Memorandum of Understanding

relating to

the working relationship between PHARMAC and DHBs

Pharmaceutical Management Agency

PHARMAC

and

20 District Health Boards

DHBs

Date

August 2021

This **Memorandum of Understanding** is made on **[** 3 September 2021 **]**

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**)

each a "party", together the "parties"

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1. BACKGROUND

DHBs and PHARMAC have had a relationship agreement since January 2002. Several updates have been made to that Memorandum of Understanding since then to better reflect how the parties work together and to reflect changes that have occurred in pharmaceutical[1] budget parameters and management.

2. RATIONALE

DHBs and PHARMAC have some common objectives and need to work together to ensure they are achieved. This Memorandum of Understanding (MOU)document outlines the shared commitment, objectives and the key principles and rules of engagement between DHBs and PHARMAC.

DHBs and PHARMAC are committed to working collaboratively - on the management of medicines, medical devices and related products - to effect improvements in the overall performance of the New Zealand health and disability sector and meet their respective legislative and accountability obligations.

The approach should be patient-and-equity focused, sustainable, and integrated between primary, community and hospital services.

The aim is to achieve this by:

- aligning PHARMAC and DHB strategic areas of focus to government health priorities, particularly equity
- using good clinical governance, innovation and planning
- enabling data and information sharing

3. FUNDAMENTAL PRINCIPLES

This MOU 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, supporting good partnership and engagement together on key issues.

The principles that will underpin the parties' relationship are as follows:

- 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;

[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".

- 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, evidence-based decision making 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 including proactively engaging on key issues;
- We will work collaboratively with 'no surprises' whilst recognizing the commercial sensitivities PHARMAC faces; and
- We will endeavour to resolve any disputes between us constructively and expeditiously.

If this MOU conflicts in any way with the parties' legal obligations or any obligations set out in formal Accountability Arrangements described in paragraph 4 below, then those obligations and arrangements will take precedence. This MOU is not intended to be legally enforceable.

4. ROLES

Both DHBs' and PHARMAC's objectives and functions are set out in the NZPHD Act and, for PHARMAC, also in ministerial directions made on 4 September 2001[2] and 18 August 2016[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, and statement of performance expectations and in the output agreement each may enter into with the Crown. Also, in order to receive funding, each DHB must have a Crown Funding Agreement in place in accordance with section 10 of the NZPHD Act, which incorporates by reference mandatory requirements specified in the Operational Policy Framework the Service Coverage Schedule (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 respective roles of PHARMAC and DHBs are detailed in Appendix One.

5. MANAGING THIS MEMORANDUM OF UNDERSTANDING

The DHB CE Group will manage this MOU through a nominated lead CE; PHARMAC will manage this MOU through its CE and its Director of Engagement and Implementation.

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

Each year the parties will agree the key budgets and actions required to support this MOU.

6. TERM

This MOU shall commence when it is signed by the parties, and will continue until amended or terminated by the written agreement of the parties. This MOU supersedes all prior memorandum of understandings between the parties.

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[2] Published in the New Zealand Gazette, 27 September 2001, notice number 6737 (http://online.gazette.govt.nz/)
[3] Published in the New Zealand Gazette, 18 August 2016, notice number 2016-go4752 (http://online.gazette.govt.nz/)
[4] NZPHD Act 2000, section 23(7)

The parties will review this MOU as required to ensure that it continues to support the roles and obligations of the parties.

7. 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 2020 (as amended from time to time).

It is further agreed that the effect of these confidentiality clauses will survive termination of this MOU.

8. APPENDICES

Appendix One: details the roles of PHARMAC and DHBs.

Schedule One: details the actions required by PHARMAC and DHBs.

Schedule Two: sets out the key areas of mutual, ongoing interest of the parties.

Schedule Three: sets out the arrangements for funding haemophilia management.

SIGNATORIES TO THIS MEMORANDUM OF UNDERSTANDING

Signed for and on behalf of PHARMAC

Sarah Fitt

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Sarah Fitt
Chief Executive
PHARMAC

Signed for and on behalf of 20 District Health Boards

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Peter Bramley

Chief Executive Officer
Canterbury and West Coast District Health Boards
(as lead CE for the DHB - PHARMAC relationship)

APPENDIX ONE – ROLES

The Pharmaceutical Schedule is managed by PHARMAC. It sets out the pharmaceuticals that are subsidised in the community, the medicines that may be used in DHB Hospitals, the level of subsidy, and any restrictions associated with patient access to that subsidy and sets out the nationally contracted medical devices. The Pharmaceutical Schedule also includes rules relating to the subsidy and use of pharmaceuticals, and funding exceptions.

DHBs provide the funding for the Combined Pharmaceutical Budget (CPB) and hospital medical devices. The CPB covers the pharmaceutical costs associated with supplying community pharmaceuticals and medicines delivered in DHB Hospitals within the Pharmaceutical Schedule Rules, as well as funding for medicines for named patients approved under the Exceptional Circumstances Framework which PHARMAC manages.

PHARMAC manages the CPB Discretionary Pharmaceutical Fund (**CPB DPF**) and the Hospital Discretionary Pharmaceutical Fund (**HDPF**). These are multi-year funds that enable the retention of pharmaceutical funding across financial years to support long-term management of expenditure. PHARMAC manages both funds pursuant to the terms of each policy.

The Government has determined that PHARMAC would eventually manage hospital medical devices[5] 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.

DHBs and PHARMAC recognise that, consistent with their respective roles and obligations as Crown agents, the process towards full budget management of hospital medical devices will require Ministerial support and full and wide-ranging stakeholder consultation to ensure all views are understood and considered. Should the Minister of Health determine that PHARMAC will manage a budget for hospital medical devices, DHBs and PHARMAC recognise they will need to work collaboratively to establish the systems and processes to implement full budget management.

[5] SOC Min (12) 17/2 and SOC Min (13) 22/6 refer;

SCHEDULE ONE - ACTIONS

PHARMAC

1. To give effect to this MOU, for its part PHARMAC will:

   a. 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.

   b. Engage with DHBs on expenditure management of hospital medical devices.

   c. Specify to DHBs and their agents[6] the information required to support PHARMAC's activities, including reasonable access to data concerning hospital medicines and hospital medical devices activity relevant to PHARMAC's functions.

   d. Work proactively and collaboratively as soon as is practicable with DHBs and their agents, 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.

   e. When making Pharmaceutical Schedule decisions, consider the total impact of proposals – both intended and unintended - on DHBs including (but not limited to) costs to DHBs' non-pharmaceutical budgets and the costs of distribution and dispensing of pharmaceuticals, including impacts on DHB national contracts (e.g. in Community Pharmacy).

   f. Promote the responsible use of pharmaceuticals. This includes providing evidence-based information to DHBs and other health providers to support optimal use of medicines as an integral part of clinical decision making.

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

   h. Invite appropriate DHB experts (including, but not limited to clinicians) to participate in PHARMAC advisory committees and establish appropriate mechanisms through which to share its clinical, operational 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.

   i. Provide DHBs with information and advice when requested in relation to pharmaceuticals to support them in engaging with the Minister of Health and Ministry of Health on management of pharmaceuticals and for the negotiation of service contracts with community pharmacies and other sector agencies.

   j. Attend regular formal meetings of DHB representatives, such as the CEs, COOs, CMOs, CFOs, GMs Planning and Funding, Directors of Allied Health, Directors of Nursing, Chief Pharmacists, and the National Haemophilia Management Group and Treaters Groups.

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

   l. 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

[6] DHB agents include shared service agencies, such as Central Region Technical Advisory Services Limited (TAS).

DHBs where there is an intention to distribute non-routine identifying information or data on pharmaceutical usage.

m. 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 implementation of the Financial Procurement and Information Management system (FPIM), and the National Product Catalogue, and the implementation of the DHB Procurement Strategy.

n. Provide training and advice to DHB personnel to develop a shared understanding of PHARMAC processes including budget management and financial impacts.

DISTRICT HEALTH BOARDS

2. To give effect to this MOU, for their part DHBs will:

a. Provide guidance and direction on DHB priorities to support PHARMAC's objective and functions, with the aim of improving the value of pharmaceutical expenditure.

b. Engage with PHARMAC and agree the joint recommendation to the Minister of Health on the annual budget and budget parameters for the CPB.

c. Engage with PHARMAC on the method to manage hospital medical devices expenditure and any shared advice to the Minister of Health on moving towards a fixed budget as outlined in Schedule One.

d. 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.

e. Ensure DHBs 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.

f. Engage proactively and collaboratively with PHARMAC consultation processes, to identify and address issues, to support effective decision-making.

g. DHBs individually and collectively and through its agents support PHARMAC on implementation and coordination of responsible use of pharmaceuticals activities.

h. Nominate and support involvement of appropriate DHB experts (including but not limited to clinicians) in PHARMAC's advisory committees, panels, and groups.

i. 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 medicines or hospital medical devices (whether related to usage, pricing or otherwise) to third parties.

j. Seek advice from PHARMAC, where appropriate, to support engagement with the Minister of Health and Ministry of Health on management of pharmaceuticals and for the negotiation of service contracts with community pharmacies and other sector agencies.

k. Invite PHARMAC to participate in regular formal meetings of DHB representatives, such as the CEs, COOs, CMOs, CFOs, GMs Planning and Funding, Directors of Allied Health, Directors of Nursing, Chief Pharmacists, and the National Haemophilia Management Group and Treaters Groups.

l. Fund an agreed level of PHARMAC's annual operational expenses for activities undertaken by PHARMAC on behalf of DHBs and assure that payments for such funding are made on a timely basis.

m. 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.

SCHEDULE TWO - KEY AREAS OF MUTUAL, ONGOING, INTEREST

CPB Setting

PHARMAC will develop forecasts of pharmaceutical expenditure to inform the annual CPB setting process undertaken in conjunction with DHBs, and the Minister of Health. The parties will work together to develop an agreed timeframe for the CPB setting process. Both PHARMAC and DHBs need to agree the recommended annual CPB to the Minister of Health.

CPB setting principles
The principles on which the parties will base their joint recommendations include:

- value for money, considering:
  - 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 can 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.

Establishment of the annual budget will also be in accordance with other relevant policies or directions and supported by advice from PHARMAC to DHBs on:

- distribution of rebates; and
- forecast use of the Discretionary Pharmaceutical Funds including DHB payments and receipts.

PHARMAC and DHBs will discuss any proposed adjustments to the agreed CPB 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.

Hospital medical devices
The annual budget setting process described above will also incorporate information about hospital medical devices, including:

- addressing this area of expenditure within the annual budget process; and
- PHARMAC consulting DHBs on any proposed changes to the expenditure management model.

PHARMAC and DHBs will discuss and consult with each other in respect to development of any shared advice to the Minister of Health on moving towards a fixed budget.

Additional services

DHBs may request PHARMAC to provide services to DHBs 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. Additional services will be discussed and agreed to via the annual budget setting process.

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

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.

- DHBs commission services in primary care, community pharmacy and aged residential care through national contracting processes and have the ability to develop local responses. Where appropriate these will be co-ordinated with national initiatives.

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.

There is the opportunity for PHARMAC and DHBs to work more closely in the management of demand/volume management programmes, through the development of the DHB National Work Plan and PHARMAC's annual work programme.

Through the annual budget setting process, DHBs and PHARMAC discuss allocation of the annual PHARMAC operational budget contribution (as a fixed dollar amount or an agreed percentage of the CPB plus any amount available via Ministry of Health funding).

Hospital medical devices

PHARMAC's medical devices management approach will continue to develop, ultimately reaching full budget management. PHARMAC will engage DHBs in the development process to:

- gather information and knowledge to inform the approach
- refine the approach – including based on stakeholder feedback, and confirm respective roles in this
- help DHBs to equip themselves to deliver changes
- build a broad awareness and understanding in DHBs of the changes.

PHARMAC will establish and seek advice from a DHB Strategic Medical Devices Advisory Group – including to gain guidance on and support for this engagement.

DHBs will support PHARMAC's work by identifying staff to participate in the various engagement activities; and making the changes necessary for their DHB to give effect to the medical devices approach.

Recalls and Out of stocks

PHARMAC will engage collaboratively with DHBs to proactively manage stock issues and recalls (unless it is contractually limited), including early notification of issues.

Where a hospital pharmaceutical is out of stock or recalled, DHBs or their agents will follow the relevant procedures in the Schedule Rules for such situations (Schedule Rules Part 9).

Hospital medicines and medical devices – supplier performance

DHBs and PHARMAC will work collaboratively, sharing information, to support the provision of hospital medicines and medical devices. This will support both parties in the procurement of and availability of medicines and devices to support, for example, planned care.

DHBs, agents and other third parties

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

- 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, unless otherwise agreed
- 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
- work collaboratively and mutually with PHARMAC to share data where appropriate.

PHARMAC will share with DHBs and their agents 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.

Data

There is an opportunity for DHBs and PHARMAC to collaborate more closely on data provision and reporting to enable better, collaborative decision-making.

Community pharmaceuticals
Contracted community pharmacies send claims for subsidised pharmaceuticals to the Ministry of Health Sector Operations Group (MOHSOG), which pays those community pharmacies on behalf of DHBs. This information is then added to a data warehouse called 'Pharmhouse'.

PHARMAC accesses Pharmhouse and uses information on claims to perform its objective and functions.

PHARMAC's focus for analysis is trends in prescription pharmaceutical usage, so analysis produced is in terms of when pharmaceuticals have been dispensed from pharmacies (rather than the date DHBs pay for them through MOHSOG).

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 this does mean that reports prepared by PHARMAC may not be exactly consistent with reports prepared by MOHSOG or DHB agents.

DHB agents work collaboratively with PHARMAC to develop the PHARMAC forecast using the data collected for the management of the integrated community pharmacy services agreement.

Vaccines
Some information on influenza vaccines is included in the Ministry of Health Sector Operations Group (MOHSOG) 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 the Named Patient Pharmaceutical Assessment). PHARMAC is continuously 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 Named Patient Pharmaceutical Assessment (NPPA) decision 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 agents will work together to develop or adapt systems to assure compliance with Pharmaceutical Schedule Rules.

PHARMAC reports
PHARMAC will provide each DHB with the CPB forecast three times per year, along with pharmaceutical expenditure reports on request. PHARMAC will consult regularly with DHBs on the type and form of forecast information provided and will make improvements to these reports based on feedback from DHBs. The forecasts will include:

- expenditure on pharmaceuticals by therapeutic group where possible;
- estimated out year forecasts by DHB; 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 may be made by PHARMAC for agreed expenses, which are generally CPB expenses that must be paid through a mechanism other than the MOHSOG payments. Agreed expenses arise following:

- A decision to list a medicine on the Pharmaceutical Schedule;
- A determination by PHARMAC that a method of distribution other than community pharmacy is appropriate; and
- Payment for those medicines is required by invoice or series of invoices over time.

A separate ledger is maintained by PHARMAC to record and report those transactions in accordance with generally accepted accounting principles. 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
PHARMAC manages the collection of some rebates from pharmaceutical companies, which it holds and distributes to DHBs. These rebates relate to the CPB and are credited back to the value of net expenditure on the CPB.

In 2009 (and reviewed in 2014) PHARMAC and DHBs agreed that PHARMAC has discretion to:

- write off rebates;
- 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.

For the avoidance of doubt, CPB rebate funds can be distributed back to DHBs, used to purchase listed pharmaceuticals as agreed expenses (including GST), or used up to the

0.1% limitation for other expenses; all other uses of rebate funds require approval of the lead DHB CE.

Rebates that relate to hospital medicines not in the CPB and purchased before 30 June 2018 will be returned to DHBs on the basis of actual purchases. After 1 July 2018, all hospital medicine rebates will be distributed to DHBs in the same way as other CPB rebates.

Confidentiality is central to rebate management and the value that can be put at risk from unauthorised disclosures is significant. 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 them beyond the DHB, including to its agents.

DHBs and PHARMAC will ensure that the rebate distribution and allocation policy agreed between them is regularly reviewed, ideally annually.

Indemnities

Payments received by PHARMAC on behalf of DHBs under contractual indemnity provisions (generally costs associated with out of stock events) are reported on separately and are credited against the CPB if they relate to CPB medicine cost.

Year-end financial information

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

- estimated pharmaceutical expenditure including rebate payments and accruals, agreed expenses and any related GST, any previous year accrual differences, and payments to or from the discretionary pharmaceutical fund;
- rebate payments, indemnity payments and accruals; and
- interest received and paid.

Exceptional Circumstances

The Exceptional Circumstances Framework sets out the approach PHARMAC takes for considering funding decisions for exceptional circumstances that fall outside of the Pharmaceutical Schedule funding process. The Framework (which includes the NPPA Policy) is detailed on PHARMAC's website.

The Pharmaceutical Schedule Rules outline the circumstances under which pharmaceuticals that are not listed in the Schedule (or are not listed for the particular indication) may be subsidised or given in a DHB hospital.

Patients approved under the previous exceptional circumstances schemes prior to 1 March 2012 continue to be funded under the previous scheme rules.

Management of Media and Official Information Act enquiries

PHARMAC will be responsible for managing media and OIA 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 high-profile issues.

Where a local response is required, that response 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 THREE - 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.

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 NHMG oversees gross expenditure on haemophilia treatments and manages the budget for haemophilia products accordingly. It does so by managing the risk pooled DHB funding of haemophilia treatments.

The HTG, in conjunction with the NHMG, has responsibilities regarding patient eligibility for funded access to haemophilia products.

The NHMG and the HTG also 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 DHBs.

PHARMAC responsibilities

PHARMAC, via listings on the Pharmaceutical Schedule, is responsible for determining which recombinant products are available in New Zealand, the procurement of those products, managing supplier relationships and collecting confidential rebates on behalf of DHBs. PHARMAC works closely with the NHMG to determine an appropriate annual funding allocation (from the CPB) on a gross basis for these treatments. DHBs will make payments directly to NHMG for the risk-pool but only net expenditure will be counted as CPB expenditure, with rebates being paid directly to DHBs in the normal way.

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 to the NHMG, 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 ("Gross 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 listed in the Pharmaceutical Schedule and 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 by PHARMAC based on actual use of recombinant haemophilia treatments and net pricing after rebates. The amount of Other Expenditure above will be negotiated between the NHMG and DHBs.
- For the avoidance of doubt, Gross Expenditure and Other Expenditure is not expenditure that is relevant to the calculation of actual expenditure from the CPB.