MINUTES OF THE PHARMACEUTICAL MANAGEMENT AGENCY (PHARMAC)

BOARD MEETING MAY 2019

The meeting was held at Level 9, 40 Mercer Street, Wellington, starting at 9.43am with the following attendees:

Board members

Steve Maharey	Chair
Jan White	Board Member
Ross Lawrenson	Board Member
Jens Mueller	Board Member
Nicole Anderson	Board Member
David Lui	Observer, CAC Chair
Marius Rademaker	Observer, Deputy PTAC Chair
Peter Bramley	Observer, DHB Representative

PHARMAC staff in attendance

Sarah Fitt	Chief Executive
Lisa Williams	Director of Operations
Alison Hill	Director of Engagement & Implementation
Michael Johnson	Director of Strategic Initiatives
Mark Woodard	Director of Corporate Services/CFO
Lizzy Cohen	Board Secretary

PHARMAC staff attended for relevant items.

1. Directors' Only Discussion

noted the change in Board membership as follows:

Jan White appointed Deputy Chair for 2 years;

Claudia Wyss appointed effective 9 April and to start on November 2019; and

Jens Mueller's third term ends in September 2019 and will not be renewed.

noted the vacancy of the sixth Board member and the feedback presented on the Board's behalf to Ministry of Health staff on potential candidates to be considered as part of the nominations process.

2. Apologies

Mark Weatherall, Observer PTAC Chair

3. Record of Previous Board and Committee Meetings

3.1 Minutes of May 2019 Board Meeting

resolved to adopt the minutes of the March 2019 meeting as being a true and correct record.

Jens Mueller and Ross Lawrenson **(carried)**

3.2 Summary of February 2019 PTAC Meeting Minutes

noted the following summary of the record of the Pharmacology and Therapeutics Advisory Committee (PTAC) meeting held on 21 and 22 February 2019; and

noted the minutes for the February PTAC meeting are published on the PHARMAC website.

3.3 Consumer Advisory Committee (CAC) Recommendations – March 2019

noted the recommendations of the Consumer Advisory Committee and the proposed/completed actions by PHARMAC staff.

4. Interests Register

noted the interests register; and

noted any decisions by the Chair to manage actual or potential conflicts of interest, as follows:

[None required]

5. Matters Arising

noted the matter's arising.

6. Chairman's Report

6.1 Verbal Report

noted the Chair's verbal report.

6.2 Correspondence

noted the correspondence report.

7. Chief Executive's Report

noted the Chief Executives Report.

8. Key Items

8.1 PHARMConnect – Phase One Update

noted the contents of this report.

8.2 Combined Pharmaceutical Budget – Overview of Forecasting and Expenditure Reporting

noted the contents of this paper.

8.3 Final Statement of Performance Expectations (SPE) 2019/20

noted the attached final draft 2019/20 Statement of Performance Expectations (SPE), which has now been reviewed by the Minister of Health and incorporates his feedback; and

resolved to approve the SPE, with two members of the Board signing the documents.

Nicole Anderson and Jan White **(carried)**

8.4 Update on PHARMAC's work on funding of medicines for rare disorders

noted the update on PHARMAC's work program with respect to funding of medicines for rare disorders; and

noted the attached draft publication: 'Funding medicines for rare disorders: insights from the New Zealand context'.

11.58am Peter Bramley left the meeting

8.5 Pharmacology and Therapeutics Advisory Committee (PTAC) Succession Planning

noted and endorse the proposed Pharmacology and Therapeutics Advisory Committee (PTAC) succession plan; and

resolved that a paper be submitted to the Director General of Health seeking approval of the succession plan.

Jens Mueller and Ross Lawrenson **(carried)**

8.6 International Travel Requests – 2019 Vancouver Group meeting and 2019 Singapore Healthcare Supply Chain Management Congress

2019 Vancouver Group meeting

resolved to approve international travel for the Chief Executive to attend and present at the 2019 Vancouver Group meeting in Glasgow, United Kingdom on 28 - 29 August 2019;

noted that this travel was included in the 2018/19 International Travel Plan which was noted by the Board in February 2018;

noted the Vancouver Group receives no funding from commercial interests, and the cost of travel and accommodation would be covered by PHARMAC; and

noted that, if this proposal is approved, the Chief Executive would provide a report back to the Board following the meeting.

2019 Singapore Healthcare Supply Chain Management Congress

resolved to approve international travel for the Chief Executive to attend and present at the 2019 Singapore Healthcare Supply Chain Management Congress, Singapore on 21-22 August 2019;

noted that this travel was not included in the 2018/19 International Travel Plan which was noted by the Board in February 2018;

noted the Congress organisers would provide return Business Class return tickets, together with accommodation and meals for the PHARMAC Chief Executive; and

noted that, if this proposal is approved, the Chief Executive would provide a report back to the Board following the Congress.

Nicole Anderson and Jens Mueller **(carried)**

9. Schedule and Funding

9.1 Medical Devices Transaction and Investment Report

noted the contents of this paper.

9.2 Pharmaceutical Transaction and Investment Report

noted the contents of this paper.

12.32pm Peter Bramley joined the meeting

9.3 Proposal to widen access and award sole supply of etanercept

resolved to accept the tender from Pfizer New Zealand Limited ("Pfizer") for Enbrel to be the sole subsidised brand of etanercept inj 25 mg, 50 mg autoinjector and 50 mg prefilled syringe from 1 September 2019 until 30 June 2024;

resolved to accept the tender from Pfizer New Zealand Limited ("Pfizer") for Enbrel to be the Hospital Supply Status brand of the Hospital Pharmaceutical inj 25 mg vial, 50 mg autoinjector and 50 mg prefilled syringe, with a DV Limit of 5%, from 1 September 2019 until 30 June 2024;

resolved to maintain the price and subsidy of etanercept (Enbrel) presentations in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 July 2019 as follows:

Chemical	**Presentation**	**Brand**	**Pack Size**	**Price and subsidy** (ex-man., ex. GST)
Etanercept	Inj 25 mg	Enbrel	4	$799.96
Etanercept	Inj 50 mg autoinjector	Enbrel	4	$1,599.96
Etanercept	Inj 50 mg prefilled syringe	Enbrel	4	$1,599.96

resolved to list a new etanercept 25 mg autoinjector presentation in Section B and Part II of Section H of the Pharmaceutical Schedule at a date to be determined, subject to Medsafe approval as follows:

Chemical	**Presentation**	**Brand**	**Pack Size**	**Price and subsidy** (ex-man., ex. GST)
Etanercept	Inj 25 mg autoinjector	Enbrel	4	$799.96

noted that the acceptance of this proposal would not result in a brand change for etanercept;

resolved to amend the Special Authority criteria that apply to severe chronic plaque psoriasis only for etanercept in Section B of the Pharmaceutical Schedule from 1 July 2019 as follows (amended criteria shown only) (additions in bold, deletions in strikethrough):

Special Authority for Subsidy
Initial application — (severe chronic plaque psoriasis) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:
Either:

1. Both:
    1.1. The patient has had an initial Special Authority approval for adalimumab for severe chronic plaque psoriasis; and
    1.2. Either:
        1.2.1. The patient has experienced intolerable side effects from adalimumab; or
        1.2.2. The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe chronic plaque psoriasis; or
2. All of the following:
    2.1. Either:
        2.1.1. Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of ~~greater than 15~~ **greater than 10**,

where lesions have been present for at least 6 months from the time of initial diagnosis; or

2.1.2. Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

2.2. Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and

2.3. A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and

2.4. The most recent PASI or DLQI assessment is no more than 1 month old at the time of application.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of ~~greater than 15~~ **greater than 10**, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Renewal — (severe chronic plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1. Either:
   1.1. Applicant is a dermatologist; or
   1.2. Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
2. Either:
   2.1. Both:
      2.1.1. Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
      2.1.2. **Either**
         2.1.2.1. Following each prior etanercept treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-treatment baseline value; or
         2.1.2.2. Following each prior etanercept treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or
   2.2. Both:
      2.2.1. Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
      2.2.2. Either:
         2.2.2.1. Following each prior etanercept treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
         2.2.2.2. Following each prior etanercept treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; and

3. Etanercept to be administered at doses no greater than 50 mg every 7 days.

Note: A treatment course is defined as a minimum of 12 weeks of etanercept treatment.

resolved to amend the Hospital Indication Restriction criteria that apply to plaque psoriasis only for etanercept in Part II of Section H of the Pharmaceutical Schedule from 1 July 2019 as follows (amended criteria shown only) (additions in bold, deletions in strikethrough):

Restricted

Initiation – **severe chronic** plaque psoriasis, prior TNF use
Dermatologist
Limited to 4 months treatment
All of the following:
1. The patient has had an initial Special Authority approval for adalimumab for severe chronic plaque psoriasis; and
2. Either:
   2.1. The patient has experienced intolerable side effects from adalimumab; or
   2.2. The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe chronic plaque psoriasis; and
3. Patient must be reassessed for continuation after 3 doses.

Initiation – **severe chronic** plaque psoriasis, treatment-naive
Dermatologist
Limited to 4 months treatment
All of the following:
1. Either:
   1.1. Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of ~~greater than 15~~ **greater than 10**, where lesions have been present for at least 6 months from the time of initial diagnosis; or
   1.2. Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
2. Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
3. A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
4. The most recent PASI assessment is no more than 1 month old at the time of initiation.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of ~~greater than 15~~ **greater than 10**, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Continuation – **severe chronic** plaque psoriasis
Dermatologist
Re-assessment required after 6 months
Both:
1. Either:

1.1. Both:

1.1.1. Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and

1.1.2. Either:

1.1.2.1. Following each prior etanercept treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-etanercept treatment baseline value; or

1.1.2.2. Following each prior etanercept treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or

1.2. Both:

1.2.1. Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and

1.2.2. Either:

1.2.2.1. Following each prior etanercept treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or

1.2.2.2. Following each prior etanercept treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-etanercept treatment baseline value; and

2. Etanercept to be administered at doses no greater than 50 mg every 7 days.

resolved to approve 2 May 2019 provisional agreement with Pfizer New Zealand Limited; and

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

Jan White and Jens Mueller **(carried)**

10. Strategic Planning and Policy

10.1 Update on work on earlier access to new medicines

noted that PHARMAC provided the Minister of Health with a high-level briefing on early access to new cancer medicines on 12 April 2019.

resolved that PHARMAC staff carry out the further work necessary to prepare for earlier assessment of new medicines, initially cancer medicines, for implementation on 1 January 2020;

resolved that PHARMAC staff work with the Ministry of Health to further explore the proposal to pilot a New Zealand version of a “cancer drug fund” and provide an update to the Board at the September Board meeting; and

noted that PHARMAC staff will keep the Board informed on the progress of this work through regular updates.

Jens Mueller and Jan White **(carried)**

10.2 Next steps for Implementation of PHARMAC Strategy

noted the contents of this paper.

Nicole Anderson and Jens Mueller **(carried)**

10.3 Communications and Engagement Strategy

noted PHARMAC's Communications and Engagement Strategy 2019-2022; and

noted the proposed phased delivery plan for the next eighteen months.

10.4 Alternative approaches to support PHARMAC requirements for management of hospital medical devices

noted the contents of this paper.

11. Regular Reports and Noting Papers

11.1 Strategies and Expectations Update

noted the contents of this paper.

11.2 Communications Report

noted the content of the Communications Report covering March and April 2019.

11.3 Implementation Update

noted the contents of this paper.

11.4 Confidential and Legally Privileged Legal Report

noted the legal report.

11.5 Combined Pharmaceutical Budget (CPB) Expenditure Report

noted the contents of this paper.

11.6 Risk Report

noted the contents of this report

11.7 Summary of Decisions Made Under Delegated Authority – March and April 2019

noted the monthly summary of decisions made under Delegated Authority by the Chief Executive, Director of Operations, Manager Pharmaceutical Funding, Senior Advisor/Team Leader and Senior Therapeutic Group Managers/Team Leaders.

12. Interest Articles

13. General Business

Date of Next Meeting

The date for the next Board meeting is set for Friday 28 June 2019 in Wellington, commencing with the Directors only from 10.00am, and attendees and relevant staff from 10.30am.

The meeting closed at 1.55pm.

Chair: Date: