

# **Memorandum of Understanding**

**relating to**

Vaccines Funding Arrangements

**Pharmaceutical Management Agency**

and

**Ministry of Health**

and

**Mid Central District Health Board for and on behalf of all the District Health Boards**

**Effective Date: 1 July 2012**

<b>1.</b>	<b>Definitions</b> .....	<b>2</b>
<b>2.</b>	<b>Tenn</b> .....	<b>4</b>
<b>3.</b>	<b>Background</b> .....	<b>4</b>
<b>4.</b>	<b>Ministry transfer of vaccines funding</b> .....	<b>4</b>
<b>5.</b>	<b>Roles and Responsibilities of the parties</b> .....	<b>5</b>
<b>6.</b>	<b>Relationship Management</b> .....	<b>7</b>
<b>7.</b>	<b>Issue/dispute resolution</b> .....	<b>8</b>
<b>8.</b>	<b>Termination of MOU</b> .....	<b>9</b>
<b>9.</b>	<b>Contact persons and addresses for correspondence</b> .....	<b>10</b>

This **Memorandum of Understanding** ("**MOU**") is deemed to have been made on 1 July 2014

- between** (1) **Pharmaceutical Management Agency, a Crown Agent for the purposes of section 7 of the Crown Entities Act 2004 ("PHARMAC")**
- and** (2) **Her Majesty the Queen in right of New Zealand acting through the Ministry of Health ("the Ministry")**
- and** (3) **MidCentral District Health Board a District Health Board established under the Crown Entities Act 2000 for and on behalf of itself and:**
- Auckland District Health Board;
  - Bay of Plenty District Health Board;
  - Canterbury District Health Board;
  - Capital and Coast District Health Board;
  - Counties Manukau District Health Board;
  - Hawkes Bay District Health Board;
  - Hutt Valley District Health Board;
  - Lakes District Health Board;
  - Nelson Marlborough District Health Board;
  - Northland District Health Board;
  - South Canterbury District Health Board;
  - Southern District Health Board;
  - Tairāwhiti District Health Board;
  - Taranaki District Health Board;
  - Waikato District Health Board;
  - Wairarapa District Health Board;
  - Waitemata District Health Board;
  - West Coast District Health Board; and
  - Whanganui District Health Board.
- ("the DHBs")

## **Introduction**

- A. Up to 30 June 2012 the Ministry funded the procurement of vaccines on the National Immunisation Schedule, including vaccines for the high risk immunisation programme ("**vaccines**") and also funded vaccines management activities, including storage **and** distribution ("**vaccines management**").
- B. From 1 July 2012 the Government transferred responsibility for a) the prioritisation and purchasing of vaccines to PHARMAC and b) the vaccines were listed on the Pharmaceutical Schedule.

- C. This MOU sets out the parties' agreement on their roles and responsibilities for vaccines management, including storage and distribution and vaccine procurement funding now that these have been transferred.
- D. The parties recognise that each has powers, functions and obligations under law. Any obligations of, or statements of intention by, any party to this MOU are subject to the discretion of each to act as necessary to perform its legal functions or obligations and to exercise any statutory powers.

## 1. Definitions

---

1.1 In this MOU, the following terms shall have the following meanings

**Cold Chain-the** system of transporting and storing vaccines within the +2°C to +8°C temperature range from the place of manufacture to the point of vaccine administration.

**Combined Pharmaceutical Budget (CpB)-means** the notional capped budget for community pharmaceuticals, cancer pharmaceuticals and vaccines managed by PHARMAC on behalf of DHBs. The CPB is set by the Minister of Health each year after receiving recommendations from PHARMAC and DHBs and advice from the Ministry of Health.

**Immunisation Subcommittee of PTAC-provides** authoritative specialist clinical and technical advice to PHARMAC, about vaccine effectiveness, coverage, safety, and vaccine preventable diseases and via PHARMAC may be commissioned at cost to the Ministry to provide advice to the Ministry about outbreak and programme management. Members are appointed for their particular immunisation expertise.

**New Zealand Pharmaceutical Schedule-means** the list of approximately 2000 medicines and therapeutic products subsidised by the Government. Section 48(a) of the New Zealand Public Health and Disability Act 2000 requires PHARMAC to "maintain and manage a pharmaceutical schedule that applies consistently throughout New Zealand".

**National Immunisation Schedule-is** a series of publicly funded vaccines available in New Zealand for babies, children, adolescents and adults (including influenza) and including vaccines offered in a targeted way in response to a recognised health need (for example children at high risk from pneumococcal disease). The National Immunisation Schedule sets the eligibility criteria to receive publicly funded vaccines.

**National Immunisation Programme ("The Programme")-aims** to prevent diseases through vaccination and achieve immunisation coverage that prevents outbreaks and epidemics. The Programme provides national oversight of immunisation services, providers and agencies, including setting national and district level targets, monitoring disease burden and populations at increased risk of vaccine preventable diseases, providing guidance to the sector, ensuring immunisation providers deliver services that are safe, effective and meet the needs of their population.

**National Immunisation Register ("NIR")-is** a computerised information system that holds immunisation details of New Zealand children born since 2005. The NIR also holds immunisation details for specific immunisation programmes.

**PTAC-is** the Pharmacology and Therapeutics Advisory Committee of PHARMAC, an expert clinical advisory committee, established to provide PHARMAC with objective advice on pharmaceuticals and their benefits and used by PHARMAC to support its pharmaceuticals funding decision making process.

**Regional Vaccine Stores-distribute** the National Immunisation Schedule vaccines (except influenza) to immunisation providers. The providers as at the commencement of this MOU are Healthcare Logistics (which distributes the seasonal influenza vaccine) and Propharma

(which distributes all other National Immunisation Schedule vaccines). ProPharma has stores situated in Whangarei, Auckland, Hamilton, Wellington, Christchurch and Dunedin.

**Vaccine storage and distribution-is** the storage and distribution of certain vaccines including National Immunisation Schedule vaccines and pre-pandemic vaccines (except influenza) at a National Vaccine Store and transfer to the Regional Vaccine Stores. As at the commencement of this MOU the National Vaccine Store is held at the Institute of Environmental Science and Research's ("ESR") Kenepuru site.

## It is agreed

### 2. Term

---

- 2.1 This MOU is deemed to have commenced on 1 July 2012, and continues in force until it is terminated in accordance *with* clause 8 of this MOU.

### 3. Background

---

- 3.1 The parties acknowledge that:
- (a) PHARMAC's Board resolved on 12 June 2012 to list the vaccines on the Pharmaceutical Schedule, subject to the Social Policy Subcommittee of Cabinet (SOC) on 13 June 2012 recommending to allocate the responsibility for vaccines budget and management to PHARMAC.
  - (b) On 13 June 2012 SOC approved the transfer of responsibility for vaccine prioritisation and purchase of vaccines from the Ministry of Health to **PHARMAC** (Cab minute SOC (12) 10/4 refers).
  - (c) The funding for the purchase of vaccines has been transferred from the Ministry to DHBs to form part of the Combined Pharmaceutical Budget from 1 July 2012.
  - (d) The funding for vaccines management including storage and distribution activities, has been transferred from the Ministry to PHARMAC (by adjusting PHARMAC's operational baseline), from 1 July 2012.

### 4. Ministry transfer of vaccines funding

---

- 4.1 The Ministry has transferred the funding for the purchase of vaccines, by way of devolving funding to the **DHBs**, through a baseline adjustment from 2012/13 onwards of \$35,100,000 (excluding GST).
- 4.2 For the avoidance of doubt, the amount of funding specified in clause 4.1 above:
- (a) is exclusive of GST,
  - (b) is net of any rebates,
  - (c) includes the indications for which vaccines are listed on the Pharmaceutical Schedule as at the date of this MOU;
  - (d) is net of any Contribution to Cost Pressure.
- 4.3 The Ministry agrees to transfer the vaccines management funding, by way of increasing PHARMAC's baseline funding, through a baseline adjustment from 2012/13 onwards of \$947,766 (exclusive of GST).
- 4.4 For the avoidance of doubt, the amount of funding specified in clause 4.3 above:
- (a) is exclusive of GST,

- (b) includes the indications for which vaccines are listed on the Pharmaceutical Schedule as at the date of this MOU.

## 5. Roles and Responsibilities of the parties

---

### 5.1 PHARMAC will:

- (a) list vaccines on the Pharmaceutical Schedule from 1 July 2012, including eligibility criteria for subsidised vaccines for personal and public health uses (authorisation for such listing was given by PHARMAC's Board of Directors on 12 June 2012),
- (b) obtain data on the demand for/prescribing of vaccines through the listing of vaccines on the Pharmaceutical Schedule (the "**PHARMAC Data**") from 1 July 2012,
- (c) manage, all future vaccine funding applications and procurement of vaccines, including,
  - (i) accountability for all decisions on vaccine funding, eligibility, and procurement,
  - (ii) any future vaccine investment decisions are subject to PHARMAC's prioritisation and decision-making,
  - (iii) undertaking economic evaluations of vaccines e.g. varicella and rotavirus,
  - (iv) seeking clinical advice on applications for funding of vaccines including from its Immunisation Subcommittee of PTAC and/or PTAC, purchasing decisions, prioritisation and implementation of best practice guidelines as required (for example in responding to outbreaks),
- (d) manage activities relating to the supply of vaccines, including:
  - (i) discuss with the Ministry of Health and affected DHBs any proposed vaccine response to localised and national outbreaks of disease, and pre-pandemic preparedness,
  - (ii) National Immunisation Schedule vaccine supply, including the contracts with vaccine manufacturers, and with vaccine storage and distribution service providers,
  - (iii) manage the vaccine supply and distribution process, including cold chain management, and manage the risk of loss of vaccine storage facilities and vaccine integrity.
  - (iv) liaise with the Regional Vaccine Store service providers on vaccine stock issues such as stock on hand, trends and sudden changes in vaccine use and if necessary advise the Ministry,
  - (v) work with the Ministry to understand best practice and sector training requirements with respect to cold chain management,
- be) be responsible for on demand requests (for example OIA requests regarding vaccine decisions, purchases, and storage and distribution), and
- (f) co-ordinate the provision of authoritative specialist clinical and technical advice from the Immunisation Subcommittee of PTAC and/or from PTAC to the Ministry about the National Immunisation Programme.

## 5.2 The Ministry will:

- (a) Undertake on-going vaccine preventable diseases and notifiable diseases surveillance and inform PHARMAC when there are regulatory or public health changes,
- (b) transfer appropriate records to **PHARMAC** to support PHARMAC's vaccine management role, including the rotavirus and varicella economic evaluations,
- (c) be responsible for the National Immunisation Programme, including providing guidance to the immunisation sector, and overseeing the delivery of safe and effective immunisation services,
- (d) seek via PHARMAC any specialist clinical and technical advice, about the National Immunisation Programme from the Immunisation Subcommittee of PTAC and/or from PTAC. For the avoidance of doubt, the Ministry may separately contract with individual(s) members of the Immunisation Subcommittee of PTAC for clinical or technical advice relating to vaccines, however the Ministry must ensure it does not place members in a position where a conflict of interest would arise,
- (e) be accountable for monitoring the Government's health targets for immunisation and notifying **PHARMAC** of emerging health targets or government priorities,
- (f) be accountable for international obligations and goals for vaccine preventable disease management,
- (g) manage the NIR to measure and record National Immunisation Programme effectiveness,
- (h) ensure adverse events following immunisation are monitored and managed as required,
- (i) provide support to DHBs as required to meet their public health obligations in responding to local communicable disease outbreaks and leadership for a co-ordinated response for national communicable disease outbreaks,
- (j) oversee vaccine preventable diseases surveillance,
- (k) discuss with PHARMAC the procurement, supply and storage of the Ministry's pre-pandemic stock,
- (l) maintain and manage cold chain management guidelines and policies and, where requested, provide information and advice to immunisation providers with regard to management of cold chain failures,
- (m) work with DHBs to ensure best practice and sector training with respect to cold chain management,
- (n) maintain the list of notifiable diseases as pursuant to the Health Act 1956 and Tuberculosis Act 1948;
- (o) as required make formal applications with the Minister of Health's approval to add vaccines to the National Immunisation Schedule,
- (p) publish the Immunisation Handbook which describes the policies and recommendations for the use of vaccines in New Zealand, and
- (q) Set the overall eligibility direction for publicly funded health and disability services in New Zealand.

5.3 **DHBs will.**

- (a) agree to **PHARMAC** managing the vaccines funding as part of the CPB budget,
- (b) fund the vaccines on the Pharmaceutical Schedule,
- (c) fund the immunisation benefit through the population based funding (CBF),
- (d) monitor and manage the cold chain practices of immunisation providers, including management of cold chain failures and cold chain accreditation assessment,
- (e) manage public health responses to local outbreaks of disease, and
- (f) fund the supply of vaccines required for responding to local outbreaks of disease.

5.4 **Mutual Responsibilities:**

- 1a) To facilitate the roles and responsibilities set out above, the parties will work together to develop a transition plan to ensure clear stakeholder expectations of vaccines management and funding,
- (b) To work closely together to ensure good decision-making, including in relation to procurement processes (tenders or otherwise), changes to the vaccines listed on the Pharmaceutical Schedule, and other decisions required to prevent or manage vaccine preventable diseases at a national level. The parties agree that good decision-making may include (but is not limited to);
  - (i) early consultation and engagement, and
  - (ii) consideration of programme management and implementation impacts, and sector engagements.
- (c) To work together to ensure that they are each able to deliver on their respective vaccine cold chain monitoring, management and advisory obligations,
- (d) To operate a no surprises policy in order to ensure timely and proactive communications management with respect to public statements and media responses about vaccines funding and/or immunisation benefits.

## 6. Relationship Management

---

- 6.1 The parties acknowledge that the successful performance of this MOU is dependent on adequate and appropriate relationship management and on the adequate and appropriate implementation of all parties roles and responsibilities recorded in clause 5 above.
- 6.2 By signing this MOU, the parties agree to be guided by the relationship management processes and the relevant decisions of the parties for vaccine eligibility and funding decisions.
- 6.3 The parties' key personnel for the purposes of relationship management and ongoing monitoring and review of the implementation of this MOU are:

<b>The Ministry</b>	<b>PHARMAC</b>	<b>DHB</b>
Senior Advisor Immunisation	Therapeutic Group Manager	Representative, GMs Planning and Funding
National Programme Manager, Immunisation	Manager, Pharmaceutical Funding	Representative, Medical Officers of Health
Director of Public Health	Director, Engagement & Implementation	Project Manager, National Services
Director Emergency Management Team	Manager, Pharmaceutical Funding	

6.4 PHARMAC and the Ministry agree to meet regularly (each a "Vaccine Meeting") and when required, to review and discuss:

- (a) the operation of this MOU;
- (b) any other matters relating to vaccines procurement funding or vaccines management,
- (c) any policy changes at an operational level that may affect any party's role or responsibilities under this MOU, and
- (d) any disputes that may have arisen.

6.5 Any amendments to this MOU resulting from a Vaccine Meeting must be in writing and signed by an authorised representative of each party.

## **7. Issuedispute resolution**

---

7.1 The parties agree that issues or disputes arising in connection with this MOU will be resolved in the first instance by personnel of each party directly involved with the issue/dispute.

7.2 If the issue/dispute is unable to be resolved in this manner, the matter can be referred for discussion at the next Vaccine Meeting. If the matter is urgent, any party may request an ad-hoc or urgent Vaccine Meeting to address the issue/dispute.

7.3 If the issue/dispute is unable to be resolved through the Vaccine Meeting process, then a party may refer the issue to be resolved at the first escalation level in the table below. For each of the levels below, if the dispute or issue has not been resolved within 20 days of being referred to that level, the dispute/issue may be referred to the next level by a party.

<b>Esealation Level</b>	<b>The Ministry</b>	<b>PHARMAC</b>	<b>DHB</b>
1.	National Programme Manager Immunisation	Manager, Pharmaceutical Funding	Project Manager National Services
2.	Deputy Director General of Sector Capability and Implementation	Director of Operations	Pharmaceuticals lead CE
3.	Director General of Health	Chief Executive	DHB Chair of Chairpersons
<u>The Minister of Health</u>			

7.4 If an issue/dispute is escalated to level three and the parties (or their respective delegates) are not able to resolve the issue/dispute within 20 working days, the parties will:

- (a) ensure the continued performance of their obligations under this MOU,
- (b) prepare an agreed summary (or failing agreement, prepare separate written summaries) of the basis of the dispute and the issues involved, together with their reasons for not reaching an agreement, and
- (c) submit the summary or summaries to the Minister of Health as soon as practicable.

7.5 PHARMAC's Chairperson, the DHB Chair of Chairpersons and the Director-General of Health (or their respective delegates) will meet with the Minister as soon as practicable after the summary/summaries are submitted, with a view to achieving a resolution of the issue/dispute.

7.6 In the event that resolution is not reached, the issue/dispute will be resolved by a decision of the Minister. The Minister's decision will be final and binding.

## **8. Termination of MOU**

---

8.1 The parties may only terminate this MOU in the event that the Government amends its decision relating to vaccines procurement and vaccines management (SOC (12) 10/4 refers) or makes additional decisions that would change the roles and responsibilities of the parties.

8.2 Where there has been a Government decision the parties will work together to provide the services under this MOU and any additional services that are reasonably necessary to enable the smooth and efficient handover of the vaccine prioritisation and purchase services as may be required to implement the Government's decision. These services could include:

- t) returning equipment, vaccine supplies, documentation (including all records) and any other property of a party to this MOU that is in the possession or control of another party,
- (b) novating any vaccine supply, vaccine distribution and vaccine storage agreements,
- (c) returning or destroying any of a parties' confidential documents or copies of such documents (together with confirmation or evidence of destruction) if the receiving party requires destruction of such documents,

- (d) migrating the services required to manage the National Immunisation Schedule vaccines (including purchase, storage and distribution of vaccines), and
- (G) all parties continuing throughout the disengagement and migration process maintain supplies and continue the distribution of the National Immunisation Schedule vaccines.

8.3 The parties also agree to:

- (a) provide all migration assistance to any party requesting such assistance,
- (b) answer all questions regarding the National Immunisation Schedule vaccines and provide all reasonable information,

8.4 For the avoidance of doubt, when the National Immunisation Schedule has been migrated to a new alternative arrangement that does not involve PHARMAC, PHARMAC will:

- (a) subject to its legal obligations, not be obliged to list vaccines on the Pharmaceutical Schedule, and
- (b) not be obliged to manage the purchase, storage and distribution of the vaccines.

## 9. **Contact persons and addresses for correspondence**

---

For the purposes of this MOU, the primary contact person and address for correspondence for each party is as follows;

(am) **For PHARMAC:**

Christine Chapman  
Therapeutic Group Manager  
(04) 916 7569 [Christine.chapman@pharmac.govt.nz](mailto:Christine.chapman@pharmac.govt.nz)  
PHARMAC, PO Box 10-254, Wellington, 6011

(b) For the Ministry:

Diana Murfitt  
Senior Advisor  
National Immunisation Programme  
(04) 816 3449 [diana\\_murfitt@moh.govt.nz](mailto:diana_murfitt@moh.govt.nz)  
Ministry of Health, PO Box 5013, Wellington

(C) For DHBs:

Jon Shapleski  
Manager National Services  
(027) 536-9811 [Jon.ShaDleski@dhbsharedservices.health.nz](mailto:Jon.ShaDleski@dhbsharedservices.health.nz)  
DHB Shared Services

(d) Alternative and additional contact persons will be agreed and communicated between the parties.

**Execution**

Signed for and on behalf of PHARMAC by



Witness Signature

Nicole Shute

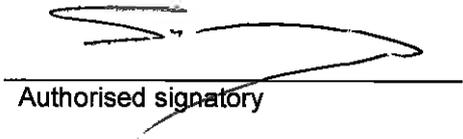
Print Name

Executive Assistant

Occupation

10 Mares St, Wellington

Address

  
\_\_\_\_\_  
Authorised signatory

Steffan Crausaz, Chief Executive

Signed for and on behalf of Her Majesty the Queen in right of New Zealand acting through the Ministry of Health by



Witness Signature

Chai Chuah

Print Name

Advisor Immunisation

Occupation

MOH, Wellington

Address



Authorised signatory

Chai Chuah, Acting Director-General of Health

Signed for and on behalf of the District Health Boards by



Witness Signature

Tania MaHock

Print Name

Executive Secretary

Occupation

MDHB - Palmerston North

Address

  
\_\_\_\_\_  
Authorised signatory

Murray Geogel, CEO, MidCentral DHB (as lead CEO of the DHB/PHARMAC relationship)