

# **Memorandum of Understanding**

**relating to**  
the working relationship between PHARMAC and DHBs

**Pharmaceutical Management Agency**  
PHARMAC

**and**

**20 District Health Boards**  
DHBs

**Date**  
September 2011

This Memorandum of Understanding is made on

116 September 2011

- between (1) **Pharmaceutical Management Agency** a Crown entity established under section 46 of the New Zealand Public Health and Disability Act 2000 (NZPHD Act) (**PHARMAC**)
- and (2) **20 District Health Boards**, all of which are Crown entities established under section 19 of the NZPHD Act (**DHBs**),
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## 1. BACKGROUND

DHBs and PHARMAC have had a relationship agreement from January 2002. A new Memorandum of Understanding replaced the 2002 agreement in 2010; and established a framework by which the parties can annually record and review the key projects, strategies and actions that they have agreed to work on together. This 2010 MOU has been updated in 2011 to reflect changes that have occurred in pharmaceutical budget parameters and management.

## 2. RATIONALE

DHBs and PHARMAC have some common objectives and need to work together to ensure they are achieved. DHBs and PHARMAC are committed to working collaboratively to effect improvements in the overall performance of the New Zealand health and disability sector and meet their respective legislative and accountability obligations.

## 3. FUNDAMENTAL PRINCIPLES

This agreement is intended to record how the parties will work together. It is motivated by a desire to maintain the current constructive and effective working relationship between DHBs and PHARMAC.

The principles that will underpin our relationship are as follows:

- We are committed to a long term, co-operative and collaborative relationship;
- We will act towards each other with honesty and in good faith;
- We will work in a constructive manner recognising each other's viewpoints and respecting differences;
- We will communicate openly with each other on a regular basis at both national and regional and DHB level;
- We recognise that each of us has both unique and common accountabilities;
- Equity of access, reducing inequalities and improving health outcomes for individuals and communities will guide our relationship and decision making;
- We will encourage new and creative ways to work together on our mutual business; and
- We will endeavour to resolve any disputes between us constructively and expeditiously.

If this Memorandum of Understanding conflicts in any way with our legislative obligations or our obligations set out in formal Accountability Arrangements, then those obligations and arrangements will take precedence.

## 4. ROLES

Both DHBs' and PHARMAC's objectives and functions are set out in the NZPHD Act and, for PHARMAC, also in a ministerial direction made on 4 September 2001<sup>1</sup>. DHBs and PHARMAC are each accountable to the Minister of Health for the performance of their objectives and functions. In addition, DHBs' and PHARMAC's obligations, commitments, strategic directions and targets are recorded in each organisation's statement of intent and in the output agreement each enters into with the Crown (the **Accountability Arrangements**).

The NZPHD Act requires that, in performing any of its functions in relation to the supply of pharmaceuticals, a DHB must not act inconsistently with the Pharmaceutical Schedule.

The Pharmaceutical Schedule is managed by PHARMAC and sets out those pharmaceuticals that are subsidised in the community and pharmaceutical cancer treatments delivered in DHB hospitals, the level of subsidy, and any restrictions associated with patient access to that subsidy; it also sets out pharmaceuticals that are available to be purchased and used by DHB Hospitals, including those for which national prices have been negotiated by PHARMAC, associated rules and discretionary variance limits, and the management of hospital exceptional circumstances.

DHBs provide the funding for the Combined Pharmaceutical Budget (the **pharmaceutical budget**) which PHARMAC manages on their behalf. The pharmaceutical budget covers the costs associated with prescribing within the Schedule Rules, as well as funding for management of named patients in community and cancer exceptional circumstances.

## 5. ACTIONS

### **PHARMAC**

To give effect to this Memorandum of Understanding, for its part PHARMAC will:

1. Engage with DHBs on the development of an annual (**pharmaceutical budget**) and **budget parameters** for community pharmaceuticals and pharmaceutical cancer treatments (PCTs) and discuss with DHBs any proposed adjustments to the base budget throughout the year including potential new investment in areas that are forecast to create net benefits to the sector. Establishment of the annual budget will be in accordance with agreed budget setting principles and other relevant policies or directions and supported by advice from PHARMAC to DHBs on:
  - forecasts of pharmaceutical expenditure, distribution of rebates and the recommended funding provision for named patients in community and cancer exceptional circumstances
  - forecast use of the Discretionary Pharmaceutical Fund including DHB payments and receipts
  - potential new investments and their associated cost/benefit to the sector.
2. Ensure that DHBs are consulted on issues, relating to the management of the Pharmaceutical Schedule, which are likely to affect them.
3. Ensure that, when making Pharmaceutical Schedule decisions, it considers the total impact of proposals on DHBs including (but not limited to) costs to DHBs' non-pharmaceutical budgets and the costs of distribution and dispensing of pharmaceuticals.
4. Develop strategies with the aim of promoting the **responsible use of pharmaceuticals**. This includes providing visible support and evidence based information to DHBs and other health providers to support optimal use of medicines as an integral part of clinical decision making.

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<sup>1</sup> Published in the New Zealand Gazette, 27 September 2001, notice number 6737 (<http://online.gazette.govt.nz/>)

5. Support implementation of policies or directions in relation to **hospital pharmaceuticals**, including the June 2010 Government decision that PHARMAC should manage the prioritisation and procurement of hospital medicines and work towards the establishment of a fixed budget for hospital medicines over a number of years.
6. **Invite** appropriate DHB clinicians to participate in PHARMAC advisory committees and take steps to **establish** appropriate mechanisms through which to share its clinical and economic assessments and its expertise to support clinical decision-making with respect to implementing the Pharmaceutical Schedule and managing exceptional circumstances from within DHBs' budgets.
7. Provide DHBs with **information and advice** requested in relation to pharmaceuticals to support them in engaging with the Minister and Ministry of Health on management of pharmaceuticals and for the negotiation of service contracts with community pharmacies.
8. Attend regular **formal meetings** of DHB representatives, such as the GMs Planning and Funding, and CEs.
9. **Invite** DHBs to participate in formal meetings of PHARMAC where appropriate.

#### **DISTRICT HEALTH BOARDS**

To give effect to this Memorandum of Understanding, for their part DHBs will:

1. Provide **guidance and direction** on district health board **priorities** to support PHARMAC's objective and functions, with the aim of improving the value of pharmaceutical expenditure.
2. Engage with PHARMAC and agree the annual **pharmaceutical budget and budget parameters** for community and cancer treatment pharmaceuticals, and the funding provision within the pharmaceutical budget to meet the costs associated with named patients in community and cancer exceptional circumstances.
3. Provide **input to consultation** processes undertaken by PHARMAC, as appropriate, to support effective decision making.
4. Individually and collectively support PHARMAC on implementation and coordination of **responsible use of pharmaceuticals activities**.
5. Nominate and **support** involvement of appropriate DHB clinicians in PHARMAC's advisory committees.
6. **Respect** that **information** provided by PHARMAC may be commercially sensitive and act accordingly, actively seeking prior approval from PHARMAC to distribute any information or data on pharmaceuticals (whether related to usage, pricing or otherwise) to third parties.
7. **Seek advice** from PHARMAC, where appropriate, to support engagement with the Minister and Ministry of Health on management of pharmaceuticals and for the negotiation of service contracts with community pharmacies.
8. **Invite** PHARMAC to participate in regular formal meetings of DHB representatives, such as the GMs Planning and Funding, and CEs.
9. **Fund** an agreed level of PHARMAC's annual operational expenses.
10. **Ensure** that they act consistently with the Pharmaceutical Schedule.

## 6. STRATEGY IMPLEMENTATION

Schedule One to this Agreement sets out the key areas of mutual, ongoing interest of the parties.

Each year the parties will agree the key budgets, projects, strategies and actions required to support this Memorandum of Understanding. These will be documented in Schedule Two to this Memorandum of Understanding which will be updated annually and approved by the lead DHB CE.

## 7. MANAGING THIS MEMORANDUM OF UNDERSTANDING

The DHB CE Group will manage this Memorandum of Understanding through a nominated lead CE; PHARMAC will manage this Memorandum of Understanding through its CE and the Manager Corporate and External Relations.

At the individual DHB level the relationship with PHARMAC will be managed CE to CE.

We acknowledge that PHARMAC will also engage with DHBs using the established DHB processes to seek a collective view on key strategic issues.

## 8. TERM

This Memorandum of Understanding shall commence when signed by the parties and will continue until amended or terminated by the written agreement of the parties.

The parties will review this Memorandum of Understanding annually to ensure that it continues to support the roles and obligations of the parties.

## 9. CONFIDENTIALITY


It is agreed that neither party shall, without prior written approval of the other party, disclose the other party's Confidential Information.

Nothing in this clause shall be construed to prevent either party from disclosing any information to a third party if required or compelled by law, including, for the avoidance of doubt, disclosing information required to be disclosed under the Ombudsmen Act 1975 or the Official Information Act 1982 or the Privacy Act 1993 (as amended from time to time).


It is further agreed that the effect of these confidentiality clauses will survive termination, or expiry of this Memorandum of Understanding.

## SIGNATORIES TO THIS MEMORANDUM OF UNDERSTANDING

Signed for and on behalf of  
PHARMAC

  
.....  
Steffan Crausaz  
Acting Chief Executive  
PHARMAC

Signed for and on behalf of  
20 District Health Boards

  
.....  
Murray Georgel  
Chief Executive Officer  
MidCentral District Health Board  
(as lead CE for the DHB - PHARMAC  
relationship)

## ***Schedule One***

### **KEY AREAS OF MUTUAL, ONGOING, INTEREST**

#### ***Budget Setting***

PHARMAC will develop forecasts of pharmaceutical expenditure to inform the annual pharmaceutical budget setting process undertaken in conjunction with DHBs, the Ministry of Health and the Minister of Health. PHARMAC will provide DHBs with information on potential new investments, their associated costs/savings and cost-effectiveness, and their relative priority for investment. The parties will work together to develop an agreed timeframe for the pharmaceutical budget setting process. Both PHARMAC and DHBs need to agree the annual budget for pharmaceuticals from within the level of funding indicated by the Government and jointly recommend its quantum and composition to the Minister.

The principles on which we will base our joint recommendations include:

- value for money, taking into account:
  - forecasts of potential volume growth;
  - the potential for new investments;
  - government health priorities;
  - opportunities for dis-investment;
  - maximising the benefits of pharmaceutical spending relative to spending on other health-related services; and
- affordability, including:
  - ensuring that DHBs are able to remain within their overall funding parameters; and
  - the budget must be sustainable in terms of increased access to medicines, the effects of government priorities and the fiscal impact on DHBs.

PHARMAC and DHBs will discuss any proposed adjustments to the agreed budget throughout the year (either up or down) within the constraints of their respective Accountability Arrangements. This includes potential new investment in areas that may create net savings to the sector.

#### ***Additional services***

DHBs may request PHARMAC to provide services to DHBs that may be in addition to those described in PHARMAC's output agreement with the Crown. DHBs acknowledge that PHARMAC may seek funding from DHBs, or DHB regional groups, for the provision of such services and DHBs will ensure that any such requests are considered on a national basis, in accordance with established prioritisation processes.

PHARMAC will highlight any proposals with financial implications so that DHBs may inform their respective Finance Directors.

#### ***Access and Optimal Use programme setting***

DHBs and PHARMAC have responsibilities for managing pharmaceutical prescribing and responsible use. PHARMAC has a legislative responsibility to promote the responsible use of pharmaceuticals and is focused on national initiatives whereas DHBs have the ability to develop local responses and where appropriate these will be co-ordinated.

Access and Optimal Use (AOU) programmes run by PHARMAC are about effectively working with providers to reduce inappropriate prescribing or increase appropriate prescribing through the flow of good evidence based information. They also include some population-based behaviour and information programmes.

DHBs and PHARMAC agree to meet annually to discuss allocation of the annual PHARMAC operational budget contribution (an agreed percentage of the pharmaceutical budget plus any amount available via Ministry of Health funding) across a range of potential programmes.

PHARMAC will complete its AOU programme prioritisation process and discuss this with DHBs. The final programme will be agreed with DHBs, although release of funding remains subject to the PHARMAC Board's approval.

### ***Data/Information***

Pharmacies send claims for subsidised pharmaceuticals to the Ministry of Health Sector Services team (MOHSS), who pay the pharmacies on behalf of DHBs. MOHSS pass information on the claims, in monthly blocks, to the New Zealand Health Information Service (NZHIS) where they are added to a data warehouse called 'Pharmhouse'.

PHARMAC accesses Pharmhouse and uses information on claims, where it is available approximately 2 months after claims are approved, in order to perform its objective and functions.

PHARMAC's focus for analysis is trends in prescription pharmaceutical usage, rather than the date MOHSS pays claims. Because of this PHARMAC analyses expenditure in terms of when drugs have been dispensed from pharmacies, rather than the date MOHSS pays for them.

The information in Pharmhouse is not a perfect match for the information held at MOHSS. The differences are minor in terms of overall expenditure, but mean that reports prepared by PHARMAC may not be exactly consistent with reports prepared by MOHSS.

DHBs are to ensure that DHB Hospitals provide PHARMAC, on a monthly basis, any volume and price data (unless restricted by contracts) held by DHB Hospitals in respect of any pharmaceuticals used in Hospitals that are listed in the Pharmaceutical Schedule.

PHARMAC will provide each DHB with quarterly pharmaceutical expenditure reports. PHARMAC also agrees to consult regularly with DHBs on the type and form of forecast information provided and to make improvements to these reports based on feedback from DHBs. The quarterly reports will include:

- Expenditure on pharmaceuticals by therapeutic group;
- Number of dispensings;
- Estimated out year forecasts by DHBs; and
- Comparisons of expenditure for each DHB with national trends, and trends for other DHBs in the same region.

### ***Trust funds***

#### ***o Accounting***

Funds received from rebates and indemnities are held on trust for DHBs, by PHARMAC. Payments are also made for agreed expenses. A separate general ledger is maintained by PHARMAC to record and report these transactions. It is important the accounting is transparent and consistent with generally-accepted accounting standards. All interest earned in trust funds is accounted for and returned separately to DHBs. Funds held in trust are excluded from PHARMAC's operational results.

#### ***o Rebates***

Confidential pharmaceutical rebates help mitigate expenditure risk on management of pharmaceutical spend.

Whilst DHBs meet the cost of most community and cancer pharmaceuticals directly via MOHSS, PHARMAC manages the collection of rebates from pharmaceutical companies and distribution of rebates to DHBs. The majority of rebates received relate to the CPB and are credited back to the value of net expenditure on the CPB. Hospital and influenza vaccine rebates do not form part of the CPB and so are reported on separately and paid directly to DHBs.

DHBs and PHARMAC will ensure that the rebate distribution and allocation policy, agreed between them, is regularly reviewed. Some payments made into the rebate account include

one-off payments associated with reimbursement for actual drug costs associated with stock supplied by another supplier.

o ***Indemnities***

Payments received on behalf of DHBs under contractual indemnity provisions (generally relating to costs associated with potential out of stock events) are reported on separately and paid directly to DHBs as these do not form part of the pharmaceutical budget.

o ***Year end financial information***

PHARMAC will provide information as at 30 June to DHBs on:

- estimated pharmaceutical expenditure including rebate payments and accruals and use of the discretionary pharmaceutical fund
- Hospital rebate payments and accruals
- Other rebate payments and accruals
- Indemnity payments and accruals
- Interest received and paid.

### ***Exceptional Circumstances***

PHARMAC is responsible for the management of exceptional circumstances (EC) as part of its management of the Pharmaceutical Schedule. Changes to the way in which PHARMAC deals with EC are planned to occur from 1 March 2012.

o ***Applications made prior to 1 March 2012***

EC applications are considered by a panel of clinicians appointed by the PHARMAC Board.

Community EC (CEC) and Cancer Exceptional Circumstances (CaEC) covers the approval of funding for pharmaceutical treatments for patients who are not eligible for funding under the Pharmaceutical Schedule and who meet certain CEC or CaEC access criteria. The funding for CEC and CaEC comes from the Pharmaceutical Budget. An annual amount (ex manufacturer drug costs, GST exclusive) is 'set aside' from within the national pharmaceutical budget to cover forecasted Community and Cancer EC expenditure. If additional funding provision is required within the CPB, PHARMAC will notify, and agree a solution with, DHBs via GMs Planning & Funding and CEs. From 1 July 2011, DHB financial approval is no longer required for CaEC applications to be assessed.

PHARMAC also manages the Hospital Exceptional Circumstances (HEC) scheme. Funding for treatments approved under HEC comes from the DHB that has agreed to fund the treatment.

PHARMAC will report quarterly to DHBs on its HEC management activities, including numbers of approvals regionally and nationally, the medicines funded via HEC approvals and an indication of DHB and national expenditure on HEC approvals. Data are reported 6-8 weeks after the end of the reporting period.

o ***Applications made post 1 March 2012***

The Named Patient Pharmaceutical Assessment Policy outlines three clear pathways for consideration of exceptional circumstances. The policy is detailed on PHARMAC's website. Funding for two of the pathways (Unusual Clinical Circumstances, and Urgent Assessment) will be met from within the CPB provision. If additional funding provision within the CPB is required for NPPA within a financial year, PHARMAC will notify, and agree a solution with, DHBs via GMs Planning & Funding and CEs.

DHBs will be responsible for meeting the costs associated with Hospital Pharmaceuticals in the Community approvals.

All requests for additional information in regard to EC or NPPA should be directed to PHARMAC's Medical Director.

***Media Management***

PHARMAC will be responsible for managing media enquiries concerning the management of the Pharmaceutical Schedule and where appropriate joint statements with DHBs will be made.

DHBs will identify lead DHBs to work with PHARMAC on particular high profile issues.

Where a local response is required these will be worked on cooperatively, prior to a statement being made by a DHB.

DHBs and PHARMAC agree not to publicly criticise each other in the media and DHBs will advise PHARMAC of any media statements they make in relation to pharmaceutical management strategies.