Initial application — (early breast cancer) ~~only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist~~ **from any relevant practitioner.** Approvals valid for 15 months for applications meeting the following criteria:
All of the following:

1. The patient has early breast cancer expressing HER 2 IHC 3+ or ISH + (including FISH or other current technology); and
2. Maximum cumulative dose of 106 mg/kg (12 months' treatment); and
3. Any of the following
   - 3.1 9 weeks' concurrent treatment with adjuvant chemotherapy is planned; or
   - 3.2 12 months' concurrent treatment with adjuvant chemotherapy is planned; or
   - 3.3 12 months' sequential treatment following adjuvant chemotherapy is planned; or
   - 3.4 12 months' treatment with neoadjuvant and adjuvant chemotherapy is planned; or
   - 3.5 Other treatment regimen, in association with adjuvant chemotherapy, is planned.

Renewal — (early breast cancer*) ~~only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist~~ **from any relevant practitioner.** Approvals valid for 12 months for applications meeting the following criteria:
~~All of the following~~ **Either:**

1. All of the following:
- **1.1** ~~1.~~ The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology): and
- **1.2** ~~2.~~ The patient received prior adjuvant trastuzumab treatment for early breast cancer; and
- **1.3** ~~3.~~ Any of the following:
  - 1.3.1 ~~3.1.~~ The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
  - 1.3.2 ~~3.2.~~ Both:
    - 1.3.2.1 ~~3.2.1.~~ The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to ~~intolerance~~ **intolerable side effects**; and
    - 1.3.2.2 ~~3.2.2.~~ The cancer did not progress whilst on lapatinib; or
  - 1.3.3 ~~3.3.~~ The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
- **1.4** ~~4.~~ Either:
  - 1.4.1 ~~4.1.~~ Trastuzumab will not be given in combination with pertuzumab; or
  - 1.4.2 ~~4.2.~~ All of the following:
    - 1.4.2.1 ~~4.2.1.~~ Trastuzumab to be administered in combination with pertuzumab; and
    - 1.4.2.2 ~~4.2.2.~~ Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
    - 1.4.2.3 ~~4.2.3.~~ The patient has good performance status (ECOG grade 0-1); and
- **1.5** ~~5.~~ Trastuzumab not to be given in combination with lapatinib; and
- **1.6** ~~6.~~ Trastuzumab to be discontinued at disease progression; **or**

2. All of the following:
- **2.1 Patient has previously discontinued treatment with trastuzumab in the metastatic setting for reasons other than severe toxicity or disease progression; and**
- **2.2 Patient has signs of disease progression; and**
- **2.3 Disease has not progressed during previous treatment with trastuzumab.**

Note: * For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer.

Initial application — (metastatic breast cancer) ~~only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist~~ **from any relevant practitioner.**
Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1. The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2. Either:
   - 2.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or

2.2 Both:
2.2.1 The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to ~~intolerance~~ **intolerable side effects**; and
2.2.2 The cancer did not progress whilst on lapatinib; and

3. Either:
3.1 Trastuzumab will not be given in combination with pertuzumab; or
3.2 All of the following:
3.2.1 Trastuzumab to be administered in combination with pertuzumab; and
3.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
3.2.3 The patient has good performance status (ECOG grade 0-1); and
4. Trastuzumab not to be given in combination with lapatinib; and
5. Trastuzumab to be discontinued at disease progression.

Renewal — (metastatic breast cancer) ~~only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist~~ **from any relevant practitioner.** Approvals valid for 12 months for applications meeting the following criteria:
~~All of the following~~ **Either**:
1. All of the following:
1.1. ~~1.~~ The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
1.2. ~~2.~~ The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
1.3. ~~3.~~ Trastuzumab not to be given in combination with lapatinib; and
1.4. ~~4.~~ Trastuzumab to be discontinued at disease progression.**; or**
2. All of the following:
2.1. Patient has previously discontinued treatment with trastuzumab for reasons other than severe toxicity or disease progression; and
2.2. Patient has signs of disease progression; and
2.3. Disease has not progressed during previous treatment with trastuzumab.

resolved to amend the hospital restrictions for trastuzumab in Part II of Section H of the Pharmaceutical Schedule from 1 October 2023 as follows (changes in bold and ~~strikethrough~~):

TRASTUZUMAB
Restricted
Initiation – Early breast cancer
Limited to 12 months treatment
All of the following:
1. The patient has early breast cancer expressing HER 2 IHC 3+ or ISH + (including FISH or other current technology); and
2. Maximum cumulative dose of 106 mg/kg (12 months' treatment); and
3. Any of the following
3.1 9 weeks' concurrent treatment with adjuvant chemotherapy is planned; or
3.2 12 months' concurrent treatment with adjuvant chemotherapy is planned; or
3.3 12 months' sequential treatment following adjuvant chemotherapy is planned; or
3.4 12 months' treatment with neoadjuvant and adjuvant chemotherapy is planned; or
3.5 Other treatment regimen, in association with adjuvant chemotherapy, is planned.

Initiation — Metastatic breast cancer (patients previously treated with trastuzumab)
Limited to 12 months treatment
~~All of the following~~ **Either:**
1. All of the following:
1.1 ~~1.~~ The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology): and
1.2 ~~3.~~ Either:
1.2.1 ~~3.1.~~ The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
1.2.2 ~~3.2.~~ Both:
1.2.2.1 ~~3.2.1.~~ The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to ~~intolerance~~ **intolerable side effects**; and
1.2.2.2 ~~3.2.2.~~ The cancer did not progress whilst on lapatinib; and

1.3 ~~4.~~ Either:
- **1.3.1** ~~4.1.~~ Trastuzumab will not be given in combination with pertuzumab; or
- **1.3.2** ~~4.2.~~ All of the following:
  - **1.3.2.1** ~~4.2.1.~~ Trastuzumab to be administered in combination with pertuzumab; and
  - **1.3.2.2** ~~4.2.2.~~ Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
  - **1.3.2.3** ~~4.2.3.~~ The patient has good performance status (ECOG grade 0-1); and

1.4 ~~5.~~ Trastuzumab not to be given in combination with lapatinib; and
1.5 ~~6.~~ Trastuzumab to be discontinued at disease progression**; or**

2. All of the following:
- **2.1 Patient has previously discontinued treatment with trastuzumab in the metastatic setting for reasons other than severe toxicity or disease progression; and**
- **2.2 Patient has signs of disease progression; and**
- **2.3 Disease has not progressed during previous treatment with trastuzumab.**

Initiation — Metastatic breast cancer (trastuzumab-naive patients)
Limited to 12 months treatment
All of the following:
1. The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2. Either:
   - 2.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
   - 2.2 Both:
     - 2.2.1 The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to intolerance; and
     - 2.2.2 The cancer did not progress whilst on lapatinib; and
3. Either:
   - 3.1 Trastuzumab will not be given in combination with pertuzumab; or
   - 3.2 All of the following:
     - 3.2.1 Trastuzumab to be administered in combination with pertuzumab; and
     - 3.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
     - 3.2.3 The patient has good performance status (ECOG grade 0-1); and
4. Trastuzumab not to be given in combination with lapatinib; and
5. Trastuzumab to be discontinued at disease progression.

Continuation — metastatic breast cancer
Re-assessment required after 12 months
~~All of the following~~ **Either**:

1. All of the following:
- **1.1.** ~~1.~~ The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- **1.2.** ~~2.~~ The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
- **1.3.** ~~3.~~ Trastuzumab not to be given in combination with lapatinib; and
- **1.4.** ~~4.~~ Trastuzumab to be discontinued at disease progression~~.~~**; or**

2. All of the following:
- **2.1. Patient has previously discontinued treatment with trastuzumab for reasons other than severe toxicity or disease progression; and**
- **2.2. Patient has signs of disease progression; and**
- **2.3. Disease has not progressed during previous treatment with trastuzumab.**

resolved to amend the Special Authority criteria for pertuzumab in Section B of the Pharmaceutical Schedule from 1 October 2023 as follows (changes in bold and ~~strikethrough~~):

PERTUZUMAB

Initial application — (metastatic breast cancer) ~~only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist~~ **from any relevant practitioner**. Approvals valid for 12 months for application meeting the following criteria:
All of the following:

1. The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2. Either:
   2.1 Patient is chemotherapy treatment naïve; or
   2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
3. The patient has good performance status (ECOG grade 0-1); and
4. Pertuzumab to be administered in combination with trastuzumab; and
5. Pertuzumab maximum first dose of 840 mg, followed by maximum of 420 mg every 3 weeks; and
6. Pertuzumab to be discontinued at disease progression.

Renewal — (metastatic breast cancer) ~~only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist~~ **from any relevant practitioner**. Approvals valid for 12 months for applications meeting the following criteria:
~~Both~~ **Either**:

1. **Both**:
   1.1 ~~1.~~The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
   1.2 ~~2.~~The cancer has not progressed at any time point during the previous 12 months whilst on pertuzumab and trastuzumab**; or**
2. **All of the following:**
   2.1 Patient has previously discontinued treatment with pertuzumab and trastuzumab for reasons other than severe toxicity or disease progression; and
   2.2 Patient has signs of disease progression; and
   2.3 Disease has not progressed during previous treatment with pertuzumab and trastuzumab.

resolved to amend the hospital restrictions for pertuzumab in Part II of Section H of the Pharmaceutical Schedule from 1 October 2023 as follows (changes in bold and ~~strikethrough~~):

PERTUZUMAB
Restricted
Initiation
Re-assessment required after 12 months
All of the following:

1. The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2. Either:
   2.1 Patient is chemotherapy treatment naïve; or
   2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
3. The patient has good performance status (ECOG grade 0-1); and
4. Pertuzumab to be administered in combination with trastuzumab; and
5. Pertuzumab maximum first dose of 840 mg, followed by maximum of 420 mg every 3 weeks; and
6. Pertuzumab to be discontinued at disease progression.

Continuation
Re-assessment required after 12 months
~~Both~~ **Either**:

1. **Both**:
   1.1 ~~1.~~The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
   1.2 ~~2.~~The cancer has not progressed at any time point during the previous 12 months whilst on pertuzumab and trastuzumab**; or**
2. **All of the following:**
   2.1 Patient has previously discontinued treatment with pertuzumab and trastuzumab for reasons other than severe toxicity or disease progression; and
   2.2 Patient has signs of disease progression; and

2.3 Disease has not progressed during previous treatment with pertuzumab and trastuzumab.

Changes from 1 December 2023

resolved to accept the proposal from Celltrion Healthcare NZ Limited for its brand to be the Principal Supply Status brand of the Community Pharmaceutical trastuzumab (Herzuma) inj 150 mg vial and 440 mg vial from 1 June 2024 until 31 May 2027;

resolved to list Celltrion Healthcare NZ Limited's brand of trastuzumab (Herzuma) inj 150 mg vial and inj 440 mg vial in the Oncology Agents and Immunosuppressants - Immunosuppressants - Monoclonal Antibodies therapeutic sub-group in Section B of the Pharmaceutical Schedule from 1 December 2023 as follows:

Chemical	Presentation	Brand	Pack Size	Price and subsidy (ex-man., ex. GST)
Trastuzumab (Herzuma)	Inj 150 mg vial	Herzuma	1	$100.00
Trastuzumab (Herzuma)	Inj 440 mg vial	Herzuma	1	$293.35
Trastuzumab (Herzuma)	Inj 1 mg for ECP	Baxter	1 mg	$0.70

resolved to apply PCT only restrictions to trastuzumab (Herzuma) in Section B of the Pharmaceutical Schedule from 1 December 2023

resolved to apply the following Special Authority criteria to trastuzumab (Herzuma) in Section B of the Pharmaceutical Schedule from 1 December 2023:

Special Authority for Subsidy
Initial application — (early breast cancer) from any relevant practitioner. Approvals valid for 15 months for applications meeting the following criteria:
Both:
1. The patient has early breast cancer expressing HER-2 IHC 3+ or ISH + (including FISH or other current technology); and
2. Maximum cumulative dose of 106 mg/kg (12 months' treatment).

Renewal — (early breast cancer*) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Either:
1. All of the following:
   - 1.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology): and
   - 1.2 The patient received prior adjuvant trastuzumab treatment for early breast cancer; and
   - 1.3 Any of the following:
     - 1.3.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
     - 1.3.2 The patient discontinued lapatinib within 3 months due to intolerable side effects and the cancer did not progress whilst on lapatinib; or
     - 1.3.3 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
   - 1.4 Either:
     - 1.4.1 Trastuzumab will not be given in combination with pertuzumab; or
     - 1.4.2 All of the following:
       - 1.4.2.1 Trastuzumab to be administered in combination with pertuzumab; and
       - 1.4.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
       - 1.4.2.3 The patient has good performance status (ECOG grade 0-1); and
   - 1.5 Trastuzumab to be discontinued at disease progression; or
2. All of the following:
   - 2.1 Patient has previously discontinued treatment with trastuzumab in the metastatic setting for reasons other than severe toxicity or disease progression; and

2.2 Patient has signs of disease progression; and
2.3 Disease has not progressed during previous treatment with trastuzumab.

Note: * For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer.

Initial application — (metastatic breast cancer) from any relevant practitioner**.** Approvals valid for 12 months for applications meeting the following criteria:
All of the following:
1. The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2. Either:
   2.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
   2.2 The patient discontinued lapatinib within 3 months due to intolerable side effects and the cancer did not progress whilst on lapatinib; and
3. Either:
   3.1 Trastuzumab will not be given in combination with pertuzumab; or
   3.2 All of the following:
      3.2.1 Trastuzumab to be administered in combination with pertuzumab; and
      3.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
      3.2.3 The patient has good performance status (ECOG grade 0-1); and
4. Trastuzumab to be discontinued at disease progression.

Renewal — (metastatic breast cancer) from any relevant practitioner**.** Approvals valid for 12 months for applications meeting the following criteria:
Either:
1. All of the following:
   1.1. The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
   1.2. The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
   1.3 Trastuzumab to be discontinued at disease progression; or
2. All of the following:
   2.1. Patient has previously discontinued treatment with trastuzumab for reasons other than severe toxicity or disease progression; and
   2.2. Patient has signs of disease progression; and
   2.3. Disease has not progressed during previous treatment with trastuzumab.

Initial application — (gastric, gastro-oesophageal junction and oesophageal cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Both:
1. The patient has locally advanced or metastatic gastric, gastro-oesophageal junction or oesophageal cancer expressing HER-2 IHC 2+ FISH+ or IHC3+ (or other current technology); or
2. Patient has an ECOG score of 0-2.

Renewal — (gastric, gastro-oesophageal junction and oesophageal cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Both:
1. The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
2. Trastuzumab to be discontinued at disease progression.

resolved to accept the proposal from Celltrion Healthcare NZ Limited for its brand to be the Principal Supply Status brand of the Hospital Pharmaceutical trastuzumab inj 150 mg vial and 440 mg vial, with a DV Limit of 5%, from 1 June 2024 until 31 May 2027;

resolved to list Celltrion Healthcare NZ Limited‘s brand of trastuzumab (Herzuma) inj 150 mg vial and inj 440 mg vial in the Oncology Agents and Immunosuppressants – Immunosuppressants – Monoclonal Antibodies therapeutic sub-group in Part II of

Section H of the Pharmaceutical Schedule from 1 December 2023 as follows:

Chemical	Presentation	Brand	Pack Size	Price (ex-man., ex. GST)
Trastuzumab (Herzuma)	Inj 150 mg vial	Herzuma	1	$100.00
Trastuzumab (Herzuma)	Inj 440 mg vial	Herzuma	1	$293.35

resolved to apply the following hospital restrictions to trastuzumab (Herzuma) in Part II of Section H of the Pharmaceutical Schedule from 1 December 2023 as follows:

TRASTUZUMAB (HERZUMA)
Initiation — Early breast cancer
Re-assessment required after 12 months
All of the following:
1. The patient has early breast cancer expressing HER-2 IHC 3+ or fSH + (including FISH or other current technology); and
2. Maximum cumulative dose of 106 mg/kg (12 months' treatment).

Renewal — Eady breast cancer*
Re-assessment required after 12 months
Either:
1. All of the following:
    - 1.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
    - 1.2 The patient received prior adjuvant trastuzumab treatment for early breast cancer; and
    - 1.3 Any of the following:
        - 1.3.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
        - 1.3.2 The patient discontinued lapatinib within 3 months due to intolerable side effects and the cancer did not progress whilst on lapatinib; or
        - 1.3.3 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
    - 1.4 Either:
        - 1.4.1 Trastuzumab will not be given in combination with pertuzumab; or
        - 1.4.2 All of the following:
            - 1.4.2.1 Trastuzumab to be administered in combination with pertuzumab; and
            - 1.4.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
            - 1.4.2.3 The patient has good performance status (ECOG grade 0-1); and
    - 1.5 Trastuzumab to be discontinued at disease progression; or
2. All of the following:
    - 2.1 Patient has previously discontinued treatment with trastuzumab in the metastatic setting for reasons other than severe toxicity or disease progression; and
    - 2.2 Patient has signs of disease progression; and
    - 2.3 Disease has not progressed during previous treatment with trastuzumab.

Note: * For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer.

Initiation — Metastatic breast cancer
Re-assessment required after 12 months
All of the following:
1. The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2. Either:
    - 2.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
    - 2.2 The patient discontinued lapatinib within 3 months due to intolerable side effects and the cancer did not progress whilst on lapatinib; and
3. Either:
    - 3.1 Trastuzumab will not be given in combination with pertuzumab; or

3.2 All of the following:
3.2.1 Trastuzumab to be administered in combination with pertuzumab; and
3.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
3.2.3 The patient has good performance status (ECOG grade 0-1); and
4. Trastuzumab to be discontinued at disease progression.

Continuation — Metastatic breast cancer
Re-assessment required after 12 months
Either:
1. All of the following:
1.1. The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
1.2. The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
1.3. Trastuzumab to be discontinued at disease progression; or
2. All of the following:
2.1. Patient has previously discontinued treatment with trastuzumab for reasons other than severe toxicity or disease progression; and
2.2. Patient has signs of disease progression; and
2.3. Disease has not progressed during previous treatment with trastuzumab.

Initiation — Gastric, gastro-oesophageal junction and oesophageal cancer
Re-assessment required after 12 months
Both:
1. The patient has locally advanced or metastatic gastric, gastro-oesophageal junction or oesophageal cancer expressing HER-2 IHC 2+ FISH+ or IHC3+ (or other current technology); and
2. Patient has an ECOG score of 0-2.

Renewal — Gastric, gastro-oesophageal junction and oesophageal cancer
Re-assessment required after 12 months
Both:
1. The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
2. Trastuzumab to be discontinued at disease progression.

resolved to amend the chemical name for trastuzumab to trastuzumab (Herceptin) in the Oncology agents and Immunosuppressants therapeutic group in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 December 2023

resolved to generate Special Authority approval numbers for trastuzumab (Herzuma) for all patients with active Special Authority approvals for trastuzumab (Herceptin) to enable ongoing renewals for existing patients from 1 December 2023

resolved to remove the initial Special Authority criteria that apply to trastuzumab (Herceptin) in Section B of the Pharmaceutical Schedule from 1 December 2023

resolved to remove the initial hospital indication restrictions that apply to trastuzumab (Herceptin) in Part II of Section H of the Pharmaceutical Schedule from 1 December 2023

Changes from 1 June 2024

resolved to delist trastuzumab (Herceptin) from Section B and Part II of Section H of the Pharmaceutical Schedule from 1 June 2024

noted that all renewal Special Authority criteria and continuation hospital restrictions that apply to trastuzumab (Herceptin) for all indications are to remain available during the transition period 1 December 2023 to 31 May 2024

noted Pharmac staff would work with Te Whatu Ora staff to manage the transition of Special Authority approvals

noted that an alternative brand allowance of 5% will apply for the duration of the Principal Supply Status period and that access to this would be managed via Pharmac's Exceptional Circumstances framework.

resolved to approve the 4 May 2023 provisional agreement with Celltrion Healthcare New Zealand Limited for supply of the Herzuma brand of trastuzumab;

resolved to approve the 2 June 2023 provisional Purchase Order with Roche Products (New Zealand) Limited for stock of the Herceptin brand of trastuzumab to secure supply of an alternative brand;

noted the acceptance of this proposal would result in a transition to a biosimilar intravenous trastuzumab for people eligible for funded intravenous trastuzumab;

noted the acceptance of this proposal would result in widened access to biosimilar trastuzumab for treatment of gastric, gastro-oesophageal junction and oesophageal cancer;

noted the planned implementation activities should the proposal be approved (Appendix Two); and

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

Anthony Jordan and Margaret Wilsher **Carried**

10.3 Prioritisation Report

The report described the prioritisation activity since the last report presented to the Board at its May 2023 meeting. It also updated the Board on the progress of selected items from the following prioritisation lists:

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

The Board **noted** the prioritisation activity undertaken by Pharmac staff since May 2023 and the progress of selected items from Pharmac's prioritisation list.

10.4 CPB Management Report

The purpose of this paper was to update the Board on the pharmaceutical budget, including the June 2023 expenditure forecast. It aimed to enable a wider discussion by the Board regarding planned activities to manage expenditure in 2023/24 and in the out-years.

The Board:

Combined Pharmaceutical Budget

2022/23

[redacted]

2023/24

[redacted]

noted that the CPB is now directly managed by Pharmac via the National Pharmaceutical Purchasing appropriation within Vote Health, and that the CPB for 2023/24 is $1.4976 billion (includes both the uplift for the impact of $5 co-payment removal and COVID-19 treatments and vaccines);

[redacted]

noted that staff will provide the Board with opportunities to reassess the appropriateness of the expenditure target at regular intervals in line with our planned forecast updates and as we gain more certainty regarding the significant investment transactions and better understand impacts of dispensing fluctuations;

noted the portfolio of current and planned transactions underway in 2023/24; and

noted that expenditure and budget management options for COVID-19 treatments and vaccines in 2023/24 is discussed as a separate paper (Board agenda item 10.6).

Talia Anderson-Town and Steve Maharey **Carried**

10.5 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 vaccines, current significant supply issues and the contentious, large or significant pharmaceutical transactions and investments that staff are currently progressing.

The Board:

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

resolved to delegate decision-making for funding of dabigatran capsules via the 2022/23 Invitation to Tender to the Chief Executive; and

resolved to delegate decision-making for human papillomavirus vaccine funding to the Chief Executive.

Margaret Wilsher and Talia Anderson-Town **Carried**

10.6 COVID-19 Vaccines and Treatments Update

This paper provided the Board with an overview of Pharmac's work to secure COVID-19 treatments and vaccines. This work is now starting to transition into our usual business processes for managing pharmaceuticals. We intend to review the need for this separate COVID-19 update later in 2023.

The Board:

resolved to delegate decision-making for a proposal to secure further supply of up to 65,000 courses of nirmatrelvir with ritonavir (Paxlovid) for the treatment of COVID-19 to the Chief Executive;

noted that Pharmac staff expect to release a consultation on changes to the COVID-19 antiviral access criteria to include people receiving Disability Support Services (DSS) and people with significant single comorbidities before the July Board meeting; and

noted the update on Pharmac's COVID-19 treatments and vaccines work.

Anthony Jordan and Peter Bramley **Carried**

10.7 Medical Devices Transactions Report

This paper described the commercial activity we have underway to support our strategic goal to achieve best health outcomes from hospital medical devices with the funding available.

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

10.8 Medical Devices Programme Update

This paper provided the Board with an update on progress of the Medical Device Programme.

The Board:

noted the update on progress with the Medical Device Programme;

noted implementation of the National Medical Device Action Plan is pending endorsement by the Te Whatu Ora Board. This will be considered at their Board meeting on 20 July;

noted that resourcing is being further discussed with Te Whatu Ora and outcomes of this discussion will be reported to the Minister of Health by the end of August ;

noted the Programme continues to investigate options for changes to scope and timing and what can be delivered by 1 July 2024 with current resourcing; and

noted more information is needed in the five key areas described in this paper to further inform rescoping Programme deliverables and timing.

10.9 Summary of Decisions made under Delegated Authority – June 2023

This report contains a summary of all decisions made by Pharmac staff under delegated authority during May 2023. These are listed under the following headings:

1. PTAC, Subcommittee, Panels and Advisory Committee Appointments
2. Pharmaceutical Schedule Listing Decisions – Medical Devices
3. COVID-19 Contingency Fund – Medicines and Medical Devices
4. Pharmaceutical Schedule Listing Decisions – Medicines
5. Named Patient Pharmaceutical Assessment (NPPA) decisions – new or declined
6. Exceptional Circumstance Application approvals made under Acting Director of Pharmaceuticals.

The Board **noted** the summary of decisions made under Delegated Authority during June 2023 by the Chief Executive, Acting Director, Pharmaceuticals, Acting Manager, Pharmaceutical Funding, Senior Exceptions Advisor/Team Leader and Senior Therapeutic Group Manager/Team Leaders.

11.0 Regular Reporting

11.1 Risk Register Q4 Report

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

The Board:

noted the risk register, which provided a summary of current and ongoing risks of relevance to the Board for the fourth quarter;

noted that the exception report for July is in addition to the Q4 register that was reviewed by the Audit and Risk Committee on 30 June 2023; and

noted that the quarter four risk register will be included in the quarterly report to the Minister of Health.

11.2 Communications and Engagement Report

This paper summarises communications and engagement activity for June 2023 and the impact of our work.

The Board:

noted that Pharmac's media impact score for quarter two (April to June) was +0.3 increasing from -0.1 last quarter;

noted that work on the new proactive media approach continues to progress and more detail will be provided at the September Board meeting;

noted that a new webpage has been created dedicated to the procurement process of continuous glucose monitors to keep the public informed about the process;

noted that Pharmac is considering the accessibility of PTAC records on the website and through the application tracker;

noted the various channels Pharmac is using to inform stakeholders about operational and strategic work; and

noted that work is underway to prepare for the Consumer Quality Safety Marker (CQSM).

12. Interest Articles

The Board **noted** the interest articles.

13. General Business

The Board acknowledged the difference that Lisa Lawrence has made to CAC and wished her well in the future.

The meeting closed at 2.45pm with a karakia.

Date of Next Meeting

The date for the next Board meeting is set for Friday 29 September 2023.

Approved and Signed *29 September 2023*

Steve Maharey, Chair **Date**