MINUTES OF THE PHARMACEUTICAL MANAGEMENT AGENCY (PHARMAC)

BOARD MEETING FEBRUARY 2022

Due to COVID-19 restrictions, the meeting was held via Zoom instead of face-to-face, as originally intended.

The meeting was held by Zoom meeting starting at 10.50am with the following attendees:

Board members

Steve Maharey	Chair
Claudia Wyss	Board member
Anthony Jordan	Board member
Talia Anderson-Town	Board member
Jan White	Board member
Elizabeth Zhu	Institute of Directors, Future Director
Jane Thomas	Observer, PTAC Chair
Lisa Lawrence	Observer, CAC Chair
Peter Bramley	Observer, DHB representative (for part of meeting)

Pharmac staff in attendance

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

Attendees joined the meeting via Zoom to present relevant papers: Jannel Fisher, Danae Staples-Moon, Andrew Davies, Adrienne Martin, Sarah Beri, Logan Heyes and Lisa Williams.

The Board Meeting started with a Karakia.

A presentation was given by Matt Benson of The Navigators on the 2021 Pharmac Stakeholder Engagement Research, a repeat of the 2020 on-line survey that measures stakeholder perceptions of Pharmac's decision impacts, cultural capabilities, sector leadership and relationship quality.

1. Directors-Only Discussion

Nothing to note.

1.1 Glossary of Terms

1.2 Board Actions

The Board **noted** the Board Actions.

1.3 Board Annual Agenda 2022

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

1.4 Draft Agenda – Board Strategy Day

The purpose of this paper is to provide a proposed outline for the Board strategy workshop on 24 March 2022 for Board discussion and agreement.

The Board:

reviewed the draft Agenda for the Board Strategy Day and discussed and **agreed** the proposed outline for the March 2022 Board strategy workshop

noted that Pharmac staff will prepare any necessary materials in support of preparation for the workshop.

2. Apologies

None.

3. Record of Previous Board and Committee Meetings

3.1 Minutes of Board Meeting held 28 January 2022

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

Anthony Jordan and Steve Maharey **(carried)**

3.2 Health and Safety Committee recommendations

A verbal update was provided by the Committee Chair on the February Health and Safety Committee Meeting.

The staff survey report was consistent in stress and vitality. The Terms of Reference is now scheduled for the Health and Safety Committee meeting on 29 July 2022. No new items of concern were added to the risk register. Topics discussed were decisions going to SLT in relation to COVID 19 vaccination, and provision for supporting flexible work patterns.

Support was given to the Wellbeing Program with proposed uptake to support stress and vitality for staff with September/October being a difficult period due to COVID-19 factors.

The Board **noted** the report.

3.3 Record of the PTAC Meeting held 18 November 2021

This paper seeks to inform the Board of recommendations made and advice given by PTAC at its **November 2021** meeting held on **18 and 19 November 2021 via Zoom**.

The Board:

noted the summary of the record of the Pharmacology and Therapeutics Advisory Committee (PTAC) meeting held on 18 and 19 November 2021 via videoconference

noted the November 2021 PTAC record was signed off by the Chair on 6 February 2022 and is published on the Pharmac website.

The recommendations from the PTAC Minutes from November 2021 were presented to the board by the PTAC Chair, along with brief details of the pharmaceuticals and the factors for consideration that lead to each recommendation.

4. Interests Register

The Board:

noted the interests register

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

5. Matters Arising

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

6. Chair's Report

6.1 Verbal Report

A verbal update was provided by the Board Chair.

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.

Health Select Committee

The 2020/21 Pharmac Annual Review by the Health Select Committee will be attended by the Board Chair and Chief Executive on the 2 March. An overview of the review will be provided after the meeting.

Pharmac Review

The Final Report of the review is due to be delivered to the Minister of Health on 28 February. The Review Committee, Secretariat and contractors are currently heavily focused on drafting the report and we are expecting to receive portions of the draft for fact-checking over the coming weeks. The Review Committee met with Pharmac's Māori Advisory Rōpū on 28 January and Pharmac staff are meeting regularly with the Secretariat.

Crown Entity Performance Assessment Framework

The Ministry of Health has introduced a new Crown Entity Performance Assessment Framework across all Crown Entities. Ministry staff have engaged with us on their review of Pharmac's 2020/21 year-end, which includes reviewing our reporting against performance measures, and we have provided feedback.

Input to Interim New Zealand Health Plan (NZHP)

One of the recommendations of the health reforms was that there would be a NZHP. Sections 44-47 outlines of the draft Pae Ora Bill outlines at a high-level the purpose, content, process for preparing and the performance reporting on the NZHP **https://legislation.govt.nz/bill/government/2021/0085/latest/LMS575533.html**

Health and Safety Update

Now working in a more hybrid-situation which was initially thought to be short-term but if this moves to a more permanent situation, proper set-up will need to implemented. The office is open but few people are in the office at any one time, and social distancing and masking is strongly encouraged. A planned return to the office is estimated to be in early April. Working at keeping connections and communication open.

7.2 Monthly Communications Report

The purpose of this paper is to summarise communications activity for January 2022 including the analysis of the 'You are a Priority' diabetes medicine campaign.

The Board:

noted that we have improved the OIA section of the website to make it easier for users to search and find information

noted that evaluation work of the 'You are a Priority' diabetes medicines PR campaign has been completed, and the campaign reached an estimated three million New Zealanders.

Media started slowly for the year, but proactive media releases are planned for the coming months with a focus on transparency. Changes have been made to the website to make OIA access easier to find information and use.

A highlight is the Whare PR diabetes medicine campaign. Feedback has been positive, and metrics show the campaign was a success. The report highlights the importance of working with Whare PR to reach Māori in a genuine way. Key learnings line-up with focus areas on how to use social media partners and engagement.

8. Strategic Planning and Policy

8.1 Medical Devices Programme Update

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

The Board:

noted Pharmac's progress with its programme to deliver on its medical devices strategic priority

noted the proposed timeframe and approach for moving to the Investment Management stage and the identified risks of this approach

noted that we will continue to develop in tandem the operational detail for the proposed investment management approach and a plan for its implementation

noted that we intend to engage a range of sector stakeholders during 2022 to seek their feedback on aspects of the proposed product and requirements for its future implementation

noted the plan for engagement with Māori stakeholders.

The Board discussed the importance of clinician engagement; and noted the pressures and constraints in health-sector staff capacity, and the reforms and COVID-19 are being factored into planning.

9. Schedule and Funding

9.1 Medical Devices Transaction and Investment Report

The purpose of this paper is to provide a monthly update to the Board on progress with medical devices national contracting activity. National contracting is the key mechanism being using to build a list of medical devices, as we work towards 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.

9.2 CPB Management Report

The purpose of this paper is to update the Board on the Combined Pharmaceutical Budget, including February 2022 CPB Forecast and COVID-19 related expenditure. It aims to enable a wider discussion by the Board regarding management's planned activities to manage expenditure in 2021/22 and in the out-years. It also provides an update on COVID-19 costs being incurred and any associated risks. We have separated the funding into three parts:

1. Combined Pharmaceutical Budget funding
2. COVID-19 expenditure and funding
3. Budget management options.

9.3 Pharmaceutical Transaction Report

This paper provides the Board with an advanced overview of current 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.

noted that the expenditure update that is usually provided in this paper is addressed in Board Agenda item 9.2, The Combined Pharmaceutical Budget Management report.

9.4 AstraZeneca multiproduct proposal to fund treatments for cancer and asthma

The purpose of this paper is to seek a decision from the Board on a significant pharmaceutical transaction which would result in new listings and amendments to contractual arrangements for already funded treatments.

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

resolved to list durvalumab (Imfinzi), benralizumab (Fasenra) in the Pharmaceutical Schedule, as set out in AstraZeneca Multiproduct Proposal in Appendix One as follows:

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

Durvalumab

resolved to list durvalumab (Imfinzi) in the Oncology Agents and Immunosuppressants Therapeutic Group (Programmed Cell Death-1 (PD-1) Inhibitors subgroup) in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 August 2022 as follows:

Chemical	Presentation	Brand	Pack Size	Price and subsidy (ex-man., ex. GST)
Durvalumab	Inj 50 mg per ml, 2.4 vial	Imfinzi	1	$1,128.00
Durvalumab	Inj 50 mg per ml, 10 ml vial	Imfinzi	1	$4,700.00
Durvalumab	Inj 1 mg for ECP	Baxter	1 mg	$9.59

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

Special Authority for Subsidy
Initial application – (Non-small cell lung cancer) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1. Patient has histologically or cytologically documented stage III, locally advanced, unresectable non-small cell lung cancer (NSCLC); and
2. Patient has received two or more cycles of platinum-based chemotherapy concurrently with definitive radiation therapy; and
3. Patient has no disease progression following the second or subsequent cycle of platinum-based chemotherapy with definitive radiation therapy treatment; and
4. Patient has a ECOG performance status of 0 or 1; and
5. Patient has completed last radiation dose within 8 weeks of starting treatment with durvalumab; and
6. Patient must not have received prior PD-1 or PD-L1 inhibitor therapy for this condition; and
7. Either:
    7.1. Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
    7.2. Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
8. Treatment with durvalumab to cease upon signs of disease progression.

Renewal – (Non-small cell lung cancer) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1. The treatment remains clinically appropriate and the patient is benefitting from treatment; and
2. Either:
   2.1. Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
   2.2. Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
3. Treatment with durvalumab to cease upon signs of disease progression; and
4. Total continuous treatment duration must not exceed 12 months.

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

Restriction
Initiation - Non-small cell lung cancer
Medical oncologist
Reassessment required after 3 months
All of the following:
1. Patient has histologically or cytologically documented stage III, locally advanced, unresectable non-small cell lung cancer (NSCLC); and
2. Patient has received two or more cycles of platinum-based chemotherapy concurrently with definitive radiation therapy; and
3. Patient has no disease progression following the second or subsequent cycle of platinum-based chemotherapy with definitive radiation therapy treatment; and
4. Patient has a ECOG performance status of 0 or 1; and
5. Patient has completed last radiation dose within 8 weeks of starting treatment with durvalumab; and
6. Patient must not have received prior PD-1 or PD-L1 inhibitor therapy for this condition; and
7. Either:
   7.1. Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
   7.2. Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
8. Treatment with durvalumab to cease upon signs of disease progression.

Continuation - Non-small cell lung cancer
Medical oncologist
Re-assessment required after 3 months
All of the following:
1. The treatment remains clinically appropriate and the patient is benefitting from treatment; and
2. Either:
   2.1. Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
   2.2. Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
3. Treatment with durvalumab to cease upon signs of disease progression; and
4. Total continuous treatment duration must not exceed 12 months.

resolved to apply PCT only – Specialist to durvalumab in Section B of the Pharmaceutical Schedule from 1 August 2022

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

noted Imfinzi would have protection from delisting and subsidy reduction until 31 July 2025.

Benralizumab

resolved to list benralizumab (Fasenra) in the Oncology Agents and Immunosuppressants Therapeutic Group (Monoclonal antibodies subgroup) in Section B and Part II of Section H of the Pharmaceutical Schedule at a date to be determined as follows:

Chemical	Presentation	Brand	Pack Size	Price and subsidy (ex-man., ex. GST)
Benralizumab	Inj 30 mg per ml, 1 ml prefilled pen	Fasenra	1	$3539.00

resolved to list benralizumab in Section B of the Pharmaceutical Schedule subject to the following restrictions at a date to be determined

Special Authority for Subsidy
Initial application — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:
1. Patient must be aged 12 years or older; and
2. Patient must have a diagnosis of severe eosinophilic asthma documented by a respiratory physician or clinical immunologist; and
3. Conditions that mimic asthma eg. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded; and
4. Patient has a blood eosinophil count of greater than 0.5 × 10^9 cells/L in the last 12 months; and
5. Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long-acting beta-2 agonist, or budesonide/formoterol as part of the anti-inflammatory reliever therapy plus maintenance regimen, unless contraindicated or not tolerated; and
6. Either:
    6.1. Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids; or
    6.2. Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months; and
7. Treatment is not to be used in combination with subsidised mepolizumab; and
8. Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment; and
9. Either:
    9.1. Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or
    9.2. Both:
        9.2.1. Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
        9.2.2. Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

Renewal — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 2 years for applications meeting the following criteria:
Both:
1. An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
2. Either:
    2.1. Exacerbations have been reduced from baseline by 50% as a result of treatment with benralizumab; or
    2.2. Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control.

resolved to list benralizumab in Part II of Section H of the Pharmaceutical Schedule subject to the following restrictions at a date to be determined and no earlier than 1 April 2022:

Restriction
Initiation – Severe eosinophilic asthma
Respiratory physician or clinical immunologist
Reassessment required after 12 months
All of the following:

1. Patient must be aged 12 years or older; and
2. Patient must have a diagnosis of severe eosinophilic asthma documented by a respiratory physician or clinical immunologist; and
3. Conditions that mimic asthma eg. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded; and
4. Patient has a blood eosinophil count of greater than 0.5 × 10^9cells/L in the last 12 months; and
5. Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long-acting beta-2 agonist, or budesonide/formoterol as part of the anti-inflammatory reliever therapy plus maintenance regimen, unless contraindicated or not tolerated; and
6. Either:
    6.1. Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids; or
    6.2. Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months; and
7. Treatment is not to be used in combination with subsidised mepolizumab; and
8. Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment; and
9. Either:
    9.1. Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or
    9.2. Both:
        9.2.1. Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
        9.2.2. Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

Continuation – Severe eosinophilic asthma
Respiratory physician or clinical immunologist
Reassessment required after 2 years
Both:

1. An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
2. Either:
    2.1. Exacerbations have been reduced from baseline by 50% as a result of treatment with benralizumab; or
    2.2. Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control.

resolved to apply Retail pharmacy restriction to benralizumab in Section B of the Pharmaceutical Schedule from 1 August 2022

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

noted Fasenra would have protection from delisting and subsidy reduction until 31 March 2025

noted that Fasenra would be listed as soon as reasonably practicable following Medsafe approval of the prefilled pen presentation.

Olaparib

resolved to maintain the current price and subsidy for the following strengths and presentations of Olaparib (Lynparza) in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 August 2022 as follows (ex-manufacturer, excluding GST)

Chemical	Presentation	Brand	Pack Size	Price and subsidy (ex-man., ex. GST)
Olaparib	Tab 100 mg	Lynparza	56	$3,701.00
Olaparib	Tab 150 mg	Lynparza	56	$3,701.00

resolved to amend the restrictions for olaparib in Section B of the Pharmaceutical Schedule from 1 August 2022 as follows (additions in **bold**, deletions in ~~strikethrough~~)

Special Authority for Subsidy
Initial application - **(Ovarian cancer)** only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1. Patient has a high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2. There is documentation confirming pathogenic germline BRCA1 or BRCA2 gene mutation; and
3. ~~Patient has received at least two lines of previous treatment with platinum-based chemotherapy; and~~
4. ~~Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line of platinum-based chemotherapy; and~~
5. ~~Patient's disease must have achieved partial or complete response to treatment with the immediately preceding platinum-based regimen; and~~
6. ~~Patient's disease has not progressed following prior treatment with olaparib; and~~
7. ~~Treatment will be commenced within 8 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and~~
3. **Either:**
    - **3.1. All of the following:**
        - **3.1.1. Patient has newly diagnosed, advanced disease; and**
        - **3.1.2. Patient has received one line** of previous treatment with platinum-based chemotherapy; and**
        - **3.1.3. Patient's disease must have experienced a partial or complete response to the first-line platinum-based regimen; or**
    - **3.2. All of the following:**
        - **3.2.1. Patient has received at least two lines** of previous treatment with platinum-based chemotherapy; and**
        - **3.2.2. Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line** of platinum-based chemotherapy; and**
        - **3.2.3. Patient's disease must have experienced a partial or complete response to treatment with the immediately preceding platinum-based regimen; and**
        - **3.2.4. Patient has not previously received funded olaparib treatment; and**
4. **Treatment will be commenced within 12 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and**
5. Treatment to be administered as maintenance treatment; and
6. Treatment not to be administered in combination with other chemotherapy.

Renewal - **(Ovarian cancer)** only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1. Treatment remains clinically appropriate and patient is benefitting from treatment; and
2. ~~No evidence of progressive disease; and~~

~~3. Treatment to be administered as maintenance treatment; and~~
~~4. Treatment not to be administered in combination with other chemotherapy~~

2. Either:
- **2.1. No evidence of progressive disease; or**
- **2.2. Evidence of residual (not progressive) disease and the patient would continue to benefit from treatment in the clinician's opinion; and**

3. Treatment to be administered as maintenance treatment; and
4. Treatment not to be administered in combination with other chemotherapy; and
5. Either:
- **5.1. Both:**
  - **5.1.1. Patient has received one line** of previous treatment with platinum-based chemotherapy; and**
  - **5.1.2. Documentation confirming that the patient has been informed and acknowledges that the funded treatment period of olaparib will not be continued beyond 2 years if the patient experiences a complete response to treatment and there is no radiological evidence of disease at 2 years; or**
- **5.2. Patient has received at least two lines** of previous treatment with platinum-based chemotherapy.**

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

resolved to amend the restrictions for olaparib in part II of Section H of the Pharmaceutical Schedule from 1 August 2022 as follows (additions in **bold**, deletions in ~~strikethrough~~)

Restricted **- Ovarian cancer**
Initiation
Medical Oncologist
Re-assessment required after 12 months
All of the following:
1. Patient has a high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2. There is documentation confirming pathogenic germline BRCA1 or BRCA2 gene mutation; and
~~3. Patient has received at least two lines of previous treatment with platinum-based chemotherapy; and~~
~~4. Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line of platinum-based chemotherapy; and~~
~~5. Patient's disease must have achieved partial or complete response to treatment with the immediately preceding platinum-based regimen; and~~
~~6. Patient's disease has not progressed following prior treatment with olaparib; and~~
~~7. Treatment will be commenced within 8 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and~~

3. Either:
- **3.1. All of the following:**
  - **3.1.1. Patient has newly diagnosed, advanced disease; and**
  - **3.1.2. Patient has received one line** of previous treatment with platinum-based chemotherapy; and**
  - **3.1.3. Patient's disease must have experienced a partial or complete response to the first-line platinum-based regimen; or**
- **3.2. All of the following:**
  - **3.2.1. Patient has received at least two lines** of previous treatment with platinum-based chemotherapy; and**
  - **3.2.2. Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line** of platinum-based chemotherapy; and**
  - **3.2.3. Patient's disease must have experienced a partial or complete response to treatment with the immediately preceding platinum-based regimen; and**
  - **3.2.4. Patient has not previously received funded olaparib treatment; and**

4. Treatment will be commenced within 12 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and
5. Treatment to be administered as maintenance treatment; and
6. Treatment not to be administered in combination with other chemotherapy.

Continuation **- Ovarian cancer**
Medical Oncologist
Re-assessment required after 12 months
All of the following:
1. Treatment remains clinically appropriate and patient is benefitting from treatment; and
~~2. No evidence of progressive disease; and~~
~~3. Treatment to be administered as maintenance treatment; and~~
~~4. Treatment not to be administered in combination with other chemotherapy~~
2. Either:
  2.1. No evidence of progressive disease; or
  2.2. Evidence of residual (not progressive) disease and the patient would continue to benefit from treatment in the clinician's opinion; and
3. Treatment to be administered as maintenance treatment; and
4. Treatment not to be administered in combination with other chemotherapy; and
5. Either:
  5.1. Both:
    5.1.1. Patient has received one line of previous treatment with platinum-based chemotherapy; and**
    5.1.2. Documentation confirming that the patient has been informed and acknowledges that the funded treatment period of olaparib will not be continued beyond 2 years if the patient experiences a complete response to treatment and there is no radiological evidence of disease at 2 years; or
  5.2. Patient has received at least two lines of previous treatment with platinum-based chemotherapy.**

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

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

noted Lynparza would have protection from delisting and subsidy reduction until 31 July 2025.

Budesonide with eformoterol powder for inhalation

resolved to amend the current price and subsidy for the following strengths and presentations of budesonide with eformoterol (Symbicort Turbuhaler) in Section B of the Pharmaceutical Schedule from 1 August 2022 as follows (ex-manufacturer, excluding GST)

Chemical	Formulation	Brand	Pack size	Current price and subsidy	Proposed price and subsidy
Budesonide with eformoterol	Powder for inhalation 200 mcg budesonide with 6 mcg eformoterol	Symbicort Turbuhaler	120 dose OP	$44.08	$33.74
Budesonide with eformoterol	Powder for inhalation 400 mcg budesonide with 12 mcg eformoterol	Symbicort Turbuhaler	60 dose OP	$44.08	$33.74

resolved to list the following brand of budesonide with eformoterol (Symbicort Turbuhaler) in Part II of Section H of the Pharmaceutical Schedule from 1 August 2022 as follows (ex-manufacturer, excluding GST)

Chemical	Formulation	Brand	Pack size	Price
Budesonide with eformoterol	Powder for inhalation 200 mcg budesonide with 6 mcg eformoterol	Symbicort Turbuhaler	120 dose	$33.74
Budesonide with eformoterol	Powder for inhalation 400 mcg budesonide with 12 mcg eformoterol	Symbicort Turbuhaler	60 dose	$33.74

noted a new confidential rebate would apply to above strengths of Symbicort Turbuhaler that would further reduce the net price to the Funder from 1 April 2022

noted there would be no changes to the current access for budesonide with eformoterol powder for inhalation (Symbicort Turbuhaler)

noted the above strengths of Symbicort Turbuhaler would have protection from delisting and subsidy reduction until 31 March 2025.

Fulvestrant

resolved to maintain the current price and subsidy for fulvestrant (Faslodex) tab 250 mg in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 April 2022 as follows (ex-manufacturer, excluding GST)

Chemical	Presentation	Brand	Pack size	Current price and subsidy
Fulvestrant	Inj 50 mg per ml, 5 ml prefilled syringe	Faslodex	2	$1,068.00

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

noted there would be no changes to the current Special Authority criteria or hospital restrictions for fulvestrant (Faslodex)

noted Faslodex would have protection from delisting and subsidy reduction until 31 March 2025.

Gefitinib

resolved to amend the current price and subsidy for gefitinib (Iressa) tab 250 mg in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 August 2022 as follows (ex-manufacturer, excluding GST)

Chemical	Formulation	Brand	Pack size	Current price and subsidy	Proposed price and subsidy
Gefitinib	Tab 250 mg	Iressa	30	$1,700.00	$918.00

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

noted there would be no changes to the current Special Authority criteria or hospital restrictions for gefitinib (Iressa)

noted Iressa would have protection from delisting and subsidy reduction until 31 March 2025.

resolved to approve the amendments to the Pharmaceutical Schedule relating to olaparib (Lynparza), budesonide with eformoterol powder for inhalation (Symbicort Turbuhaler), Fulvestrant (Faslodex), and gefitinib (Iressa), as set out in Appendix One above

resolved to approve the 14 February 2021 agreement with AstraZeneca Pty Limited

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

Claudia Wyss and Jan White **(carried)**

9.5 Summary of Decisions Made Under Delegated Authority – January 2022

This report contains a summary of all decisions made by Pharmac staff under delegated authority since the last Board meeting, i.e. decisions made during January 2022.

The Board **noted** the summary of decisions made under Delegated Authority during January 2022 by the Chief Executive, Director of Operations, Acting Director of Operations Manager Pharmaceutical Funding, Senior Advisor/Team Leader and Senior Therapeutic Group Managers/Team Leaders.

The Board observed the consistent delivery of in-depth and informative reports despite pressures and specifically recognised that staff were dealing with individual pressures from the disruption to working environments due to the existence of COVID-19 in the community.

10. Regular Reports and Noting Papers

10.1 Risk Register

The full risk register is considered by the Audit and Risk Committee and provided to the Board as an information item. The register lists risks that exceed the Board's identified risk tolerance. This paper is an exception report for the Board about changes to the register since it was considered at the Audit and Risk Committee.

The Board:

noted the risk register which provides a summary of current and ongoing risks of relevance to the Board

noted the Board received the quarter two report risk report at its January 2022 meeting.

The Risk Report remains consistent with the previous report.

11. Interest Articles

The Board **noted** the interest articles.

12. General Business

The Chair met with Sue Chetwin and gave an update.

The meeting closed at 2.30pm with a karakia.

Date of Next Meeting

The date for the next Board meeting is set for Friday 25 March 2022.

Chair: _____ Date: _____
Steve Maharey