

OUTPUT AGREEMENT

between

**HER MAJESTY THE QUEEN IN RIGHT OF HER
GOVERNMENT IN NEW ZEALAND**

acting by and through the Minister of Health

and the

PHARMACEUTICAL MANAGEMENT AGENCY

**a Crown entity established under section 46 of the
New Zealand Public Health and Disability Act 2000**

for the Period: 1 July 2016 to 30 June 2017

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1. INTRODUCTION

Parties and Term

- 1.1 This Output Agreement (the “Agreement”) is an agreement between Her Majesty The Queen in Right of Her Government in New Zealand (“the Crown”), acting by and through the Minister of Health (“the Minister”), and the Pharmaceutical Management Agency (“PHARMAC”).
- 1.2 This Agreement commences on 1 July 2016 and will expire on 30 June 2017.

Purpose of the Agreement

- 1.3 This Agreement assists the Minister of Health (the Minister) and PHARMAC to clarify, align, and manage their respective expectations and responsibilities. It sets out the:
- 1.3.1 services and reports that PHARMAC will provide and the standards for the provision of those services and reports
 - 1.3.2 various obligations of the parties relating to the provision of information and assistance
 - 1.3.2 amount of funding the Crown will pay to PHARMAC.

Background and construction

- 1.4 PHARMAC is a Crown Agent for the purposes of the Crown Entities Act 2004 (the CE Act).
- 1.5 PHARMAC’s functions are set out in section 48 of its enabling legislation, the New Zealand Public Health and Disability Act 2000 (the NZPHD Act). Funding for those functions is provided by the Crown and by district health boards.
- 1.6 Defined terms used in this Agreement are set out in Schedule A of this Agreement.

Roles of the Parties

PHARMAC

- 1.7 PHARMAC shall perform the Services set out in Appendix B to this Agreement.
- 1.8 PHARMAC is accountable to the Minister for its performance under this Agreement, including the delivery and performance of the Services, reporting, and achieving the financial performance set out in its Statement of Performance Expectations (including any part of its operations that it has contracted a third party to deliver).
- 1.9 In providing the Services, PHARMAC will comply with all of its legal obligations, and will use its best endeavours to give effect to:
- 1.9.1 the Government’s Expectations, as defined in Schedule A
 - 1.9.2 the Government’s Expectations for Pay and Employment Conditions in the State Sector.

- 1.10 PHARMAC is responsible for maintaining the capability needed to meet its responsibilities under this Agreement at all times.

Minister of Health on behalf of the Crown

- 1.11 The Minister is accountable to Parliament for the performance of PHARMAC. The role of the Minister in relation to this Agreement includes:
- 1.11.1 determining the New Zealand Health Strategy and the New Zealand Disability Strategy
 - 1.11.2 obtaining Parliamentary appropriations with which to fund PHARMAC
 - 1.11.3 setting expectations to inform and guide PHARMAC's preparation of its Agreement, Statement of Intent, and Statement of Performance Expectations consistent with the level of funding available
 - 1.11.4 monitoring and reviewing the performance of PHARMAC, including against this Agreement
 - 1.11.5 holding PHARMAC accountable for its performance, including under this Agreement
 - 1.11.6 undertaking other roles as set out in the CE Act, the New Zealand Public Health and Disability Act 2000, the Public Finance Act 1989 and other relevant statutes and regulations.

Ministry of Health on behalf of the Minister of Health

- 1.12 The Ministry of Health ("the Ministry") acts as the Minister's agent in the Minister's relationship with PHARMAC. The Ministry's role includes:
- 1.12.1 reviewing PHARMAC's Statement of Intent, Statement of Performance Expectations and financial statements
 - 1.12.2 negotiating an annual output agreement and any protocols, as required by the Minister
 - 1.12.3 assessing and advising the Minister on PHARMAC's performance and performance reporting, including any risks or potential risks that may arise from time to time
 - 1.12.4 advising the Minister on the compliance of PHARMAC with its legislation
 - 1.12.5 advising the Minister on PHARMAC's capability to achieve its results
 - 1.12.6 managing payments to PHARMAC under this Agreement
 - 1.12.7 transmitting information to PHARMAC about relevant decisions and/or changes in policy by the Government, relevant government processes, especially the Budget and the Government's Expectations of PHARMAC
 - 1.12.8 providing ongoing briefings to the Minister on PHARMAC's performance and attending meetings between the Minister and PHARMAC, as required

- 1.12.9 advising and assisting the Minister to develop/set the Annual Letter of Expectations.

2. SERVICE DELIVERY PERFORMANCE

Services

- 2.1 PHARMAC will perform and deliver the Services in accordance with the quantitative and qualitative performance measures set out in Schedule B.
- 2.2 The Services specified in Schedule B to this Agreement are be provided by PHARMAC, whether directly or indirectly funded (via District Health Boards or otherwise) through Vote Health.
- 2.3 In the event of a material risk that PHARMAC will be unable to meet any of its performance measures or deliver any of the Services, PHARMAC will provide the Minister and the Ministry with the details of the risk and proposed management strategies as soon as practicable. Depending on the significance of the matter, PHARMAC may advise the Minister and the Ministry prior to the next scheduled report.

Intellectual Property

- 2.4 Without limiting any other rights of the Crown, the Ministry may use (including copy, modify, develop or distribute) for health purposes, free of charge, any intellectual property in anything created by PHARMAC in pursuance of its statutory functions.
- 2.5 Prior to any proposed use or modification of PHARMAC intellectual property by the Ministry, the Ministry must consult with PHARMAC.
- 2.6 Clauses 2.4 and 2.5 above will survive expiry or termination of this Agreement.

3. FINANCIAL MANAGEMENT

Funding from Vote Health

- 3.1 The Ministry will pay PHARMAC a total of twenty one million, nine hundred and eighty eight thousand dollars (\$21,988,000) (GST exclusive) from Vote Health: National Contracted Services, Other, to deliver the Services.
- 3.2 The method and timing of payments is set out in Schedule C of this Agreement.
- 3.3 PHARMAC acknowledges that the funding set out in clause 3.1 above is allocated from appropriations pursuant to the Public Finance Act 1989. PHARMAC will only use the funding for provision of the Services, and will comply with all applicable legislation (including without limitation the CE Act and any relevant provisions of the Public Finance Act 1989).

Crown Accounting Policies

- 3.4 PHARMAC will follow current generally accepted accounting practices within the accounting profession and, in particular, will follow Crown accounting policies.

Application of the CE Act

- 3.5 The Minister and PHARMAC also note that PHARMAC will produce a Statement of Intent, Statement of Performance Expectations and Annual Report as stated in section 139, section 149C and section 150 of the CE Act and that the Statement of Performance Expectations will consolidate the projected performance of the whole of PHARMAC's operations.

Use of Surplus Funding

- 3.6 Annual net surpluses, arising from the efficient delivery of Services, may be retained by PHARMAC for use in subsequent years, subject to section 165 of the CE Act and clauses 3.8 to 3.10 of this Agreement.
- 3.7 Expenditure of any net surplus is at the discretion of PHARMAC, provided that any expenditure must be consistent with:
- 3.7.1 PHARMAC's Statement of Intent and Statement of Performance Expectations
 - 3.7.2 Government health objectives and not be contrary to Government policy
 - 3.7.3 PHARMAC's statutory functions.
- 3.8 Under section 165 of the CE Act, the Minister of Finance may direct PHARMAC to pay to the Crown any net surpluses.
- 3.9 PHARMAC must put in place measures to achieve and maintain the optimal accumulated equity levels agreed with the Ministry from time to time. For 2016/17, the agreed level is \$5,000,000 as retained earnings and reserves. In addition, there currently exists a Herceptin SOLD trial reserve; a Legal Risk Fund reserve; a Combined Pharmaceutical Budget Discretionary Pharmaceutical Fund and a Hospital Discretionary Pharmaceutical Fund.
- 3.10 The Ministry and PHARMAC will together use the baseline review of PHARMAC's expenditure and revenue undertaken in 2009/10, in order to assist with developing future revenue bids.

4. REPORTING REQUIREMENTS

Formal Reporting

- 4.1 PHARMAC will provide the Minister and the Ministry with information that enables monitoring of its performance. The Minister and the Ministry will likewise provide PHARMAC with the information it requires to fulfil its obligations under this Agreement.
- 4.2 Ongoing dialogue and meetings between the Minister, Ministry and PHARMAC will support formal reporting. The Minister will meet periodically with the PHARMAC board (or the PHARMAC Chair on the board's behalf) during the year to discuss matters raised by the Minister and the board. The Minister will meet with the Chief Executive of PHARMAC ("the Chief Executive") periodically during the year to discuss specific issues raised by the Minister and the Chief Executive.

Monthly Reports

- 4.3 PHARMAC will provide the Minister and the Ministry of Health with a monthly performance report within three working days of the following PHARMAC Board meeting, covering, at a minimum:
- 4.3.1 major Schedule decisions
 - 4.3.2 significant issues or developments the Minister or Ministry should be aware of, including any potential non-performance against the Output Agreement
 - 4.3.3 PHARMAC's financial performance (including in respect of operational and community pharmaceutical budgets) showing:
 - 4.3.3.1 Year to date financial performance (and monthly): actual, budget, full year forecast, variance (\$), variance (%), from Schedule D, with commentary to explain any significant variances
 - 4.3.3.2 Year to date financial position
 - 4.3.3.4 Year end forecast
 - 4.3.3.3 Year end budget
 - 4.3.3.4 Commentary on any significant variances.

Quarterly Reports

- 4.4 PHARMAC will provide quarterly performance reports to the Minister, each being the monthly report as specified in clause 4.3 above plus additional information described in clause 4.5 below, copied to the Ministry, on the following dates (or the last Thursday of the relevant month, whichever is the later):

Quarter	Quarterly Report Period	Report due date
Quarter 1	1 July 2016 to 30 September 2016	Within three working days following the October 2016 Board meeting
Quarter 2	1 October 2016 to 31 December 2016	Within three working days following the January 2017 Board meeting
Quarter 3	1 January 2017 to 31 March 2017	Within three working days following the April 2017 Board meeting
Quarter 4	1 April 2017 to 30 June 2017	Within three working days following the July 2017 Board meeting

- 4.5 Each quarterly report will, where relevant to that quarter's activity, contain details on:
- 4.5.1 as may be meaningful quarterly, and no less than annually:
 - (i) performance against all 2016/17 deliverables set out in Schedule B
 - (ii) progress against Outcome measures, targets or indicators of success (as set out in its Statement of Performance Expectations)
 - 4.5.2 how PHARMAC has responded to the Government's Expectations, in particular those seeking a focus on value for money and stakeholder engagement, and the longer term economic and fiscal impacts of its activities, linking to particular events or issues if possible
 - 4.5.3 full financial Statements for all activities administered by PHARMAC
 - 4.5.4 use of the Legal Risk Fund, including explaining why the Fund has been used
 - 4.5.5 use of the Discretionary Pharmaceutical Fund, including year-end forecast
 - 4.5.6 risks, their expected impact, consequence and actual or proposed management
 - 4.5.7 equity levels including an explanation of progress with reaching/maintaining agreed optimal accumulated equity level.
- 4.6 Each report shall report the following staff information: budgeted number of staff members, the actual number of staff members, the budgeted number of contractors and the actual number of contractors. All staff and contractor numbers, budget and actual, will be expressed as full time equivalents (FTE).
- 4.7 The Quarter 4 report will also include a schedule setting out aggregated information on remuneration movement over the year and future remuneration plans, the details of which will be advised by the Ministry or the State Services Commission from time to time. A copy of this section of the Quarter 4 report should be copied to the State Services Commission.

PHARMAC Informal Reports

- 4.8 In addition to the formal reports specified in clauses 4.1 to 4.6 above, PHARMAC will operate on a 'no surprises' basis, and will at any time as appropriate:
- 4.8.1 alert the Minister and the Ministry to any non-delivery or material factors that could preclude the achievement of any obligation or expectation set out in this Agreement or in any Government Expectations issued by the Minister, together with a recovery and/or management plan
 - 4.8.2 inform the Minister and the Ministry of any issue likely to be of significance to the Minister or the Government
 - 4.8.3 inform the Minister and the Ministry of any issue likely to be of significance to the Minister or the Government as owner of PHARMAC, for example any capability issues impacting on the ability of PHARMAC to fulfil any of its functions under New Zealand Public Health and Disability Act 2000

- 4.8.4 use its best endeavours to accommodate any specific requests for information or assistance from the Minister or Ministry, including with respect to the deadlines for requests and notification periods for meetings.

Ministerial Servicing

- 4.9 From time to time the Ministry or the Minister will require information from PHARMAC to:

- 4.9.1 prepare ministerial briefings and draft speech notes in relation to PHARMAC
- 4.9.2 deal with ministerial correspondence and select committee inquiries in relation to PHARMAC
- 4.9.3 respond to Parliamentary questions in relation to PHARMAC.

PHARMAC agrees to provide the Ministry with this information within the following timeframes when requested, subject to any legal restrictions:

Request Type	Response Time
Ministerial briefings	As agreed with the Ministry at the time of the request
Speeches	As agreed with the Ministry at the time of the request
Parliamentary questions (PQs)	Written PQs – within two working days Oral PQs – by 12 midday on same day as receipt
Routine ministerial correspondence	Within four working days,
Select Committee enquiries	As agreed at the time of the request

- 4.10 In the event that information provided by PHARMAC under clause 4.8 above is used the Ministry shall use its best endeavours to ensure that PHARMAC is provided a reasonable opportunity to review relevant documents prior to their publication or delivery.

Minister's Advice to PHARMAC

- 4.11 The Ministry, on behalf of the Minister will, in a timely manner:
- 4.11.1 alert PHARMAC to any emerging factors that could preclude the achievement by either party of any obligation or expectation set out in this Agreement
- 4.11.2 inform PHARMAC of any issue likely to be of significance to it
- 4.11.3 use its best endeavours to accommodate any specific requests for information or assistance from PHARMAC, including with respect to the deadlines for requests and notification periods for meetings.

Management of Policy Change

- 4.12 The Minister, on behalf of the Crown, will, to the extent that it is appropriate and not contrary to the exercise of statutory powers, functions, or duties:
- 4.12.1 ensure PHARMAC is consulted prior to introducing any new or materially changed policy that might impact significantly on PHARMAC
 - 4.12.2 negotiate with PHARMAC, in the context of the development of PHARMAC's Statement of Performance Expectations, and/or Output Agreement, changes to the range or scope of services to be funded
 - 4.12.3 negotiate with PHARMAC, in the context of the development of PHARMAC's Statement of Performance Expectations and/or Output Agreement, any changes to current funding strategies or methodologies.

5. VARIATIONS TO THE AGREEMENT AND NEXT AGREEMENT

- 5.1 This Agreement may be varied at any time during its term by written agreement. All amendments shall be recorded in writing and signed by the Chair of PHARMAC and the Minister. Copies of the original Agreement and any variations to this Agreement will be held by both PHARMAC and the Ministry.
- 5.2 In the event that PHARMAC considers the specification of Services to no longer be appropriate or that a significant change to the Services is required, PHARMAC will propose a variation to this Agreement. In seeking a variation PHARMAC will include a description of the issue and the nature of the variation sought, as well as justification for the variation and a statement of the financial implications.
- 5.3 PHARMAC and the Ministry on behalf of the Minister, agree that they will negotiate with each other in good faith with a view to entering into an output agreement for the next financial year, 2017/18, prior to its commencement.

6. DISPUTES RESOLUTION PROCESS

- 6.1 If any dispute arises between the parties under this Agreement that is regarded by either party as material and is unable to be resolved informally, the dispute resolution process described in this section shall apply.
- 6.2 Except as set out in this clause, this dispute resolution process shall not limit the ability of the Minister, the Ministry, or PHARMAC to carry out their statutory functions, duties, and powers at any time.

Notification of Dispute

- 6.3 PHARMAC's Chairperson, the Director-General of Health or their respective delegates may provide written notice of a dispute under this Agreement to the other. In the event that one party gives written notice under this clause, the parties will first endeavour to settle the concerns by discussion between nominated representatives.
- 6.4 The parties agree to undertake these discussions in good faith and with a view to reaching settlement within 20 working days and without the necessity to escalate the matter.

Referral to the Minister

- 6.5 In the event that PHARMAC's Chairperson, the Director-General of Health or their respective delegates are unable to resolve the dispute within 20 working days (or such longer period as may be agreed by both parties) the parties shall in good faith:
- 6.5.1 ensure the uninterrupted provision of the Services Schedule B
 - 6.5.2 ensure the continuation of payments according to Schedule C
 - 6.5.3 prepare an agreed summary (or failing agreement, prepare separate written summaries) of the basis of the dispute and the issues involved, together with their reasons for not reaching an agreement
 - 6.5.4 submit the summary or summaries to the Minister as soon as practicable.

Meeting with the Minister

- 6.6 The Director-General of Health and PHARMAC's Chairperson or their respective delegates will meet with the Minister as soon as practicable after the summary or the summaries are submitted, with a view to achieving a resolution of the dispute.
- 6.7 In the event that resolution is not reached, the dispute or difference will be resolved by a decision of the Minister. The Minister's decision shall be final and binding.

7. REVIEW AND AUDIT

- 7.1 The Minister may review the operations and performance of PHARMAC at any time, in accordance with section 132 of the CE Act. The Ministry may undertake this review, if requested to do so by the Minister.
- 7.2 PHARMAC must take all reasonable steps to enable such a review to be conducted, including providing to the Minister or Ministry all applicable information within the control of PHARMAC that enables the Ministry on the Minister's behalf, to conduct reviews and audits of PHARMAC's performance and/or finances, which may be carried out as often as the Crown reasonably believes those reviews and audits are required

8. ADDRESSES FOR CORRESPONDENCE

- 8.1 For the purposes of this Agreement, the addresses for correspondence between the parties are:

Ms Jacinda Lean
General Manager
Ministerial, Executive and Government
Services
Ministry of Health
PO Box 5013
WELLINGTON 6145

Mr Steffan Crausaz
Chief Executive
PHARMAC
PO Box 10-254
WELLINGTON 6143

9. AGREEMENT AND SIGNATURES

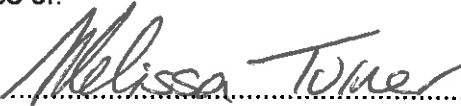
EXECUTED by HER MAJESTY THE QUEEN IN RIGHT OF HER GOVERNMENT IN NEW ZEALAND acting by and through

Hon Dr Jonathan Coleman
Minister of Health

Signature: 

Date: 5/7/16

in the presence of:

Signature: 

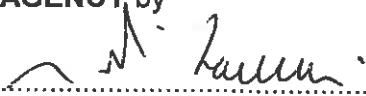
Name: Melissa Turner

Address: 30 Hindmarsh St, Johnsonville, Wgtn

Occupation: Senior Private Secretary

And for the **PHARMACEUTICAL MANAGEMENT AGENCY** by

Stuart McLauchlan
Chairperson

Signature: 

Date: 26-8-16

in the presence of:

Signature: 

Name: Elizabeth Cohen

Address: 5/6 Armour Avenue, Mt Victoria, Wellington

Occupation: Executive Assistant to Chief Executive / Board Secretary

SCHEDULE A: DEFINITIONS AND INTERPRETATION

Definitions

The words used in this Agreement have the meanings given to them in the New Zealand Public Health and Disability Services Act 2000, unless the context requires otherwise or they are defined below:

- **“Agreement”** means this Output Agreement.
- **“Annual Letter of Expectations”** means the letter from the Minister of Health setting out his expectations for PHARMAC.
- **“Enduring Letter of Expectations”** means a letter from the Government to entities, including PHARMAC, setting out generally applicable expectations.
- **“Crown entity”** has the same meaning as in section 7 of the CE Act.
- **“day”** means any period of up to 24 consecutive hours ending at midnight.
- **“disability services”** means “disability support services” as defined in section 6(1) of the New Zealand Public Health and Disability Act 2000.
- **“Discretionary Pharmaceutical Fund”** means PHARMAC’s discretionary fund to purchase pharmaceuticals as part of the overall Community Pharmaceutical Budget.
- **“Government Expectations”** means the expectations of Government as set out in documents which include, but are not limited to, the Annual Letter of Expectations and the Enduring Letter of Expectations.
- **“Minister”** means the Minister of Health.
- **“Ministry”** means the Ministry of Health.
- **“PHARMAC”** means the Pharmaceutical Management Agency (PHARMAC) established under the New Zealand Public Health and Disability Act 2000.
- **“Legal Risk Fund”** means PHARMAC’s fund to meet legal costs and expenses incurred when defending, avoiding or initiating litigation.
- **“Parties”** means PHARMAC and the Crown.
- **“Public Equity”** means net assets.
- **“Responsible Minister”** means the Minister of Health.
- **“Services”** means the services described in Schedule B to this Agreement.
- **“Statement of Intent”** means a statement of intent for PHARMAC, prepared in accordance with the requirements of the New Zealand Public Health and Disability Act 2000 and the CE Act.
- **“Statement of Performance Expectations”** means a statement of performance expectations for PHARMAC, prepared in accordance with the requirements of the CE Act.

Interpretation

Unless the context requires otherwise:

- (a) headings shall be ignored and shall not affect the construction of this document;
- (b) the singular shall include the plural and vice versa;
- (c) a reference to one gender shall include the other;
- (d) “person” shall include any individual, company, corporation, firm, partnership, joint venture, association, organisation, trust, in each case whether or not having a separate legal personality;
- (e) expressions referring to “writing” shall be construed as including references to words printed, typewritten or otherwise visibly represented, copied or reproduced (including by facsimile);

- (f) the expressions “papers” and “records” shall be construed as including writings or material, whether in their original or any copied form or at any time stored or recorded in any data retrieval system; and
- (g) a reference to any legislation (or any provision of legislation) shall be read as if the words “including any legislative modification or re-enactment of it or any legislation substituted for it” were added to the reference.

SCHEDULE B: SERVICES TO BE PROVIDED

The services are the outputs listed in PHARMAC'S Statement of Performance Expectations 2016 – 17.

In providing the Services, PHARMAC will meet the service description and performance measures in the Statement of Performance Expectations.

The Services include reporting requirements, as per this Agreement and compliance with all Acts, Regulations, Orders in Council, *Gazette* notices, and Ministerial directions.

For responsibilities under this Agreement with unspecified deliverables, it is the responsibility of PHARMAC to agree with the Ministry the timing and quality requirements for the discharge of those responsibilities.

SCHEDULE C: PAYMENT TERMS AND SCHEDULE OF PAYMENTS

The Minister shall pay a total sum of twenty one million, nine hundred and eighty eight thousand dollars (\$21,988,000) (GST exclusive) for the period 1 July 2016 to 30 June 2017 by way of direct credit to PHARMAC's nominated bank account in instalments as detailed in the following Schedule of Payments:

PERIOD	PAYMENT DATE	\$ (GST excl)
July 2016	4 July 2016	1,832,333.33
August 2016	4 August 2016	1,832,333.33
September 2016	4 September 2016	1,832,333.33
October 2016	4 October 2016	1,832,333.33
November 2016	4 November 2016	1,832,333.33
December 2016	4 December 2016	1,832,333.33
January 2017	4 January 2017	1,832,333.33
February 2017	4 February 2017	1,832,333.33
March 2017	4 March 2017	1,832,333.33
April 2017	4 April 2017	1,832,333.33
May 2017	4 May 2017	1,832,333.33
June 2017	4 June 2017	1,832,333.33
TOTAL		21,988,000.00