Memorandum of Understanding

relating to

the working relationship between PHARMAC and DHBs

Pharmaceutical Management Agency

PHARMAC

and

20 District Health Boards

DHBs

Date

October 2015

This **Memorandum of Understanding** is made on [19 October 2015]

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 since 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 was updated in 2011 and 2013 to reflect changes that have occurred in pharmaceutical[1] budget parameters and management. This current version also includes updated sections to reflect PHARMAC's expanded role in hospital pharmaceuticals (medicines and medical devices), and the role of DHB agencies[2] in assisting DHBs to meet their medicines and medical devices procurement objectives.

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 national, 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;

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[1] "Pharmaceutical" as used in this document is as per the NZPHD Act definition: "a medicine, therapeutic medical device, or related product or related thing".

[2] Shared Support Agency has the same meaning as under the Crown Funding Agreement, "means a Shared Support Agency/shared services organisation set up by the DHB as a multi parent subsidiary (whether individually or together with other DHBs) to provide operational support or services to those DHBs in their roles as funders of health and disability services, in areas identified by those DHBs as likely to benefit from a national, regional or sub-regional approach."

- 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[3]. 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, statement of performance expectations and in the output agreement each may enter into with the Crown (the **Accountability Arrangements**).

The NZPHD Act[4] requires that, in performing any of its functions in relation to the supply of pharmaceuticals, a DHB may not act inconsistently with the Pharmaceutical Schedule. This requirement is reinforced via the Operational Policy Framework and other key funding documents.

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 the pharmaceuticals that may be purchased and used by DHB Hospitals (including contracted hospital medical devices). The Schedule includes rules relating to the subsidy and use of pharmaceuticals. In addition, it sets out the process for exceptions, including the Named Patient Pharmaceutical Assessment process in both the community and hospital settings.

DHBs provide the funding for the Combined Pharmaceutical Budget (the **CPB**), hospital medicines and medical devices and for the Discretionary Pharmaceutical Fund which is held in PHARMAC's accounts. The CPB covers the pharmaceutical costs associated with prescribing community pharmaceuticals (including hospital-provided treatments for cancer and haemophilia and vaccines) within the Schedule Rules, as well as funding for management of named patients approved under PHARMAC's Named Patient Pharmaceutical Assessment (NPPA) policy.

Government has determined that PHARMAC would eventually manage hospital medicines[5] and hospital medical devices[6] within a fixed budget on behalf of DHBs as with the CPB and that key enablers for hospital medical devices, such as the National Products Catalogue and finance system milestones, would firstly need to be delivered. In the interim, DHBs are responsible for funding medicines and medical devices for in-hospital use, including medicines for named patients approved under PHARMAC's NPPA policy. DHBs and PHARMAC have agreed to a method of expenditure management for hospital medicines and to use identified savings to make new investments in hospital medicines.

DHBs and PHARMAC recognise that, consistent with their respective roles and obligations as Crown agents, the process towards full budget management of hospital medicines or medical devices will require Ministerial support and full and wide-ranging stakeholder consultation to ensure all views are understood and considered.

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[3] Published in the New Zealand Gazette, 27 September 2001, notice number 6737 (http://online.gazette.govt.nz/)
[4] NZPHD Act 2000, section 23(7)
[5] SOC Min (10) 14/1 refers
[6] SOC Min (12) 17/2 and SOC Min (13) 22/6 refer;

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 budget and ***budget parameters*** for the CPB 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 as outlined in Schedule One.

2. ***Engage*** with DHBs on the method to manage hospital medicines and medical devices ***expenditure*** until such a time as management within a fixed budget commences as outlined in Schedule One.

3. ***Engage*** with DHBs on providing advice to Government on the establishment of a ***fixed budget*** for hospital medicines and medical devices as outlined in Schedule One.

4. ***Specify to DHB agencies*** the information required to support PHARMAC's activities, including reasonable access to data concerning hospital medicines and medical devices activity relevant to PHARMAC's functions; and ensure that DHBs are copied into any such requirements.

5. Ensure that DHBs and their agencies are ***consulted on issues***, relating to the management of the Pharmaceutical Schedule, which are likely to affect DHBs and work in good faith to accomplish the goals as agreed in this MOU.

6. 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.

7. 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.

8. Support implementation of policies or directions in relation to ***hospital pharmaceuticals***.

9. Support implementation of policies or directions in relation to ***hospital medical devices***.

10. ***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.

11. Provide DHBs with ***information and advice*** when 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 and other sector agencies.

12. Attend regular ***formal meetings*** of DHB representatives, such as the GMs Planning and Funding, COOs, CFOs, CEs and CMOs as agreed.

13. ***Invite*** DHBs to participate in formal meetings of PHARMAC where appropriate.

14. ***Respect*** DHB information provided to PHARMAC so that it can deliver on its statutory objective, and use best endeavours to ensure 'no surprises' to DHBs in

publishing or sharing non-routine information or data. This includes informing DHBs where there is an intention to distribute non-routine identifying information or data on pharmaceutical usage.

15. Work with New Zealand Health Partnerships Ltd, and its agents, to jointly develop advice to the DHBs, the Ministry of Health, the PHARMAC Board and Government on the future development of the FPSC Business Case and in particular the Procurement and Finance elements of that Business Case including agreeing procurement scopes for all parties and access and input to any data hub.

DISTRICT HEALTH BOARDS

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

1. Provide ***guidance and direction*** on DHB ***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 ***budget*** and ***budget parameters*** for the CPB, and the funding provision within the pharmaceutical budget to meet the costs associated with named patients in community and cancer exceptional circumstances, and the method to manage hospital pharmaceutical and medical devices expenditure until such time as management within a fixed budget commences as outlined in Schedule One.

3. ***Engage*** with PHARMAC on providing advice to Government on the establishment of a ***fixed budget*** for hospital pharmaceutical and medical devices as outlined in Schedule One.

4. ***Provide*** data and other forms of information on hospital usage, pricing and expenditure for medicines and medical devices as may from time to time be requested by PHARMAC to fulfil its statutory objective.

5. ***Ensure DHB agencies*** and others acting on their behalf support PHARMAC's activities by ***providing services*** agreed with PHARMAC as necessary to assist DHBs meet the intent of this MOU as outlined in Schedule One.

6. Provide ***input to consultation*** processes undertaken by PHARMAC, as appropriate, to support effective decision making.

7. Individually and collectively and through its agencies support PHARMAC on implementation and coordination of ***responsible use of pharmaceuticals activities***.

8. Nominate and ***support*** involvement of appropriate DHB clinicians in PHARMAC's advisory committees.

9. ***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.

10. ***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 and other sector agencies.

11. ***Invite*** PHARMAC to participate in regular formal meetings of DHB representatives, such as the GMs Planning and Funding, COOs, CMOs and CEs.

12. ***Fund*** an agreed level of PHARMAC's annual operational expenses, and assure that payments for such funding are made on a timely basis.

13. Ensure that they and others acting on their behalf ***act consistently with the Pharmaceutical Schedule***. Specifically, DHBs will not operate programmes to fund pharmaceuticals for use in DHB hospitals, the community, or any other setting, outside the circumstances provided for in the Pharmaceutical Schedule.

6. STRATEGY IMPLEMENTATION

Schedule One to this Agreement sets out the key areas of mutual, ongoing interest of the parties. Schedule Two to the Agreement sets out the arrangements for funding haemophilia management.

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 Three to this Memorandum of Understanding. All Schedules will be reviewed and updated annually and approved by DHBs through 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 Director of Engagement and Implementation.

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

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Steffan Crausaz
Chief Executive
PHARMAC

Signed for and on behalf of 20 District Health Boards

6.10.15

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Phil Cammish
Chief Executive Officer
Bay of Plenty 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.

Budget parameters
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 or expenditure management approach 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.

CPB
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 under PHARMAC's NPPA policy;
- forecast use of the Discretionary Pharmaceutical Fund including DHB payments and receipts; and
- potential new investments and their associated cost/benefit to the sector

Expenditure management
In respect to hospital medicines and medical devices, the consultation process will include:

- addressing these areas of expenditure within the annual budget process;
- PHARMAC obtaining individual DHB resolutions for any proposed changes to the expenditure management model; and
- regular updates on expenditure management activities.

Hospitals fixed budgets
In respect to development of shared advice to the Minister on moving towards a fixed budget, the engagement process will include:

- PHARMAC discussion of options with General Managers Planning & Funding, Chief Operating Officers and Chief Financial Officers and other DHB agencies;
- establishment of a DHB advisory group to support PHARMAC in refining options;
- engagement with the Ministry of Health on options;
- development of an engagement plan;

- PHARMAC obtaining individual DHB resolutions for any proposed options for budget management;
- liaison with the Minister of Health including preparation of joint advice;
- implementation of agreed engagement plan;
- implementation of any agreed changes; and
- reporting on progress.

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.

Recalls and Out of stocks

Medicines
If a medicine (listed in Part II of Section H of the pharmaceutical schedule) is out of stock or recalled then DHBs or DHB agencies will contact PHARMAC to ensure that PHARMAC is aware of the stock situation. If DHBs or their agencies are attempting to source an alternative (or have already done so) they will ensure this information is provided to PHARMAC. If a DHB or DHB agency needs to urgently source stock and it cannot be sourced from the contract supplier, then the DHB or its agencies can buy stock directly from a different source. If the medicine is a Hospital Sole Supply product the DHB or DHB agency will make a note of these purchases to assist with Discretionary Variance wash ups.

Devices
If a medical device listed under "Optional Pharmaceuticals" (Part III of Section H of the pharmaceutical schedule) is out of stock or recalled, DHBs or DHB agencies should ensure that alternatives are in place. Should PHARMAC contract for products with market share obligations, any such products will be identified on the schedule and PHARMAC will take responsibility for ensuring continuity of supply including sourcing of alternatives. If a DHB or DHB agency needs to urgently source a product and it cannot be sourced from the contract supplier, then the DHB or its agencies can buy stock directly from a different source and will ensure this information is provided to PHARMAC as soon as practical.

DHB agencies and other third parties

DHB and their agencies will agree with PHARMAC how access to DHB data concerning hospital medicines and medical devices activities relevant to PHARMAC's functions will be managed and shared. Specifically, DHBs will ensure that its agencies:

- recognise PHARMAC's need for information for items that are within the scope of this MOU
- do not levy charges to PHARMAC for delivery of any services provided within the scope of this MOU
- work in good faith with PHARMAC to accomplish the goals as agreed in this MOU
- provide agreed medical devices contract information currently held on behalf of DHBs
- invite PHARMAC to participate in information and distribution system development;
- keep PHARMAC up-to-date on plans for system implementation and work collaboratively and constructively on areas of mutual interest.

PHARMAC will share with DHBs and their agencies any data not otherwise subject to commercial in-confidence obligations, where it is reasonably able to do so, and where this is required to enable DHBs to conduct their activities within the scope of this MOU.

Hospital medicines and medical devices – supplier performance

DHBs should contact PHARMAC if they have concerns about suppliers not meeting their contract terms. DHBs can approach suppliers in the first instance to resolve their issues if they wish.

Responsible 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.

Demand/ volume management 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 regularly 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.

Data

Community pharmaceuticals
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 weekly blocks, to the National Collections and Reporting, Information Group, National Health Board, Ministry of Health. 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 payments made by DHBs. PHARMAC considers that these 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.

Vaccines
Information on influenza vaccines is included in the MOHSS claims data along with the service fee. Other vaccines information is not part of Pharmhouse and is sourced separately.

Hospital medicines
DHBs are to provide data on usage and purchases to PHARMAC as laid out in the Pharmaceutical Schedule or any accompanying policies (such as NPPA). This includes DHB Hospitals providing to PHARMAC, on a monthly basis, any volume and price data held by DHB Hospitals in respect of any pharmaceuticals used in Hospitals. PHARMAC is working

with DHBs to improve the quality of hospital expenditure data. In anticipation of this, DHBs will be asked to support the extraction of relevant price and costs data.

DHBs must report to PHARMAC within one month on any NPPA decisions that they have made as Rapid Assessments, and any free stock programmes or other information required to support effective operation of the Schedule Rules. Such reporting must include information on what has been approved, for what indication and the rationale for the decision.

Hospital medical devices
PHARMAC's role in medical devices budget management is dependent on the development of a national data set and a national catalogue of medical devices that give effect to the Pharmaceutical Schedule Rules. PHARMAC, DHBs and their agencies agree they will need to work together to develop or adapt systems to assure compliance with Pharmaceutical Schedule Rules.

PHARMAC reports
PHARMAC will provide each DHB with the forecast three times per year for the CPB, along with pharmaceutical expenditure reports on request. 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 where possible;
- 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

Accounting
Funds received from rebates and indemnities are held on trust for DHBs, by PHARMAC. Payments are also made by PHARMAC for agreed expenses, which are generally CPB expenses that must be paid through a mechanism other than the Ministry of Health Sector Operations Group (MHSOG) payments. A separate 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.

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 MOHSOG, PHARMAC manages the collection of rebates from pharmaceutical companies directly 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 rebates do not form part of the CPB (unless they are PCTs) and so are reported and paid separately.

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.

Where PHARMAC collects, holds, and distributes rebates it does so as agent of the DHBs. Pursuant to a policy agreed with DHBs in 2009 and reviewed in 2014, PHARMAC has discretion to write off rebates, and to settle disputes regarding rebates, and address minor supply chain matters in circumstances where it reasonably believes it is in the best interests of DHBs to do so up to 0.1% of the CPB.

DHBs agree that PHARMAC does not require specific resolution for use of CPB rebate funds for CPB expenses where the value is less than 0.1% of the CPB.

Confidentiality is central to rebate management. PHARMAC often gives a contractual undertaking to a supplier, but also from time-to-time needs to disclose this information to DHBs. DHBs therefore need to take reasonable steps to keep any disclosures confidential, and to seek PHARMAC's permission before releasing beyond the DHB, including to its agencies, as the value that is put at risk from unauthorised disclosures is significant.

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.

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

- estimated pharmaceutical expenditure including rebate payments and accruals and payments to or from 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.

The Named Patient Pharmaceutical Assessment Policy sets out the approach PHARMAC takes for considering exceptional circumstances as required by the NZPHD Act. The policy is detailed on PHARMAC's website. Funding is met from within the CPB provision where the named patient application is approved by PHARMAC and treatment is administered in the community, or where the approved treatment is a PCT. 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.

DHB provider arms are responsible for meeting the costs associated with NPPA approvals made by DHBs under the hospital rapid assessment process for named patient applications, where the treatment commences in the hospital as well as any continuation in the community. Applications approved by PHARMAC for hospital treatment that is approved for continuation in the community may either continue to be funded by the hospital or may be funded under the CPB.

Patients approved under the previous Exceptional Circumstances (EC) Schemes prior to 1 March 2012 continue to be funded under the previous scheme rules.

All requests for additional information in regard to EC or NPPA should be directed to PHARMAC's Manager Pharmaceutical Funding.

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.

Schedule Two

HAEMOPHILIA MANAGEMENT

Background

The National Haemophilia Management Group (NHMG) was established in 2006 and is responsible, on behalf of 20 District Health Boards, for management of haemophilia treatments in New Zealand, which includes both recombinant and plasma derived products. The Haemophilia Treaters' Group (HTG) is made up of clinicians who are involved in the clinical management of patients with haemophilia in New Zealand, and it collaborates closely with the NHMG.

Following the listing of haemophilia treatments on Sections B and H of the Pharmaceutical Schedule, funding of these products was incorporated into the CPB from 1 July 2013. The NHMG and HTG each continue to have a role in determining patients' funded access to haemophilia treatments listed in the Pharmaceutical Schedule, whether for in-hospital or in-community use. The Haemophilia Treatments Panel (HTP) is convened by PHARMAC to assist in applying criteria for access to factor VIII. The NHMG continues to oversee expenditure on recombinant blood factors and FEIBA.

The NHMG and the HTG have a role in relation to management of expenditure on related health services (such as physiotherapy) and other plasma-derived products for haemophilia on behalf of District Health Boards.

PHARMAC responsibilities

PHARMAC works closely with the NHMG to determine an appropriate annual funding allocation (from the Combined Pharmaceutical Budget) for these treatments. DHBs will make payments directly to NHMG for the risk-pool, and payments made in accordance with the MOU between NHMG and PHARMAC will be counted as CPB expenditure.

In exceptional circumstances, for instance when there is a need to address urgent clinical situations such as acute bleeding episodes, surgery or for urgent tolerisations and where this cannot be met from the annual funding allocation, PHARMAC will decide whether to approve additional funding.

New haemophilia treatments, which may become available in the future, will be assessed by PHARMAC for funding (using the same processes currently applying to other pharmaceuticals).

In considering applications for funding of new haemophilia treatments, PHARMAC may seek clinical advice from the HTG, the Pharmacology and Therapeutics Advisory Committee (PTAC) and/or the Haematology Subcommittee of PTAC.

DHB responsibilities

- DHBs will provide funds to the NHMG to:
  (a) manage the risk-pooling activity around the Schedule-listed products ("CPB Expenditure"), and
  (b) fund (and risk-pool) other related products and services ("Other Expenditure").
- In its role of managing haemophilia treatments in accordance with the Pharmaceutical Schedule, NHMG may approve treatments that are consistent with established clinical practice within the DHBs (the annual funding provision will be set at a level which is expected to be sufficient, generally, to cover all such treatments).
- Following discussion with PHARMAC, the amount of funds required for reimbursement of the above will be estimated by the NHMG at the start of each financial year, and DHBs must pay their contribution by no later than the date specified in each invoice.
- There will be a wash-up calculated by the NHMG at the end of each financial year, and DHBs will need to pay any additional money by no later than the date stated in the invoice.
- The quantum of CPB Expenditure will be determined based on actual use of recombinant blood factors and FEIBA under terms agreed by PHARMAC, and the amount of Other Expenditure above will be negotiated with DHBs.
- For the avoidance of doubt, Other Expenditure is not expenditure that is relevant to the calculation of actual expenditure from the CPB.