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 2012 to 30 June 2013

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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 Minster of Health ("the Minister"), and the Pharmaceutical Management Agency ("PHARMAC").

1.2 This Agreement commences on 1 July 2012 and will expire on 30 June 2013.

Purpose of the Agreement

1.3 This Agreement is required pursuant to section 170 of the Crown Entities Act 2004 and assists the Minister and PHARMAC to clarify, align, and manage their respective expectations and responsibilities.

1.4 This Agreement sets out:

1.4.1 the Services that PHARMAC will provide and the standards for the provision of those Services;

1.4.2 various matters relating to the roles of the Parties, financial management, formalising variations to this Agreement and reporting obligations; and

1.4.3 the amount of Funding the Crown will pay to PHARMAC.

Background

1.5 PHARMAC is a Crown entity established under section 46 of the New Zealand Public Health and Disability Act 2000 ("the NZPHD Act"), and is a Crown agent for the purposes of the Crown Entities Act 2004.

1.6 Pursuant to section 7 of the Crown Entities Act 2004, PHARMAC must give effect to Government policy when directed by the Responsible Minister.

1.7 PHARMAC's enabling legislation, the NZPHD Act, sets out its functions. Funding for those functions is provided by the Crown and by District Health Boards.

1.8 The Minister is the Responsible Minister for PHARMAC. One or more Associate Ministers of Health may also hold an interest in the PHARMAC.

1.9 The Minister has authorised the Ministry of Health ("the Ministry") to act as the agent of the Minister in general matters relating to governance and accountability.

1.10 Defined terms used in this Agreement are set out in Schedule A to this Agreement.

1.11 The Services specified in Schedule B to this Agreement are all Services that PHARMAC provides.

1.12 The Crown and PHARMAC have agreed to enter into this Agreement to set out the terms and conditions on which PHARMAC will provide its Services.

Respective roles of the Parties

Minister of Health on behalf of the Crown

1.13 The Minister is accountable to Parliament for the performance of PHARMAC. The role of the Minister in relation to this Agreement includes:

1.13.1 determining the New Zealand Health Strategy and the New Zealand Disability Strategy;

1.13.2 obtaining Parliamentary appropriations with which to fund PHARMAC;

1.13.3 setting expectations to inform and guide PHARMAC's preparation of its Statement of Intent, consistent with the level of funding available;

1.13.4 monitoring and reviewing the performance of PHARMAC, including against this Agreement;

1.13.5 holding PHARMAC accountable for its performance, including under this Agreement; and

1.13.6 undertaking other roles as set out in the NZPHD Act, the Crown Entities Act 2004, the Public Finance Act 1989 and other relevant statutes and regulations.

Ministry of Health on behalf of the Minister of Health

1.14 The Ministry acts as the Minister's agent in the Minister's relationship with PHARMAC. The Ministry's role includes:

1.14.1 reviewing PHARMAC's Statement of Intent and financial statements;

1.14.2 negotiating an annual Agreement and any protocols, as required by the Minister;

1.14.3 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;

1.14.4 advising the Minister on the compliance of PHARMAC with its legislation;

1.14.5 advising the Minister on PHARMAC's capability to achieve its results;

1.14.6 managing payments to PHARMAC under this Agreement;

1.14.7 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;

1.14.8 providing regular briefings to the Minister on PHARMAC's performance and attending meetings between the Minister and PHARMAC, as required; and

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

PHARMAC

1.15 PHARMAC shall perform the Services.

1.16 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 Intent (including any part of its operations that it has contracted a third party to deliver).

1.17 PHARMAC is responsible for maintaining the capability needed to meet its responsibilities under this Agreement at all times. PHARMAC must inform the Ministry of any significant capability issues that are likely to interfere with the delivery of the Services.

1.18 In providing the Services specified in this Agreement, PHARMAC will comply with all of its legal obligations.

1.19 In providing the Services, PHARMAC will have regard for the Government's Expectations, as defined in Schedule A. Further, in developing and implementing its Employment Relations Strategy, PHARMAC will take into account the Government's Expectations for Pay and Employment Conditions in the State Sector.

2. SERVICE DELIVERY PERFORMANCE

Services to be provided

2.1 PHARMAC will 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 to be provided by PHARMAC, whether directly or indirectly funded (via District Health Boards or otherwise) through Vote Health.

2.3 In the event that PHARMAC may be unable to meet any of its performance measures, PHARMAC will provide the Ministry with the details of the risk as soon as practicable. Depending on the significance of the matter, PHARMAC may advise the Ministry prior to the next scheduled report.

2.4 PHARMAC will, as part of that advice, propose the responses or actions it will take to achieve the provision of the Services as specified.

Intellectual property

2.5 Without limiting any other rights that the Crown may already have, the Ministry may use (which includes copying, modifying, developing or distributing) any intellectual property in anything provided to it by or on behalf of PHARMAC free of charge under this Agreement as it thinks fit.

2.6 Clause 2.5 shall survive expiry or termination of this Agreement.

3. FINANCIAL MANAGEMENT

Funding from Vote Health

3.1 The Ministry will pay PHARMAC a total of fifteen million, one hundred and thirty-five thousand dollars ($15,135,000), GST exclusive from Vote Health to deliver the Services.

3.2 The method and timing of payments is set out in Schedule C to this Agreement.

3.3 The Parties agree that the payments in clause 3.2 above, plus any other sources of income in accordance with the Statement of Intent, are sufficient to provide the Services.

Projected financial performance

3.4 The projected financial performance of PHARMAC for the term of this Agreement is set out in Appendix D. This information supersedes the indicative projected financial performance set out in PHARMAC's 2012/13 Statement of Intent.

Financial operating environment

3.5 The financial operating environment for PHARMAC is based on the Public Finance Act 1989 and the Crown Entities Act 2004.

Crown accounting policies

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

Application of the Public Finance Act 1989 and the Crown Entities Act 2004

3.7 The Parties agree that Parliament has appropriated the money provided under this Agreement for delivery of the Services, and that the Public Finance Act 1989 and the Crown Entities Act 2004 apply to the appropriation, including the restrictions on investments in section 161 of the Crown Entities Act 2004.

Use of surplus funding

3.8 Annual net surpluses, arising from the efficient delivery of Services, may be retained by PHARMAC for use in subsequent years, subject to clauses 3.8 to 3.11 of this Agreement.

3.9 Expenditure of any surplus will be made in accordance with PHARMAC's Statement of Intent and reflected in the projected financial performance.

3.10 Approved spending of any surpluses must be consistent with Government health objectives and not be contrary to Government policy.

3.11 Under section 165 of the CE Act, the Minister of Finance may direct PHARMAC to pay to the Crown any surpluses.

3.12 Measures must be put in place to achieve and maintain the optimal accumulated equity levels, to be agreed with the Ministry. For 2012/13, the agreed level is $1,600,000 as retained earnings and reserves. In addition, there currently exists a

Herceptin SOLD trial reserve; a Legal Risk Fund reserve; and a minimum level of $10,000,000 for the Discretionary Pharmaceutical Fund (DPF).

4. REPORTING REQUIREMENTS

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 and Associate Ministers, the Ministry and PHARMAC will support formal reporting.

Formal reporting

4.3 PHARMAC will comply with the reporting requirements of the Crown Entities Act 2004.

Monthly reports

4.4 PHARMAC will provide the Minister and the Ministry with a monthly performance report within three working days following the regular PHARMAC board meeting, covering, at a minimum:

4.4.1 major Schedule decisions;

4.4.2 significant issues or developments the Minister or Ministry should be aware of, including any potential non-performance against the Agreement; and

4.4.3 PHARMAC's financial performance (including in respect of operational and combined pharmaceutical budgets) showing:

4.4.3.1 full financial statements;

4.4.3.2 forecast full year actual for PHARMAC (in Quarters 2 and 3);

4.4.3.3 expenditure against budget for each output class (in Quarters 2, 3, and 4), and year to date and forecast position at year end;

4.4.3.4 value for money indicators and benchmarks;

4.4.3.5 any new financial risks, their probability and consequence and how they are or will be managed;

4.4.3.6 an explanation of any significant variances; and

4.4.3.7 an explanation of progress with reaching/maintaining the agreed optimal accumulated equity level.

Quarterly reports

4.5 PHARMAC will provide quarterly performance reports to the Minister, each being the monthly report as specified in clause 4.4 above plus additional information described in clause 4.6 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 2012 to 30 September 2012	within 3 working days following the October 2012 board meeting
Quarter 2	1 October 2012 to 31 December 2012	within 3 working days following the January 2013 board meeting
Quarter 3	1 January 2013 to 31 March 2013	within 3 working days following the April 2013 board meeting
Quarter 4	1 April 2013 to 30 June 2013	within 3 working days following the July 2013 board meeting

4.6 Each report will, if relevant and material to performance in the quarter, include the following performance information:

4.6.1 a brief comparative analysis of performance measure results. This analysis should draw together the results to ensure a clear picture of performance by including, where applicable, the following information:

4.6.1.1 an overview of highlights and overall performance (major activities), including any unusual events in the reporting period;

4.6.1.2 how PHARMAC has responded to the Government's Expectations, and the longer term economic and fiscal impacts of its activities, linking to particular events or issues if possible;

4.6.1.3 how PHARMAC's performance measure results have or will help decision-making (and what action has resulted);

4.6.1.4 trends over time, benchmarking with comparable New Zealand or international organisations, and sector-wide perspectives;

4.6.1.5 use of the Legal Risk Fund, including explaining why the Fund has been used;

4.6.1.6 use of the Discretionary Pharmaceutical Fund, including year end forecast; and

4.6.1.7 any new risks, their probability and consequence and how they are or will be managed;

4.6.1.8 stakeholder satisfaction/involvement;

4.6.1.9 any capability issues; and

4.6.1.10 any initiatives to ensure value for money.

4.6.2 list the measures from Schedule B with the status of each measure, for example, the measures that have been achieved or have not been achieved in relation to the deliverables that fell due in that period;

4.6.3 for those measures that have not been achieved, why they were not met, the corrective actions taken or planned and any consequences;

4.6.4 a description of any work that is underway for deliverables due in subsequent periods, noting the key actions commenced towards their completion; and

4.6.5 a description of any other ongoing or 'as required' work that was performed during the period for deliverables with specific timeframes, for the completion of those deliverables.

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.

Informal reports and communication

4.8 In addition to the formal reports specified 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 in advance 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 statement of the Government's Expectations. This advice should include any proposed remedial action;

4.8.2 inform the Minister and the Ministry sufficiently in advance of any issue, risk or public comment likely to be of significance to the Minister or the Government, relating to PHARMAC and/or its performance and the proposed plan of action;

4.8.3 promptly provide the Ministry with all information within PHARMAC's control in relation to the Agreement that the Ministry requests from time to time, during and after the term of the Agreement; and

4.8.4 keep the Ministry informed of upcoming key meetings with, or information requests from, Ministers, Members of Parliament, Select Committees and so forth.

Ministerial servicing

4.9 From time to time the Ministry or the Minister will require PHARMAC to provide information in relation to PHARMAC that includes, but is not limited to, the following:

4.9.1 the preparation of Ministerial briefings and draft speech notes;

4.9.2 Ministerial correspondence and Select Committee inquiries; and

4.9.3 Parliamentary questions.

4.10 PHARMAC agrees to provide the Ministry or the Minister 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 of Health at the time of the request

Speeches	As agreed with the Ministry of Health at the time of the request

Parliamentary questions (PQs)	Written: within 2 working days Oral: by 12 noon same day
Routine Ministerial correspondence	Within 4 working days
Select Committee inquiries	As agreed with the Ministry of Health at the time of the request

Minister's advice to PHARMAC

4.11 The Ministry, on behalf of the Minister will, in a timely manner:

4.11.1 inform PHARMAC of any issue likely to be of significance to it and provide the information that PHARMAC requires to fulfil its obligations under this Agreement; and

4.11.2 use its best endeavours to accommodate specific requests from PHARMAC, including for attendance at relevant meetings.

Management of policy change

4.12 The Minister and the Ministry will, to the extent that this is appropriate and not related to the exercise of statutory powers, functions, or duties:

4.12.1 ensure PHARMAC is consulted prior to introducing any new policy that will or may impact significantly on PHARMAC; and

4.12.2 negotiate with PHARMAC, in the context of the development of the PHARMAC's Statement of Intent and/or this Agreement, changes to the range or scope of Services to be funded and/or any changes to current funding strategies or methodologies.

4.13 PHARMAC will use its best endeavours to consult with the appropriate Ministry personnel during the development of any significant operational initiatives related to the Services in this Agreement.

5. VARIATIONS TO THE AGREEMENT AND NEXT AGREEMENT

Variations to the Agreement

5.1 This Agreement may be varied at any time during its term by the mutual consent of both Parties. All amendments shall be recorded in writing and signed by the Chair of PHARMAC and by the Minister.

5.2 In the event that PHARMAC considers the specification of Services to no longer be appropriate or that a significant shift in the Services is required, PHARMAC will propose a variation to this Agreement.

5.3 In seeking a variation PHARMAC will include a description of the situation and the nature of the variation sought, as well as justification for the variation and a statement of the financial implications.

5.4 Any agreed and signed variations will be read as part of this Agreement. Copies of the original Agreement and variations to this Agreement will be held by both PHARMAC and the Ministry.

Next Agreement

5.5 PHARMAC and the Minister agree that they will negotiate with each other in good faith with a view to entering into an Agreement for the next financial year, 2013/14, prior to its commencement.

6. DISPUTES RESOLUTION PROCESS

6.1 If any dispute arises between PHARMAC and the Ministry concerning this Agreement, PHARMAC and the Ministry will actively, openly and in good faith discuss that difference or dispute with a view to resolving it by mutual agreement.

6.2 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

7.1 The Minister may review the operations and performance of PHARMAC at any time, as per section 132 of the Crown Entities Act 2004. 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 Ministry all applicable information within the control of PHARMAC.

8. ADDRESSES FOR CORRESPONDENCE

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

Mr David Pannett
Manager, Governance & Crown Entities
Ministry of Health
PO Box 5013
Wellington

Mr Steffan Crausaz
Chief Executive
PHARMAC
PO Box 10-254
Wellington

9. AGREEMENT AND SIGNATURES

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

Hon Tony Ryall
Minister of Health

Signature: Ryall

Date: .....

in the presence of:

Signature: .....

Name: Kimberly Gilmore

Address: Rm 6.3, EXECUTIVE WING, PARLIAMENT BUILDINGS.

Occupation: Health Advisor

And for the **PHARMACEUTICAL MANAGEMENT AGENCY** by

Mr Stuart McLauchlan
Chairperson

Signature: .....

Date: 24-12-12

in the presence of:

Signature: .....

Name: Karen Thomas

Address: Areala

Occupation: Accountant

SCHEDULE A: DEFINITIONS AND INTERPRETATION

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
- **"Crown"** means Her Majesty The Queen in Right of Her Government in New Zealand
- **"Crown entity"** has the same meaning as in section 7 of the Crown Entities Act 2004
- **"day"** means any period of up to 24 consecutive hours ending at midnight
- **"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
- **"Legal Risk Fund"** means PHARMAC's fund to meet legal costs and expenses incurred when defending, avoiding or initiating litigation
- **"the NZPHD Act"** means the New Zealand Public Health and Disability Act 2000, as amended
- **"Parties"** means the Crown and PHARMAC
- **"PHARMAC"** means the Pharmaceutical Management Agency, established under the New Zealand Public Health and Disability Act 2000
- **"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 Crown Entities Act 2004.

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

Outputs

The Services are as per the Statement of Intent 2012-2015, Statement of Forecast Service Performance below.

In providing the Services, the Commission will meet the service description and performance measures in the Statement of Forecast Service Performance.

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 Commission to agree with the Ministry the timing and quality requirements for the discharge of those responsibilities.

STATEMENT OF FORECAST SERVICE PERFORMANCE (FROM STATEMENT OF INTENT 2012-2015)

(Begins overleaf)

Statement of Forecast Service Performance for 2012/13

Outputs – PHARMAC's activities

Our main activities for the financial year 1 July 2012 to 30 June 2013 are set out below. The output classifications align with those illustrated in the chart on page 5. We have also indicated the level of expenditure budgeted on each output class. Expenditure figures relate to spending from PHARMAC's operational budget, not the $783.6 million Combined Pharmaceutical Budget. Note that not all outputs are measured and reported on.

Output class 1 – Making decisions about pharmaceuticals — $7.99 million

We want to ensure our processes are as efficient and effective as possible, because good quality processes increase the likelihood of making the best possible decisions. Our decisions follow a standard process that involves economic analysis, clinical advice from the Pharmacology and Therapeutics Advisory Committee (PTAC), negotiations with pharmaceutical suppliers and, often, public consultation. In making its decisions PHARMAC uses nine decision criteria (see box panel).

Our decisions around whether to fund medicines are a major component of our role in securing for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided. PHARMAC is tasked with managing the notional budget set aside by DHBs for community pharmaceuticals. From 2011/12 funding for pharmaceutical cancer treatments was met from within the expanded Combined Pharmaceutical Budget. From 2012/13, the CPB also includes funds for vaccines. PHARMAC does not hold these funds – however, it monitors spending with the aim of ensuring that spending does not exceed that agreed notional budget. From 2010/11 PHARMAC established a Discretionary Pharmaceutical Fund that supports pharmaceutical decision-making.

Decisions involve choice. One of the ways in which PHARMAC's performance can be measured is in considering the average value for money of the choices it makes compared with the average value of all available choices. Assurance to the question, "is PHARMAC making good choices" is met through the robust inputs employed by PHARMAC to manage its decision-making processes.

PHARMAC's Decision Criteria

PHARMAC uses the criteria set out below, where applicable and giving such weight to each criterion as PHARMAC considers appropriate, when making Pharmaceutical Schedule decisions:

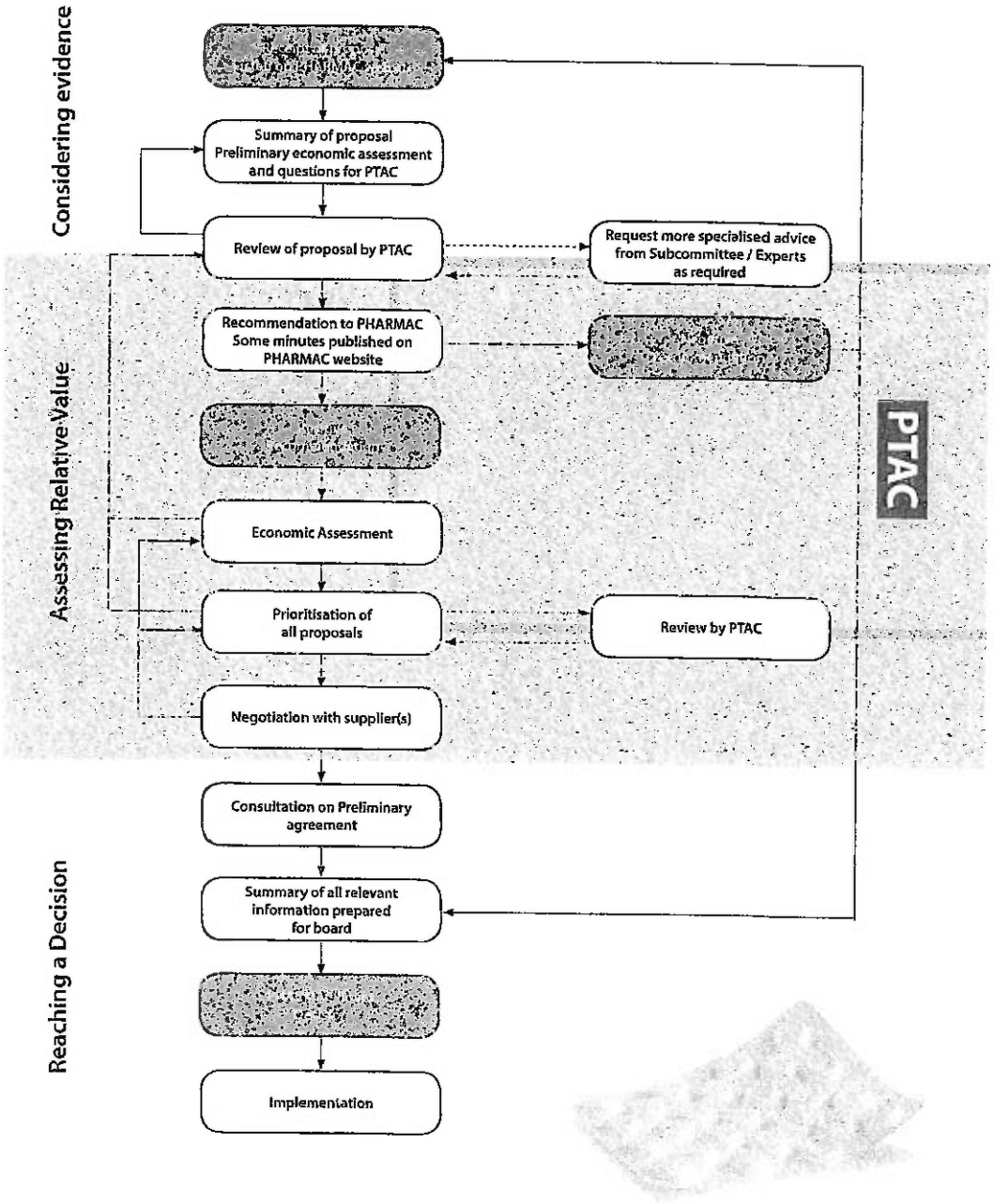
- The health needs of all eligible people;
- The particular health needs of Māori and Pacific peoples;
- The availability and suitability of existing medicines, therapeutic medical devices and related products and related things;
- The clinical benefits and risks of pharmaceuticals;
- The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health & disability support services;
- The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Schedule;
- The direct cost to health service users;
- The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement or elsewhere, *and*
- Such other criteria as PHARMAC thinks fit.

One of our activities in support of effective decision making involves monitoring pharmaceutical patents and, where appropriate, questioning or challenging them.

Not all of PHARMAC's decisions result in funding medicines – PHARMAC can also decline funding. These are decisions that also have impacts – for example, ensuring funding is available for other, more cost-effective medicines. An online Application Tracker on PHARMAC's website (www.pharmac.govt.nz) enables consumers, clinicians and industry representatives to track the progress of population-based funding applications.

Schedule decision making process

The process set out in this diagram is intended to be indicative of the process that may follow where a supplier or other applicant wishes a pharmaceutical to be funded on the Pharmaceutical Schedule. PHARMAC may, at its discretion, adopt a different process or variations of the process (for example, decisions on whether or not it is appropriate to undertake consultation are made on a case-by-case basis).



PHARMAC's decision-making framework is described in its Operating Policies and Procedures. A consultation process to review these is under way.

Output 1.1 Community Pharmaceutical Schedule

This is the list of medicines funded for all New Zealanders, and dispensed in the community. The Schedule is a comprehensive list of medicines covering the majority of New Zealanders' health needs. The Schedule decision-making process is outlined in the diagram on page 19.

Output 1.2 Pharmaceutical Cancer Treatments (PCTs)

PCTs are listed in the Schedule and from 2011/12 are included in the Combined Pharmaceutical budget. PHARMAC is also helping fund a multi-year international clinical trial to assess the relative efficacy of short or long duration (SOLD) treatment with the breast cancer medicine trastuzumab (Herceptin).

Output 1.3 Section H, Hospital Schedule

In addition to the Community Pharmaceutical Schedule, PHARMAC also manages Section H, a list of hospital medicines for which PHARMAC has negotiated national supply terms. Section H medicines are funded through DHB hospitals, so are not included in the CPB. In 2010 Government tasked PHARMAC with managing all hospital pharmaceuticals (see box panel).

Output 1.4 Special Access Panels

Some medicines are very expensive, and to help ensure these are appropriately targeted PHARMAC manages panels of expert doctors to apply the criteria on which patients can access treatment. Panels are maintained for:

- Cystic Fibrosis;
- Gaucher's Disease;
- Multiple Sclerosis;
- Pulmonary Arterial Hypertension;
- Human Growth Hormone (children and adult); and
- Treatments for chronic myeloid leukaemia (imatinib, dasatinib).

Around 4000 panel applications are received each year.

Output 1.5 Named Patient Pharmaceutical Assessment

This is the mechanism that gives individual patients access to medicines that are not otherwise funded through the Pharmaceutical Schedule or through DHB Hospitals. PHARMAC introduced the NPPA in 2012 following a comprehensive review of the previous Exceptional Circumstances schemes for community, hospital, and cancer medicines. Expenditure for NPPA community and cancer treatments continue to be drawn from the CPB, while hospital pharmaceuticals in the community approvals are funded by individual DHB hospitals.

HOSPITAL MEDICINES AND MEDICAL DEVICES

During 2010 the Government gave PHARMAC expanded roles including taking a greater role in managing hospital medicines, and in planning for the management of medical devices. These are multi-year projects that will see changes being implemented over the next two to three years.

Hospital Medicines

There is variation in the hospital medicines each DHB funds for its patients. The hospital medicines project aims to construct a list of medicines that every DHB funds, with changes made on a nationally-consistent basis. This aims to eliminate the phenomenon known as postcode prescribing, and may also create greater efficiencies through using a central agency (PHARMAC).

This is a multi-year project involving a staged approach to information-gathering and engagement with hospital clinicians, DHB managers, consumers and industry. PHARMAC will conduct therapeutic group reviews to construct a nationally binding hospital medicines schedule. The first three therapeutic groups to be reviewed (beginning in 2011) were cardiovascular, musculoskeletal (including arthritis), and infections.

Medical Devices

Government agencies are working to examine national management of medical devices. The Chairs and CEs of PHARMAC, Health Benefits Ltd and the National Health Committee have agreed to identify a small number of specific projects to work on in 2012/13 in order to develop how the three entities would work together.

The aim is to work towards completing a National Implementation Plan that would include establishing a national catalogue of devices, in consultation with clinicians, consumers, DHB managers and industry. This will feed into future decisions to be made by Cabinet.

Output 1.6 Schedule Rules

Once a medicine is listed, it may be prescribed for a patient within the Schedule rules. Community pharmaceuticals are dispensed by pharmacists, who are contracted by their DHBs to provide services. Pharmacy claims are paid by Ministry of Health Sector Services, on behalf of DHBs.

Output 1.7 Medical devices

We are responsible for a small number of medical devices. In the community these include:

- Pregnancy test kits;
- Blood glucose testing and management (i.e. test strips/meters and insulin needles/syringes);
- Asthma management (peak flow meters, spacers, masks);
- Contraception/IUDs; and
- Urine testing for blood/protein.

In DHB Hospitals we administer contracts for volatile anaesthetic agents which require a vaporiser device (Sevoflurane, Isoflurane, Desflurane). The device is supplied under the contract for the anaesthetic agent. We also procure radiological contrast media.

During 2010/11 PHARMAC was given greater responsibility to begin assuming responsibility for purchasing medical devices (see box panel P20) and this work is likely to grow in consultation with other health sector agencies. PHARMAC undertook funding consideration of insulin pumps, a new medical device, in 2012.

Making decisions about pharmaceuticals output measures

Impact		Output	2010/11 actual	2011/12 estimate	2012/13 target
Access	1.1	Community pharmaceutical Schedule decisions.	PHARMAC's clinical advisory committee PTAC met face to face on four occasions, with a further teleconference. PHARMAC completed 64 new or updated cost utility analyses.	We estimate that all funding decisions will be supported by evidence and made using PHARMAC's nine decision criteria.	All funding decisions are supported by evidence and made using PHARMAC's nine decision criteria.
Economic and system			Decisions were made on 85% of line items (excluding bids held open while awaiting Medsafe registration or patent expiry) within six months of the tender closing.	We estimate that decisions on >90% of line items (excluding bids held open while awaiting Medsafe registration) will be made within 6 months of the tender closing.	Decisions on >90% of line items (excluding bids held open while awaiting Medsafe registration) made within 6 months of the tender closing.

Output class 2 - Influencing medicines use — $9.54 million

Making decisions to subsidise medicines is only part of the pathway in medicines reaching New Zealanders. We have a legislative role to promote the responsible use of medicines. To do this, we communicate our decisions and provide information and support to help ensure medicines are prescribed and used well. This helps people to understand the reasons behind decisions. It also helps ensure that the health outcomes sought through the funding decision are realised, and that medicines aren't overused, underused or misused by patients. Medicine adherence – ensuring patients take the medicine prescribed for them in the way intended by their prescriber – is a further important component. Beyond providing information, this work includes workforce development, seeking community input, and working with health professionals to deliver the programmes so that the medicines that are funded for people are used optimally.

Output 2.1 Explaining decisions/ sharing information

We work to better explain our decisions through our notification letters, the PHARMAC website and information sent to health professionals and patients to help them adjust to the introduction of new medicines or brand changes. Our Consumer Advisory Committee provides advice to PHARMAC from a patient or consumer point of view on obtaining consumer views, communicating and engaging with them.

Output 2.2 Population Health Programmes

Our population health programmes are developed in response to evidence-based analysis and identified unmet need, and aim to improve access and promote optimal use of medicines. Key projects to be advanced in 2012/13 are outlined in the box opposite.

Sometimes decision implementation is supported by information provided to health professionals and consumers through our health education programmes, such as He Rongoā Pai He Oranga Whānau, a programme that provides seminars to Māori Community Health Workers and Primary Care Nurses.

We also work to share information and promote evidence-based prescribing to health professionals through our management of the PHARMAC Seminar Series and the work of bpac$_{nz}$ who currently provide (following a competitive tender) services to promote appropriate prescribing through high-quality educational materials and resources.

Our Population Health Programmes

One Heart Many Lives - aims to increase awareness of cardiovascular risk and provide tools for reduction of cardiovascular risk, particularly among Māori and Pacific men aged over 35.

Space to Breathe - aims to reduce hospitalisations among Māori and Pacific children with asthma through education and the use of preventer medication and self management plans.

Generic medicines - aims to reduce the concerns people have about generic medicines, such as effectiveness, safety, side effects and country of manufacture.

Antipsychotics in dementia - aims initially to assess the extent of inappropriate prescribing of antipsychotics for behavioural and psychological symptoms of dementia in residential care facilities. This review will inform development of an appropriate education resource and support programme to address inappropriate prescribing of antipsychotics in this setting.

Influencing medicines use output measures

Impact	Output		2010/11 actual	2011/12 estimate	2012/13 target
Access	2.2	Population health programmes.	Not reported in 2010/11	We estimate that demand for campaign materials will be equal to/ greater than previous year,	Amount of campaign materials distributed is greater than previous year.
Usage	2.2	Population health programmes	Not reported in 2010/11. Surveys from the five Seminar Series held in the first quarter of 2011/12 showed an average of 92.6% of respondents rated their satisfaction with the Series at least a 4 out of 5.	We estimate that Surveys of Seminar Series attendees will show minimum 90% of respondents rate their satisfaction with the Seminars at least four out of five (where 1 = poor, 5 = excellent)	Surveys of Seminar Series attendees show minimum 90% of respondents rate their satisfaction with the Seminars at least four out of five (where 1 = poor, 5 = excellent).

Output class 3 – Managing supply of pharmaceuticals $1.49 million

When a medicine is funded, this usually results in a supply contract that is negotiated between PHARMAC and the supplier.

Output 3.1 Contract management

PHARMAC has dedicated contract management resources which enable us to be more aware of when supply shortages might arise, and taking action to mitigate them. Better contract management has also enabled PHARMAC to more effectively manage rebate payments from pharmaceutical suppliers.

Output 3.2 Supply vigilance

We're also aware that medicines not on contract are important to patients and need to be monitored. This requires ongoing vigilance of the supply chain to ensure adequate supplies between pharmaceutical companies, wholesalers, pharmacists and patients.

Output 3.3 Direct distribution

PHARMAC also manages direct distribution of some high cost medicines directly to patients. This includes some medicines used to treat leukaemia, multiple sclerosis and enzyme deficiency disorders. In these cases, PHARMAC's active management helps ensure patients have timely access to the medicines they need, and that wastage of these expensive medicines is kept to a minimum. This helps ensure public funding for these medicines is used efficiently. In addition, PHARMAC helps manage ordering and distribution of nicotine replacement therapies to providers contracted by the Ministry of Health.

Managing supply of pharmaceuticals output measure

Impact	Output		2010/11 actual	2011/12 estimate	2012/13 target
Economic and system	3.1	Contract management.	Not reported in 2010/11	We anticipate that all low medicine stock situations are identified and managed.	Respond to low medicine stock reports, communicate effectively and take action as necessary to ensure patient needs for medicines are met.

Output class 4 – Providing policy advice and support $1.51 million

Output 4.1 Advice and support services to the health sector

PHARMAC provides advice and support work for other health sector agencies to improve the cost effectiveness of health spending. This includes management of pharmaceutical spending in the community, advice and support to DHBs on a range of matters including pharmacy contracting and medicines distribution, and contribution to the development of a NZ Universal List of Medicines and National Formulary, amongst other sector-wide initiatives including those that seek to reduce the administrative workload of clinicians.

We undertake work to assist health sector procurement where it fits with PHARMAC's skills, for example with the influenza vaccine and some blood products. Government has identified further potential value-for-money initiatives that PHARMAC can contribute to – either through its activities or through providing advice and support to DHBs or the Ministry of Health.

Output 4.2 Policy advice

We provide specialist operational policy advice to Ministers and officials from a range of government agencies. This includes meetings, papers, submissions, Ministerial support services and other information.

Output 4.3 Fund management

PHARMAC manages pharmaceutical expenditure on behalf of DHBs within the amount approved by the Minister of Health. PHARMAC collects rebates from pharmaceutical suppliers and distributes these back to District Health Boards.

PHARMAC also has access to a legal risk fund, with a value of $6.3 million in 2012/13, which is used to meet litigation costs that are not otherwise met from PHARMAC's regular operational spending on legal services.

From 2010/11 PHARMAC established the Discretionary Pharmaceutical Fund, a funding mechanism to enable more effective use of the pharmaceutical budget across financial years.

Providing policy advice and support output measure

Impact	Output		2010/11 actual	2011/12 estimate	2012/13 target
Economic and system	4.2	Policy advice.	A baseline survey of PHARMAC's policy requesters was conducted in June/July 2011. The results of the survey give PHARMAC an average, out of a possible score of 5, of: • 4.33 for timeliness of advice; • 4.78 for quality of analysis given; • 4.89 for relevance of the advice; • 4.56 for thoroughness; • 4.33 for clarity; and • 4.56 for informal policy support and availability.	We estimate an average survey score of at least 4 in each area.	An average survey score of at least 4.5 in each area.
Economic and system	4.3	Rebates distribution	All identified rebates due were collected and distributed to DHBs in a timely fashion	We estimate all identified rebates will be distributed by the end of the quarter following.	All fund use is in accordance with PHARMAC policy.

SCHEDULE C: PAYMENT TERMS AND SCHEDULE OF PAYMENTS

The Minister shall pay a total sum of fifteen million, one hundred and thirty-five thousand dollars ($15,135,000) (GST exclusive) from Vote Health for the period 1 July 2012 to 30 June 2013 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 2012	4 July 2012	1,182,250
August 2012	4 August 2012	1,182,250
September 2012	4 September 2012	1,182,250
October 2012	4 October 2012	1,182,250
November 2012	4 November 2012	1,182,250
December 2012	4 December 2012	1,656,250
January 2013	4 January 2013	1,261,250
February 2013	4 February 2013	1,261,250
March 2013	4 March 2013	1,261,250
April 2013	4 April 2013	1,261,250
May 2013	4 May 2013	1,261,250
June 2013	4 June 2013	1,261,250
	TOTAL	**15,135,000**

SCHEDULE D: PROJECTED FINANCIAL STATEMENTS

Prospective Statement of Comprehensive Income

	Note	For the period of 1 July 2012 to 30 June 2013	For the period of 1 July 2013 to 30 June 2014	For the period of 1 July 2014 to 30 June 2015
	1	$000 (GST excl)	$000 (GST excl)	$000 (GST excl)
Revenue				
Crown contribution		15,135	15,135	15,135
DHB Contribution		3,312	3,372	3,427
Additional Sector Contribution		1,400	6,170	6,170
Discretionary Pharmaceutical Fund (DPF)				
Other Revenue		189	315	215
Interest Revenue		130	140	140
Legal Risk Fund (LRF) Interest Revenue	2	200	200	200
Total revenue		**20,366**	**25,332**	**25,287**
Expenditure				
Personnel Costs		8,860	11,673	11,807
Operating Costs		11,184	13,384	13,497
Herceptin Sold Trial		574	519	150
Depreciation		528	528	528
DPF payments to DHBs	3	578	0	0
LRF payments for litigation costs		200	200	200
Finance costs		9	12	12
Total Expenditure		**21,933**	**26,316**	**26,194**
Net Surplus/(deficit)		**(1,567)**	**(984)**	**(907)**
Other Comprehensive Income		0	0	0
Total Comprehensive Income		**$(1,567)**	**$(984)**	**$(907)**

1. The above statement should be read in conjunction with the accounting policies set out in Appendix 1.
2. LRF interest rate calculation 3.17% on an average balance $6,300k.
3. DPF forecast is linked to CPB forecast.

Prospective Statement of Comprehensive Income, by Output Class

Output Expenditure Budget 2012/13	Funding MOH	Funding DHB	Funding Other	Output Expenditure	Net surplus/ (deficit)
Decision-making	7,010	150	900	(8,892)	(832)
Influencing medicine use	6,042	2,342	900	(9,936)	(652)
Supply management	1,090	300	19	(1,494)	(85)
Policy advice and support	993	520	100	(1,611)	2
Total Expenditure	**15,135**	**3,312**	**1,919**	**(21,933)**	**(1567)**

Output Expenditure Budget 2013/2014	Funding MOH	Funding DHB	Funding Other	Output Expenditure	Net surplus/ (deficit)
Decision-making	7,010	1,005	4,920	(13,325)	(390)
Influencing medicine use	6,042	1,547	1,500	(9,736)	(647)
Supply management	1,090	300	155	(1,494)	51
Policy advice and support	993	520	250	(1,761)	2
Total Expenditure	**15,135**	**3,372**	**6,825**	**(26,316)**	**(984)**

Output Expenditure Budget 2014/2015	Funding MOH	Funding DHB	Funding Other	Output Expenditure	Net surplus/ (deficit)
Decision-making	7,010	1,005	4,920	(13,325)	(390)
Influencing medicine use	6,042	1,547	1,500	(9,636)	(547)
Supply management	1,090	355	55	(1,472)	28
Policy advice and support	993	520	250	(1,761)	2
Total Expenditure	**15,135**	**3,427**	**6,725**	**(26,194)**	**(907)**

Prospective Statement of Financial Position

	Note	For the period of 1 July 2012 to 30 June 2013	For the period of 1 July 2013 to 30 June 2014	For the period of 1 July 2014 to 30 June 2015
	1	$000 (GST excl)	$000 (GST excl)	$000 (GST excl)
PUBLIC EQUITY				
Retained Earnings & Reserves		2,822	2,357	1,600
Herceptin Sold Trial Reserve		809	290	140
Discretionary Pharmaceutical Fund (DPF)	2	14,969	14,969	14,969
Legal Risk Fund		6,343	6,343	6,343
TOTAL PUBLIC EQUITY		**24,943**	**23,959**	**23,052**
Represented by:				
Current Assets				
Cash and bank		26,943	25,959	25,052
Receivables and prepayments		100	100	100
Total current assets		27,043	26,059	25,152
Non-current assets				
Property, Plant and Equipment		700	700	700
Intangible assets		200	200	200
Total non-current assets		900	900	900
Total assets		**27,943**	**26,959**	**26,052**
Current Liabilities				
Creditors and other payables		2,500	2,500	2,500
Employee entitlements		500	500	500
Total current liabilities		3,000	3,000	3,000
NET ASSETS		**24,943**	**23,959**	**23,052**

Note:
1. The above statement should be read in conjunction with the accounting policies set out in Appendix 1.
2. Discretionary Pharmaceutical Fund forecast is linked to CPB forecast.

Prospective Cash Flow Statement

	For the period of 1 July 2012 to 30 June 2013	For the period of 1 July 2013 to 30 June 2014	For the period of 1 July 2014 to 30 June 2015
	$000 (GST incl)	$000 (GST incl)	$000 (GST incl)
Cash flows – Operating activities			
Cash was provided from:			
- Crown Contribution	15,135	15,135	15,135
- DHB Contribution	3,312	3,372	3,427
- Additional Sector Contribution	1,400	6,170	6,170
- Interest Revenue	130	140	140
- LRF Interest revenue	200	200	200
- Other Income	189	315	215
	20,366	25,332	25,287
Cash was disbursed to:			
- Cash outflow to suppliers and employees	(20,405)	(25,188)	(25,066)
- Net GST	(500)	(600)	(600)
	(20,905)	(25,788)	(25,666)
Net cash flow from operating activities	**(539)**	**(456)**	**(379)**
Cash flows – Investing activities			
Cash was disbursed to:			
- Purchase of fixed assets	(528)	(528)	(528)
Net cash flow from investing activities	**(528)**	**(528)**	**(528)**
Cash flows – Financing activities	0	0	0
Net cash flow from financing activities	**0**	**0**	**0**
Net increase/(decrease) in cash held	(1,567)	(984)	(907)
Add opening cash brought forward	28,510	26,943	25,959
Closing cash balance	**26,943**	**25,959**	**25,052**

Note: The above statement should be read in conjunction with the accounting policies set out in Appendix 1.

Prospective Movement in Equity

	For the period 1 July 2012 to 30 June 2013	For the period 1 July 2013 to 30 June 2014	For the period 1 July 2014 to 30 June 2015
	$000 (GST incl)	$000 (GST incl)	$000 (GST incl)
RETAINED EARNINGS			
Balance at 1 July	3,237	2,822	2,357
Net surplus/(deficit)	(1,567)	(984)	(907)
Net transfer from/(to) Herceptin SOLD trial fund	574	519	150
Net transfer from/(to) discretionary pharmaceutical fund	578	0	0
Net transfer from/(to) legal risk fund	0	0	0
Balance at 30 June	**$2,822**	**$2,357**	**$1,600**
HERCEPTIN SOLD TRIAL FUND			
Balance at 1 July	1,383	809	290
Add: Net transfer from/(to) retained earnings	(574)	(519)	(150)
Balance at 30 June	**$809**	**$290**	**$140**
DISCRETIONARY PHARMACEUTICAL FUND			
Balance at 1 July	15,547	14,969	14,969
Add: Income received transferred from/(to) retained earnings	0	0	0
Less: Pharmaceutical expenses transferred from/(to) retained earnings	(578)	0	0
Balance at 30 June	**$14,969**	**$14,969**	**$14,969**
LEGAL RISK FUND			
Balance at 1 July	6,343	6,343	6,343
Add: Interest received transferred from/(to) retained earnings	200	200	200
Add: Other Income received transferred from/(to) retained earnings	0	0	0
Less: Litigation expenses transferred from/(to) retained earnings	(200)	(200)	(200)
Balance at 30 June	**$6,343**	**$6,343**	**$6,343**
TOTAL PUBLIC EQUITY	**$24,943**	**$23,959**	**$23,052**

Note: The above statement should be read in conjunction with the accounting policies set out in Appendix 1.

Reconciliation of Net Surplus to Cash Flow from Operating Activities

	For the period of 1 July 2012 to 30 June 2013	For the period of 1 July 2013 to 30 June 2014	For the period of 1 July 2014 to 30 June 2015
	$000 (GST excl)	$000 (GST excl)	$000 (GST excl)
Net operating surplus/(deficit)	**(1,567)**	**(984)**	**(907)**
Add non-cash items:			
Depreciation	528	528	528
Total	**(1,039)**	**(456)**	**(379)**
Add/(less) working capital movements:			
Decrease (increase) in receivables	0	0	0
Increase (decrease) in payables	500	0	0
Working Capital Movement – net	500	0	0
Net cash flow from operating activities	**(539)**	**(456)**	**(379)**

Note: The above statement should be read in conjunction with the accounting policies set out in Appendix 1.