03 August 2016

Dear Supplier

INVITATION TO TENDER – SUPPLY OF PHARMACEUTICALS TO DHB HOSPITALS AND/OR TO COMMUNITY PHARMACIES

PHARMAC invites tenders for the supply of certain pharmaceuticals to DHB hospitals and/or to community pharmacies in New Zealand.

This invitation to tender incorporates the following schedules:

- (a) Schedule 1 sets out the definitions used in this invitation;
- (b) Schedule 2 specifies the pharmaceuticals for which you may submit a Tender Bid in relation to community supply and/or hospital supply;
- (c) Schedule 3 describes the process PHARMAC intends to follow in relation to this tender, and provides instructions on how to submit a Tender Bid in relation to community supply and/or hospital supply;
- (d) Schedule 4 sets out terms that will apply if your Tender Bid in relation to community and/or hospital supply is awarded Sole Supply Status and/or Hospital Supply Status;
- (e) Schedule 5 sets out the additional terms that will apply if your Tender Bid in relation to community supply is awarded Sole Supply Status; and
- (f) Schedule 6 sets out the additional terms that will apply if your Tender Bid in relation to hospital supply is awarded Hospital Supply Status.

This invitation to tender also incorporates the information on the Electronic Portal referred to in this invitation.

If you wish to submit a Tender Bid in relation to community supply and/or hospital supply, you must submit it via the Electronic Portal to PHARMAC no later than **5pm** (New Zealand time) on **Thursday 15 December 2016**.

If you have any inquiries about this invitation you should contact the **Tender Analysts** at tender@pharmac.govt.nz (Tim Nuthall on (04) 901 3233 or Katie Brownless on (04) 916 7522).

We look forward to receiving your tender.

Yours sincerely

Sarah Fitt Director of Operations

Contents

Sch	edule 1: Definitions and interpretation4
1.	Definitions4
2.	Interpretation11
Sch	edule 2: Products to be tendered12
1.	Information about Tender Items12
2.	List of Products15
Sch	edule 3: Tender Process
1.	General
2.	Information about submitting a Tender Bid
3.	What to include in your Offer Letter and Tender Submission Form
4.	How to submit a Tender Bid
5.	Evaluation
6.	Conformity41
7.	Decision41
8.	Back-up supply43
9.	Dealing with information
10.	Miscellaneous
Sch	edule 4: Contract terms for both Sole Supply Status and Hospital Supply Status 46
1.	General
2.	Crown Direction
3.	Audit
4.	Miscellaneous
Sch	edule 5: Additional contract terms for Sole Supply Status
1.	Effect of Sole Supply Status
2.	Consents
3.	Price
4.	Shelf-life of Pharmaceutical
5.	Out-of-stock arrangements
6.	Termination and restrictions
7.	Guarantee

Sch	edule 6: Additional contract terms for Hospital Supply Status	. 61
1.	Effect of Hospital Supply Status	61
2.	Consents	68
3.	Price	69
4.	Invoicing and Payment	70
5.	Emergency and disaster supply	72
6.	Defective and short-dated Pharmaceuticals	72
7.	Out-of-stock arrangements	73
8.	Termination and restrictions	75
9.	Guarantee	76
10.	Access by PHARMAC to price and volume data	76
11.	PCTs	77

Schedule 1: Definitions and interpretation

1. Definitions

In this Invitation:

Additional Stock Pharmaceutical (or ASP) means a Pharmaceutical, marked with a "@", for which the supplier of the successful Tender Bid would be required:

- (a) to hold additional stock; and
- (b) to report to PHARMAC on the level of that additional stock each Quarter;

Aggregated Tender Bid means a Tender Bid for more than one Tender Item, which PHARMAC is to consider in aggregate, and can include a Tender Bid for more than one Tender Item of the same Chemical Entity but not aggregation within a single Tender Item;

Agreement means:

- (a) Schedule Four; and
- (b) in relation to a Pharmaceutical with Sole Subsidised Supply Status, Schedule Five; or
- (c) in relation to a Pharmaceutical with Hospital Supply Status, Schedule Six,

and includes, to the extent applicable, the other Schedules and the information on the Electronic Portal comprising the Invitation;

Alternative Pharmaceutical means an alternative brand of a Pharmaceutical that PHARMAC, following consultation with PTAC or its sub-committees, considers to be an acceptable substitute for that Pharmaceutical;

Back-up Supply Agreement means an alternative agreement or arrangement negotiated by PHARMAC, at its sole discretion, with a supplier other than the supplier with Sole Supply Status and/or Hospital Supply Status in respect of a particular Tender Item, to cover the contingency that Sole Supply Status and/or Hospital Supply Status is suspended or withdrawn under the terms of this Agreement in respect of that Tender Item, or that the Tender Item is otherwise out of stock or unavailable for supply;

Chemical Entity means any pharmaceutical that contains, and is described generically according to, the relevant active ingredient specified in Schedule Two and the Electronic Portal. For the avoidance of doubt, the term Chemical Entity does not include any Medical Device;

Combined Community/Hospital Tender Bid means a Community Tender Bid and a Hospital Tender Bid that you submit in combination for the same Tender Item;

Community Tender Bid means a Tender Bid in relation to community supply;

Confidential Information means all information exchanged between us under this Invitation or in relation to your Tender Bid, including during all negotiations relating to your Tender Bid;

Schedule 1

Consents means all consents, permits, licences and authorisations, whether statutory or otherwise, required for the supply of the Tender Item in New Zealand (including Ministry of Health market approval);

Contract Manufacturer means a manufacturer or a supplier that is a party to a contract with the relevant DHB Hospital to compound Pharmaceuticals, on request from that DHB Hospital;

Cost Brand Source Product means a pharmaceutical where there is no price agreed upon by PHARMAC, but the pharmaceutical is subsidised by the Funder at the price obtained by pharmacies;

Crown Direction means any ministerial direction given to PHARMAC under section 103 of the Crown Entities Act 2004;

CTPP means Containered Trade Product Pack SNOMED CT code, which is the unique identifier that describes the packaged, branded product and the container it is dispensed in, as used within the New Zealand Medicines Terminology;

Deadline means 5 pm, Thursday 15 December 2016 (New Zealand time);

Designated Delivery Point means at a DHB Hospital's discretion:

- (a) a delivery point agreed between you and the relevant DHB Hospital, to which delivery point you must supply the Pharmaceutical directly at the Price; and/or
- (b) any delivery point designated by the relevant DHB Hospital or PHARMAC, such delivery point being within 30km of your national distribution centre;

DHB Hospital means a DHB, including its hospital or associated provider unit for which that DHB purchases pharmaceuticals;

District Health Board (or DHB) has the same meaning as in the New Zealand Public Health and Disability Act 2000;

DV Limit means, for a particular Pharmaceutical, the National Discretionary Variance (DV) Limit or the Individual DV Limit;

DV Pharmaceutical means a discretionary variance Pharmaceutical, being an Alternative Pharmaceutical that does not have Hospital Supply Status, and includes a pharmaceutical which (unless PHARMAC specifies otherwise in Schedule Two of this Agreement and the Electronic Portal, or we agree otherwise in writing):

- (a) is listed as a DV Pharmaceutical, in association with the relevant Pharmaceutical having Hospital Supply Status, in the then current Section H of the Pharmaceutical Schedule; or
- (b) in the case of a pharmaceutical that is not a Medical Device, is the same Chemical Entity, at the same strength, and in the same or a similar presentation or form, as the relevant Pharmaceutical with Hospital Supply Status, but which is not yet listed as a DV Pharmaceutical.

For the avoidance of doubt, a pharmaceutical which:

(c) in the case of a pharmaceutical that is not a Medical Device, is a different Chemical Entity from the Pharmaceutical with Hospital Supply Status; and

(d) is not listed as a DV Pharmaceutical in the then current Section H of the Pharmaceutical Schedule,

is not a DV Pharmaceutical;

Electronic Portal means the electronic tender system available via the internet address provided to you by PHARMAC through which you are required to submit your Tender Bid(s);

End Date means the last day of the Hospital Supply Status Period, or Sole Supply Period, as applicable;

Evaluation Committee means a committee established by PHARMAC to evaluate Tender Bids;

Final Transition Period means, in respect of a Pharmaceutical with Sole Supply Status or Hospital Supply Status, as applicable, the period of three calendar months beginning on the day after the relevant End Date;

First Transition Period means, in respect of a Pharmaceutical with Sole Supply Status or Hospital Supply Status, the period beginning on the first day of the month following the Market Notification Date and ending on the last day of the month following the month in which the Start Date occurs (or such different or longer period as PHARMAC determines under clause 1.2 of Schedule Three);

Funder means the body or bodies responsible, pursuant to the New Zealand Public Health and Disability Act 2000, for the funding of pharmaceuticals listed on the Pharmaceutical Schedule (which may be, without limitation, one or more District Health Boards and/or the Ministry of Health) and their successors;

GTIN means the Global Trade Item Number for a Pharmaceutical;

Hospital Supply Status means the status of being the brand of the relevant Pharmaceutical listed in Section H of the Pharmaceutical Schedule as having such status, which Pharmaceutical DHB Hospitals must (or in the case of Medical Devices, may) purchase, subject to any DV Limit for that Pharmaceutical, for the Hospital Supply Status Period;

Hospital Supply Status Period means the period beginning on the day after the end of the First Transition Period and ending on 30 June 2020;

Hospital Tender Bid means a Tender Bid in relation to Hospital Supply;

Individual DV Limit means, for:

- (a) a particular Pharmaceutical; and
- (b) a particular DHB Hospital,

the discretionary variance limit, being a percentage of the Individual Total Market Volume, which equals the percentage of the National DV Limit for that Pharmaceutical, up to which that DHB Hospital may purchase DV Pharmaceuticals of that Pharmaceutical. The Individual DV Limit is set:

(c) for the number of months during which the Hospital Supply Status Period applies during the period ending on 30 June 2018 and

Schedule 1

- (d) the number of months during which the Hospital Supply Status Period applies during the twelve month period ending on 30 June 2019 and
- (e) the number of months during which the Hospital Supply Status Period applies during the twelve month period ending on 30 June 2020.

Individual Total Market Volume means for:

- (a) a particular Pharmaceutical; and
- (b) a particular DHB Hospital,

in any given period, in accordance with data available to PHARMAC, the sum of:

- (c) the total number of Units of the relevant Pharmaceutical with Hospital Supply Status purchased by the relevant DHB Hospital; and
- (d) the total number of Units of all the relevant DV Pharmaceuticals, listed in Section H in association with that Pharmaceutical, purchased by that DHB Hospital;

Invitation means this invitation to tender and includes the cover letter, each of the Schedules and the information on the Electronic Portal referred to in this invitation;

Lead Time means the number of months (being whole months only) indicated on your Tender Bid that, if your Tender Bid is accepted, you would require following the Successful Tenderer Notification Date in order to source sufficient stock of your brand of the Tender Item to meet the entire market demand for the Tender Item as at the Start Date. For the avoidance of doubt, the Lead Time does not affect, and should incorporate the extra time needed to allow for, your obligations in clause 3.1 of Schedule 5 and clause 3.1 of Schedule 6;

Market Notification Date means the date on which PHARMAC notifies the market that your Tender Bid, in respect of a particular Tender Item, has been accepted, being greater than one month prior to the Start Date;

Medical Device means a medical device as that term is defined in the Medicines Act 1981;

National DV Limit means, for a particular Pharmaceutical, the discretionary variance limit, being the specified percentage of the National Total Market Volume up to which all DHB Hospitals may collectively purchase DV Pharmaceuticals of that Pharmaceutical. The National DV Limit is set for DHB Hospitals nationally:

- (a) for the number of months during which the Hospital Supply Status Period applies during the period ending on 30 June 2018; and
- (b) the number of months during which the Hospital Supply Status Period applies during the twelve month period ending on 30 June 2019; and
- (c) the number of months during which the Hospital Supply Status Period applies during the twelve month period ending on 30 June 2020.

National Total Market Volume means, for a particular Pharmaceutical in any given period, in accordance with data available to PHARMAC, the sum of:

(a) the total number of Units of the relevant Pharmaceutical with Hospital Supply Status purchased by all DHB Hospitals; and

(b) the total number of Units of all the relevant DV Pharmaceuticals, listed in Section H in association with that Pharmaceutical, purchased by all DHB Hospitals;

Offer Letter means the letter of offer which must be attached to your Tender Submission Form, in the form set out in the Electronic Portal;

OPPs means PHARMAC's then current Operating Policies and Procedures and any relevant supplements, as applicable;

PCT means Pharmaceutical Cancer Treatment. Tender Items that are PCTs are indicated with "PCT" in the list in clause 2 of Schedule Two and the Electronic Portal;

Pharmaceutical means the relevant Tender Item (which may be a Medical Device) for which you have submitted, and PHARMAC has accepted on behalf of the Funder, a Tender Bid;

Pharmacode means the unique six or seven digit identifier assigned to a pharmaceutical and notified to you by the Pharmacy Guild. Suppliers must apply to the Pharmacy Guild of New Zealand to receive a Pharmacode for each presentation of their pharmaceutical before it is listed;

Potential Out-of-Stock Event means:

- (a) in relation to community or hospital supply, your stock of the Pharmaceutical in New Zealand falls below two-thirds of your most recent three months' total Unit sales of the Tender Item, or, where the Pharmaceutical is designated an ASP, your stock of the Pharmaceutical in New Zealand falls below your most recent four months' total Unit sales of the Tender Item; or
- (b) in relation to community or hospital supply, forecast sales demand in respect of the next two-month period is greater than your stock of the Pharmaceutical, or, where the Pharmaceutical is designated an ASP, forecast sales demand in respect of the next four-month period is greater than your stock of the Pharmaceutical; or
- (c) in relation to hospital supply, your stock of the Pharmaceutical in New Zealand falls below the average volume of stock of the Pharmaceutical required to supply the entire New Zealand DHB Hospital market for the Pharmaceutical for any given two-month period, or, where the Pharmaceutical is designated an ASP, your stock of the Pharmaceutical in New Zealand falls below the average volume of stock of the Pharmaceutical required to supply the entire New Zealand DHB Hospital market for the Pharmaceutical for any given four-month period; or
- (d) in relation to community supply, your stock of the Pharmaceutical in New Zealand falls below one-sixth of the Unit Volume, or, where the Pharmaceutical is designated an ASP, your stock of the Pharmaceutical in New Zealand falls below one-third of the Unit Volume;
- (e) in relation to community or hospital supply, your stock of the Pharmaceutical in New Zealand is insufficient to enable you to fully fill all orders as they are received (without restricting quantities that may be ordered); or
- (f) in relation to New Zealand manufactured products if either:
 - (i) forecast sales demand in respect of the next two-month period is greater than your stock of the Pharmaceutical; or

- (ii) you have insufficient to enable you to fully fill all orders as they are received; or
- (iii) your stock of the active pharmaceutical ingredient taking into account manufacturing and stock on hand falls below two months stock for the Pharmaceutical in New Zealand;

For the avoidance of doubt, references to 'your stock' in (a) to (f) above refer to stock physically held by you or on your behalf in New Zealand and do not include stock held in New Zealand by wholesalers or other parties;

Price means the price (in New Zealand dollars and exclusive of GST) at which the Pharmaceutical is to be supplied, or made available for sale and supply, by you to:

- (a) in relation to community supply, wholesalers and other such distributors, and at which the Pharmaceutical is to be subsidised by the Funder, being the price specified in your successful Tender Submission Form, unless there has been a subsequent price change in accordance with the terms of the Invitation, in which case the Price will be the price notified to you by PHARMAC upon acceptance of your Tender Bid; or
- (b) in relation to hospital supply, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), being the price specified in your successful Tender Submission Form, unless there has been a subsequent price change in accordance with the terms of the Invitation, in which case the Price will be the price notified to you by PHARMAC upon acceptance of your Tender Bid;

PTAC means the Pharmacology and Therapeutics Advisory Committee;

Quarter means the periods:

- (a) 1 January until 31 March;
- (b) 1 April until 30 June;
- (c) 1 July until 30 September; and
- (d) 1 October until 31 December;

Second Transition Period means, in relation to community supply, the period of three calendar months beginning on the day after the expiry of the First Transition Period (or such different or longer period as PHARMAC determines under clause 1.2 of Schedule Three);

Section B means the relevant section or sections of the Pharmaceutical Schedule relating to community pharmaceuticals;

Section H means the relevant section or sections of the Pharmaceutical Schedule identified as such, which relate to pharmaceuticals for use in hospitals;

Sole Supply Period means the period beginning on the day after the expiry of the Second Transition Period and ending on 30 June 2020;

Sole Supply Status means, in relation to community supply, the status of being the sole subsidised supplier of the particular Tender Item for the Sole Supply Period;

Start Date means:

- (a) in relation to a Tender Item for which your Tender Bid has been accepted unconditionally, the first day of the month following the date that represents:
 - (i) the Successful Tenderer Notification Date; plus
 - (ii) the Lead Time; or
- (b) in relation to a Tender Item for which your Tender Bid has received conditional acceptance, in terms of clause 7.4 of Schedule Three, the first day of the month following the date that represents:
 - (i) the date that such acceptance ceases to be conditional; plus
 - (ii) the Lead Time; or
- (c) such other date that is negotiated between you and PHARMAC under clause 1.6 of Schedule Three;

Successful Tenderer Notification Date means the date on which PHARMAC notifies you, in relation to a Tender Item for which you have submitted a Tender Bid, that your Tender Bid has been accepted;

Tender Bid means the Offer Letter together with the Tender Submission Form submitted through the Electronic Portal for a particular Tender Item, including the Lead Time, and includes a Community Tender Bid, a Hospital Tender Bid and a Combined Community/Hospital Tender Bid;

Tender Item means:

- (a) in the case of a pharmaceutical that is not a Medical Device, the form and strength of a Chemical Entity (or entities, if applicable) for which you may submit a Tender Bid; or
- (b) in respect of a Medical Device, an item conforming to the individual specifications described for such item in the product list in clause 2 of Schedule Two for which you may submit a Tender Bid;

Tender Submission Form means the form on which you must submit your bid for each Tender Item, as set out in the Electronic Portal;

Transition Periods collectively refers to the First, and Second (if applicable), and Final Transition Periods;

Unit means an individual unit of a Tender Item (e.g. tablet, 1 ml of an oral liquid, ampoule, syringe, bag, suture or needle, roll or a dressing);

Unit Price means the relevant Price specified for a pack (or equivalent grouping for any Medical Device) of that Tender Item in Section H of the Pharmaceutical Schedule, divided by the number of Units in the pack specified in the Pharmaceutical Schedule as being the listed pack size for that Tender Item (and where that Tender Item is not listed on the Pharmaceutical Schedule, the price and pack size in the most recent issue of the Pharmaceutical Schedule published prior to that Tender Item being delisted);

Unit Subsidy means the subsidy specified for a pack of that Tender Item in Sections A to G of the Pharmaceutical Schedule, divided by the number of Units in the pack specified in the Pharmaceutical Schedule as being the subsidised pack size for that Tender Item (and where that Tender Item is not listed on the Pharmaceutical Schedule, the subsidy and pack size

Schedule 1

specified in the most recent issue of the Pharmaceutical Schedule published prior to that Tender Item being delisted); and

Unit Volume means, in relation to community supply, the approximate number of Units of the Tender Item subsidised by PHARMAC, and claimed for by community pharmacies, in one year, as specified in Schedule Two and the Electronic Portal.

2. Interpretation

In the construction of this Invitation, unless the context otherwise requires:

- (a) a reference to a clause or a Schedule is a reference to a clause of, or a Schedule to, this Invitation;
- (b) a reference to a statute or other law includes regulations and other instruments under it and consolidations, amendments, re-enactments or replacements of any of them (whether before or after the date of this Agreement);
- (c) the singular includes the plural and vice versa;
- (d) the word person includes an individual, a body corporate, an association of persons (whether corporate or not), a trust, a state and an agency of state, in each case, whether or not having a separate legal personality;
- (e) a reference to a person includes a reference to the person's executors, administrators, successors, substitutes, (including, but not limited to, persons taking by novation) and permitted assignees;
- (f) words importing one gender include the other genders;
- (g) headings in this Agreement or in the Electronic Portal are for convenience only and have no legal effect; and
- (h) unless the context requires otherwise, references to the "listing" of a Pharmaceutical:
 - (i) in relation to hospital supply, are to the listing of that Pharmaceutical in Section H of the Pharmaceutical Schedule and are deemed to include any written notification by PHARMAC of that Pharmaceutical being the subject of a national supply contract negotiated by PHARMAC on behalf of DHBs, where such written notification is in advance of the actual listing of that Pharmaceutical in Section H of the Pharmaceutical Schedule (and references to "list", "listed", "delist", "delisted", and "delisting" are to be interpreted accordingly);
 - (ii) in relation to community supply, are to the actual listing of that Pharmaceutical in Sections A to G of the Pharmaceutical Schedule (and references to "list", "listed", "delist", "delisted", and "delisting" are to be interpreted accordingly).

Schedule 2: Products to be tendered

1. Information about Tender Items

1.1 List of Tender Items

This Schedule sets out the Tender Items and information about the Tender Items. While PHARMAC has taken all reasonable care in preparing the information contained in this Schedule, it accepts no liability for any errors or omissions in the information.

1.2 Patents

- (a) Where possible, PHARMAC has identified Tender Items that it understands may be the subject of a patent that it believes is due to expire after the Deadline.
- (b) Where PHARMAC has been advised of the existence of a patent prior to sending out this Invitation, it has shown this in the attached list by the use of a + symbol.
- (c) However, PHARMAC makes no representation as to the patent status of the Tender Items and accepts no liability for any patent infringement that might occur as a result of this tender process or PHARMAC's acceptance of a Tender Bid, including infringement of process patents.

1.3 Unit Volume and market value figures

- (a) Except where indicated otherwise, the Unit Volume figures, in relation to community supply, are based on actual volumes for the year ending 30 June 2016.
- (b) Market value figures, in relation to community supply, are expressed as the Unit Volume in the year ending 30 June 2016, multiplied by the Unit Subsidy as at 1 July 2016.
- (c) The figures referred to in paragraphs (a) and (b):
 - (i) are approximate and indicative only. PHARMAC makes no representation as to the accuracy of these figures or as to the level of sales or likely sales of any Tender Item. In particular, if these figures change at any time during the period from PHARMAC's pre-tender consultation until decisions have been made about the acceptance of Tender Bids for all Tender Items, PHARMAC is not obliged to notify you of any such change; and
 - unless specified by PHARMAC do not include DHB Hospital volumes. For the avoidance of doubt, PHARMAC makes no representation as to the size of the DHB Hospital market for any Tender Item, in relation to hospital supply.
- (d) You acknowledge and agree that in submitting your Tender Bid you will rely on your own knowledge, skill and independent advice or assessment of the market size for any Tender Item and PHARMAC is to have no liability in that regard.

1.4 **Special terms**

Where there are any special terms relating to a particular Tender Item, those terms are indicated in the column entitled "Comments" in the list.

1.5 Subsidies

- (a) The level at which each Tender Item, in relation to community supply, is specified in the attached list as being subsidised per Unit as at 1 July 2015.
- (b) Subsidies of Tender Items, in relation to community supply, may change before a Tender Bid is accepted.
- (c) Where a "*" symbol is indicated next to the Unit Subsidy in the attached list, there is no fully funded product available, in relation to community supply, for that Tender Item as at 1 July 2016.

1.6 **DV Limits**

Where there is a DV Limit relating to a particular Tender Item, in relation to hospital supply, that limit is indicated as a percentage amount in the column entitled "DV Limit" in the attached list and is also shown in the Electronic Portal.

1.7 Tender Items subject to sole supply arrangements

Where a Tender Item is underlined in the list of products below, that item is subject to a sole supply contract as at the date of this Invitation. Accordingly, the subsidy for those items is fixed until 30 June 2017 (unless otherwise indicated) and, for items that are the subject of a sole supply contract, the listing of a new brand, in relation to community supply, could only occur after that date. This information is not available in the Electronic Portal.

1.8 **Hospital only products**

Where an "H" is indicated, you may submit a Tender Bid for Hospital Supply Status for that Tender Item.

1.9 **Community only Products**

Where a "C" is indicated, you may submit a Tender Bid for Sole Supply Status for that Tender Item.

1.10 **Community and Hospital Products**

Where a "C" and an "H" are indicated, you may submit a Tender Bid for Sole Supply Status and/or a Tender Bid for Hospital Supply Status for that Tender Item. You may also submit a Combined Community/Hospital Tender Bid in accordance with clause 2.5 of Schedule Three.

1.11 **PCTs**

Where a "PCT" is indicated, you may submit a Tender Bid for Hospital Supply Status for that Tender Item on the basis that, if PHARMAC accepts your Tender Bid, the Tender Item would be listed in Section B and/or Part II of Section H of the Pharmaceutical Schedule subject to clause 11 of Schedule Six. This information is also shown in the Electronic Portal.

1.12 **Capsule and tablet form**

Unless otherwise stated, where a Tender Item specifies either:

(a) a capsule; or

(b) a tablet,

form of the Chemical Entity, your brand of the relevant Chemical Entity for which you submit a bid may be in either tablet or capsule form, provided that:

- (c) your brand of the relevant Chemical Entity is the same strength as the Tender Item; and
- (d) where the Tender Item specifies both the tablet and capsule form of that Chemical Entity as separate line items, you must submit a bid for the same form and strength for each line item.

1.13 **Pack size preference**

Where a Tender Item is specified as being available for a Tender Bid for Sole Supply Status, it is the preference of PHARMAC that the pack size for such a Tender Item is a 30 or 90 day pack where the Tender Item is in a tablet or capsule form.

Notwithstanding the preference of PHARMAC for Tender Items to be in pack sizes as specified above, pack sizes may be specified in the comments column in the attached list or you may submit, and PHARMAC will consider and may accept, a Tender Bid for any pack size, including larger pack sizes, following its evaluation of Tender Bids under clause 5 of Schedule Three.

1.14 **Pack size for use in DHB Hospitals**

Where a Tender Item is specified as being available for a Tender Bid for Hospital Supply Status, it is the preference of DHB Hospitals that the pack size for such a Tender Item is:

- (a) 500 ml or less, where the Tender Item is in liquid form;
- (b) 200 tablets or capsules, where the Tender Item is in tablet or capsule form; and
- (c) 10 injections, where the Tender Item is in injection form.

Notwithstanding the preference of DHB Hospitals for Tender Items to be in pack sizes as specified in paragraphs (a) to (c) above, pack sizes may be specified in the comments column in the attached list or you may submit, and PHARMAC will consider and may accept, a Tender Bid for any pack size, including larger pack sizes, following its evaluation of Tender Bids under clause 5 of Schedule Three. For the avoidance of doubt, DHB Hospitals do not have a pack (or other equivalent grouping) size preference for Medical Devices and you may submit, and PHARMAC will consider and may accept, a Tender Bid for any pack size (or other equivalent grouping) following its evaluation of Tender Bids under clause 5 of Schedule Three.

1.15 **Pack size for oral contraceptives**

Where an oral contraceptive is included in Schedule Two and on the Electronic Portal, 21 and 28 calendar packs would be considered as different Tender Items (where applicable).

S	CHEDULE	TWO: PRO	DUCTS 1	O BE T	END	ERE	D
Chemical Name Line Item	Units	Cost	Unit Subsidy			DV Limi	t Comments
Abacavir sulphate			,				
<u>Oral lig 20 mg per ml</u>	2,880	\$3,076	\$1.0680		СН	1%	
Tab 300 mg	28,732	\$109,661	\$3.8167		СН	1%	
Acetazolamide	,						
Inj 500 mg					н	1%	
<u>Tab 250 mg</u>	535,844	\$91,254	\$0.1703		сн	1%	
-	000,044	ψ01,204	φ0.1700		011	170	
Acitretin	405 0 40	¢400 700	¢0.0077		<u> </u>	4.07	
<u>Cap 10 mg</u>	435,848	\$129,739	\$0.2977		СН	1%	Special Authority restrictions may apply
<u>Cap 25 mg</u>	96,391	\$66,445	\$0.6893		СН	1%	Special Authority restrictions may apply
Adapalene							
Crm 0.1%	279,510	\$213,266	\$0.7630#		СН	1%	
Gel 0.1%	491,700	\$375,167	\$0.7630#		СН	1%	
Albendazole							
Tab 200 mg					СН	1%	Not currently listed in Section B of the Pharmaceutical Schedule. Any listing may be subject to Special Authority restrictions
Tab 400 mg	1,069	\$8,360	\$7.8200		СН	1%	Special Authority restrictions may apply
Alfentanil							
Inj 0.5 mg per ml, 2 ml ampoule					Н	1%	
Allopurinol							
Tab 100 mg	22,426,546	\$338,865	\$0.0151		СН	1%	A scored tablet is preferred
Tab 300 mg	15,786,424	\$502,324	\$0.0318		СН	1%	A scored tablet is preferred
	10,700,424	¥302,324	ψ0.0010		011	170	
Amantadine hydrochloride Cap 100 mg	758,528	\$483,433	\$0.6373		СН	1%	
Amikacin							
Inj 250 mg per ml, 2 ml					Н	1%	Preference for syringes
Aminophylline Inj 25 mg per ml, 10 ml	2,500	\$59,125	\$23.6500		СН	1%	
Amitriptyline							
Tab 10 mg	19,223,082	\$322,948	\$0.0168		СН	1%	
Tab 25 mg	7,989,633	\$134,226	\$0.0168		СН	1%	
Tab 50 mg	2,565,953	\$72,360	\$0.0282		СН	1%	
-	, ,	+ ,			-		
Amlodipine Tab 2.5 mg	5,741,476	\$126,887	\$0.0221		СН	1%	
						1%	
Tab 5 mg	14,772,761	\$297,819	\$0.0202		СН		
<u>Tab 10 mg</u>	7,725,949	\$222,816	\$0.0288		СН	1%	
Amoxicillin Grans for oral liq 125 mg per 5 ml	27,712,090	\$243,866	\$0.0088		СН	1%	More than one brand currently listed in Section B of the Pharmaceutical Schedule. Unit subsidy shown is the average unit subsidy of the products listed
Grans for oral liq 250 mg per 5 ml	32,430,667	\$335,982	\$0.0104		СН	1%	in 2015 FYR More than one brand currently listed in Section B of the Pharmaceutical Schedule. Unit subsidy shown is the average unit subsidy of the products listed in 2015 FYR
<u>lnj 250 mg</u>	356	\$380	\$1.0670		СН	1%	
						1%	
Inj 500 mg	1,222	\$1,517 \$11,420	\$1.2410 \$1.7200		СН		
<u>lnj 1 g</u>	6,610	\$11,429	\$1.7290		СН	1%	
Amoxicillin clavulanate <u>Tab amoxycillin 500 mg with potassium</u> <u>clavulanate 125 mg</u>	16,059,781	\$1,565,829	\$0.0975	@	СН	1%	
Amphotericin B							
Inj 50 mg (non-liposomal)					Н	1%	

SC	SCHEDULE TWO: PRODUCTS TO BE TENDERED						
Chemical Name			Unit		DV	_	
Line Item	Units	Cost	Subsidy	L	_imi	t Comments	
Apraclonidine							
Eye drops 0.5%			\$3.9540	СН	1%	Not currently listed in Section B of the Pharmaceutical Schedule	
Aprepitant							
<u>Cap 2 x 80 mg and 1 x 125 mg</u>	23,646	\$788,200	\$33.3333	СН	1%	Special Authority restrictions may apply	
Artemether with lumefantrine Tab 20 mg with lumefantrine 120 mg				Н	1%		
Artesunate							
lnj 60 mg				Н	1%		
Atazanavir Sulphate							
Cap 150 mg	170,050	\$1,610,770	\$9.4723	СН	1%	Special Authority restrictions may apply	
Cap 200 mg	36,354	\$459,145	\$12.6298	СН	1%	Special Authority restrictions may apply	
Atovaquone with proguanil hydrochloride	9						
Tab 250 mg with proguanil hydrochloride 100 mg	-			Н	1%		
Tab 62.5mg with proguanil hydrochloride 25 mg (Paediatric)				Н	1%		
Atropine sulphate							
Eye drops 1%	107,355	\$124,245	\$1.1573	СН	1%		
Aztreonam							
lnj 1 g				н	1%		
Baclofen							
<u>Tab 10 mg</u>	4,595,482	\$176,926	\$0.0385	СН	1%		
Bendroflumethiazide [Bendrofluazide]							
Tab 2.5 mg	23,694,660	\$259,693	\$0.0110	СН	1%		
<u>Tab 5 mg</u>	3,090,761	\$55,325	\$0.0179	СН	1%		
Benzoyl peroxide							
Soln 5%				н	1%		
Benzylpenicillin sodium [Penicillin G]							
Inj 600 mg	6,704	\$6,939	\$1.0350	СН	1%		
Betahistine dihydrochloride							
<u>Tab 16 mg</u>	2,967,917	\$174,899	\$0.0589	СН	1%		
Betamethasone valerate with clioquinol							
Crm 0.1% with clioquinol 3%	77,460	\$18,023	\$0.2327	СН	1%	There may be a preference for a pack size	
						of 50 g or less. There may be a preference for tubes	
Betaxolol hydrochloride							
Eye drops 0.25%	21,355	\$50,398	\$2.3600	СН	1%	For products containing BAK, PHARMAC reserves its right to list a BAK or preservative free product for a restricted market	
Eye drops 0.5%	6,340	\$9,510	\$1.5000	СН	1%	For products containing BAK, PHARMAC reserves its right to list a BAK or preservative free product for a restricted market	
Disclutomide							
Bicalutamide Tab 50 mg	405,107	\$70,894	\$0.1750	СН	1%		
-	100,107	ψι 0,004	<i>\\</i> 0.1100	011	. 70		
Bisoprolol Fumarate Tab 2.5 mg	3,546,502	\$283,720	\$0.0800	СН	1%	PHARMAC reserves the right to implement 3 monthly (stat) dispensing from 1 July 2017 for this product	
<u>Tab 5 mg</u>	2,232,240	\$260,435	\$0.1167	СН	1%	PHARMAC reserves the right to implement 3 monthly (stat) dispensing from 1 July 2017 for this product	
<u>Tab 10 mg</u>	830,118	\$177,089	\$0.2133	СН	1%	PHARMAC reserves the right to implement 3 monthly (stat) dispensing from 1 July 2017 for this product	

SC	HEDULE	TWO: PRO	DUCTS TO	D BE TEND	ERE	D
Chemical Name			Unit		DV	
Line Item	Units	Cost	Subsidy		Limi	t Comments
Brimonidine						
Gel 0.5%				СН	1%	Not currently listed in the Pharmaceutical Schedule.
Brimonidine tartrate						
<u>Eye Drops 0.15% - 0.2%</u>	191,515	\$165,469	\$0.8640	СН	1%	For products containing BAK, PHARMAC reserves its right to list a BAK or preservative free product for a restricted market
Brimonidine Tartrate with Timolol Maleate						
Eye drops 0.2% with timolol maleate 0.5%	224,810	\$831,797	\$3.7000#	СН	1%	For products containing BAK, PHARMAC reserves its right to list a BAK or preservative free product for a restricted market. Unit subsidy expressed as "per ml
Bupivacaine hydrochloride						
lnj 2.5 mg per ml, 100 ml bag Inj 5 mg per ml, 4 ml				н Н	1% 1%	
Bupivacaine hydrochloride with adrenaline	•					
Inj 2.5 mg per ml with adrenaline 1:400,000, 20 ml sterile pack				Н	1%	
Inj 5 mg per mI with adrenaline 1:200,000, 20 mI sterile pack				Н	1%	
Buprenorphine with Naloxone						
Tab sublingual 2 mg with naloxone 0.5 mg	253,760	\$520,207	\$2.0500#	СН	1%	Special Authority restrictions may apply
Tab sublingual 8 mg with naloxone 2 mg	290,040	\$1,719,523	\$5.9286#	СН	1%	Special Authority restrictions may apply
Bupropion hydrochloride						
Tab modified-release 150 mg	2,147,912	\$355,845	\$0.1657	СН	1%	
Calcitonin						
<u>Inj 100 iu per ml, 1 ml</u>	593	\$14,351	\$24.2000	СН	1%	
Calcium carbonate Tab eff 0.875 - 1.75 g (0.5 g - 1 g elemental)	455,940	\$94,380	\$0.2070	СН	1%	Tab eff 1.75 g is currently listed on the Pharmaceutical Schedule. Units shown are for tab eff 1.75 g
<u>Tab 1.25 g (500 mg elemental) - Tab 1.5 g</u> (600 mg elemental)	9,767,931	\$210,206	\$0.0215	СН	1%	Tab 1.25 g is currently listed on the Pharmaceutical Schedule. Units shown are for tab 1.25 g
Calcium folinate						
Inj 50 mg				PCT C H	1%	
Inj 100 mg				PCT H	1%	
lnj 300 mg				PCT H	1%	
lnj 1 g				PCT H	1%	
Carmellose sodium with gelatin and pectin						
Paste	25,268	\$7,677	\$0.3038	СН	1%	
Powder	1,568	\$475	\$0.3029	СН	1%	
Carvedilol		A 404.004	4 0.0050	0.11	4.07	
Tab 12.5 mg	2,289,689	\$194,624 \$287,077	\$0.0850 \$0.1050	СН	1%	
Tab 6 25 mg	2,734,068 2,639,122	\$287,077 \$171 543	\$0.1050 \$0.0650	СН СН	1% 1%	
<u>Tab 6.25 mg</u>	2,039,122	\$171,543	υσου.υφ	СП	170	
Cefazolin sodium Inj 500 mg	201	\$160	\$0.7980	СН	1%	
Inj 1 g	18,448	\$12,471	\$0.7980 \$0.6760	СН	1%	
Cefotaxime	, 110	¥.=, II I	÷1.0.00	011		
Inj 500 mg Inj 1 g				н	1% 1%	
Ceftazidime					1 70	
Inj 500 mg				Н	1%	
lnj 1 g				Н	1%	
lnj 2 g				н	1%	
sole supply						=rebate *=part charge @=ASP +=patent
<u></u>					11	

SCHEDULE TWO: PRODUCTS TO BE TENDERED								
Chemical Name			Unit	I	DV			
Line Item	Units	Cost	Subsidy	L	imi	t Comments		
Cefuroxime								
Oral suspension 25 mg per ml				СН	1%	Not currently listed in Section B of the Pharmaceutical Schedule. Any listing may be subject to Special Authority restrictions		
Oral suspension 50 mg per ml				СН	1%	Not currently listed in Section B of the Pharmaceutical Schedule. Any listing may be subject to Special Authority restrictions		
Cefuroxime sodium								
Inj 750 mg					1%			
lnj 1.5 g				Н	1%			
Cetirizine hydrochloride	40 4 40 545	¢404 504	¢0.0450	0.11	4.07			
<u>Oral liq 1 mg per ml</u>	12,140,515	\$181,501	\$0.0150	СН	1%			
Cetrimide Solution 20% (pack size equal to or less				СН	1%	Not currently listed in the Pharmaceutical		
than 100 ml)				CH	1 /0	Schedule.		
Chlorhexidine with ethanol								
Soln 2% with ethanol 70%, non-staining (pink) 100 ml				Н	1%			
Soln 2% with ethanol 70%, non-staining pink (pack size less than 50 ml)					1%			
Soln 2% with ethanol 70%, staining (red) 100 ml				Н	1%			
Soln 2% with ethanol 70%, staining red (pack size less than 50 ml)				н	1%			
Chloroquine phosphate								
Tab 250 mg				Н	1%			
Cholecalciferol								
Tab 1.25 mg (50,000 iu)	1,735,766	\$556,834	\$0.3208	СН	1%			
Cidofovir								
lnj 75 mg per ml, 5 ml				Н	1%			
Ciprofloxacin	045 444	¢45.040	¢0.0005	0.11	4.07			
<u>Tab 250 mg</u>	245,441	\$15,340 \$06.042	\$0.0625 \$0.0714		1% 1%			
<u>Tab 500 mg</u> <u>Tab 750 mg</u>	1,357,159 28,413	\$96,942 \$3,805	\$0.0714 \$0.1339		1% 1%			
-	20,410	ψ0,000	ψ0.1000	011	170			
Ciprofloxacin (current access) Eye Drops 0.3%	92,955	\$231,086	\$2.4860	СН	1%	PHARMAC would only award a tender for		
	02,000	φ <u>2</u> 01,000	Q2.1000	C II	170	either current access or widened access. PHARMAC reserves the right to amend access		
Ciprofloxacin (widened access)								
Eye drops 0.3%				СН	1%	PHARMAC would only award a tender for either current access or widened access. PHARMAC reserves the right to amend access		
Ciprofloxacin with Hydrocortisone								
Ear drops 0.2% with hydrocortisone 1%				Н	1%			
Clarithromycin								
Inj 500 mg					1%			
<u>Tab 250 mg</u>	69,788	\$19,840	\$0.2843		1%	Special Authority restrictions may apply		
<u>Tab 500 mg</u>				Н	1%			
Clofazimine	6 400	¢00.004	¢4 4000	0.11	10/			
Cap 50 mg	6,489	\$28,681	\$4.4200	СН	1%			
Clonidine TDDS 2.5 mg, 100 mcg per day	53,152	\$170,086	\$3.2000	СН	1%			
<u>TDDS 5 mg, 200 mcg per day</u>	20,039	\$170,086 \$90,376	\$3.2000 \$4.5100		1%			
TDDS 7.5 mg, 300 mcg per day	14,867	\$84,296	\$5.6700		1%			

SC	HEDULE	TWO: PRO	DUCTS TO	BE TENDERE	D
Chemical Name			Unit	DV	
Line Item	Units	Cost	Subsidy	Limit	Comments
Clotrimazole			· · · · · · · · · · · · · · · · · · ·		
Crm 1%	4,045,380	\$105,180	\$0.0260	CH 1%	
Coal tar	.,,	. ,			
Shampoo 4% (pack size equal to or less than 100 ml)				CH 1%	Not currently listed in the Pharmaceutical Schedule
Cyclopentolate hydrochloride					
Eye drops 1%	66,105	\$38,605	\$0.5840	CH 1%	
Cycloserine					
Cap 250 mg	2,989	\$38,693	\$12.9450	CH 1%	
Cyproterone acetate with ethinyloestradio	I				
Tab 2 mg with ethinyloestradiol 35 mcg and 7 inert tablets	10,887,268	\$347,304	\$0.0319	CH 1%	
Dapsone					
Tab 100 mg	36,347	\$39,981	\$1.1000	CH 1%	
<u>Tab 25 mg</u>	74,057	\$70,354	\$0.9500	CH 1%	
Demeclocycline					
Cap 150 mg				H 1%	
Cap 300 mg				H 1%	
Desmopressin					
Nasal spray 10 mcg per dose	82,986	\$317,421	\$3.8250	CH 1%	
Dexamethasone					
Eve drops 0.1 %	130,640	\$117,576	\$0.9000	CH 1%	
<u>Eve oint 0.1%</u>	20,073	\$33,607	\$1.6743	CH 1%	
Dexamethasone with framycetin and gram		+)	•		
Ear/eye drops 500 mcg with framycetin suplhate 5 mg and gramicidin 50 mcg per ml	502,152	\$282,461	\$0.5625	CH 1%	
Dexamethasone with neomycin sulphate a	nd polymyxin	B sulphate			
Eve drops 0.1% with neomycin sulphate 0.35% and polymyxin B sulphate 6,000 u per ml	102,780	\$92,502	\$0.9000	CH 1%	
Eye oint 0.1% with neomycin sulphate 0.35% and polymyxin B sulphate 6.000 u per g	34,073	\$52,472	\$1.5400	CH 1%	
Dexamethasone with tobramycin					
Eye drops 0.1% with tobramycin 0.3%			\$2.5280	CH 1%	Not currently listed in Section B of the Pharmaceutical Schedule
Dexmedetomidine hydrochloride					
Inj 100 mcg per ml, 2 ml vial				H 1%	
Diazepam					
Tab 2 mg	2,858,314	\$65,398	\$0.0229	CH 1%	
Tab 5 mg	4,278,085	\$117,305	\$0.0274	CH 1%	
Diclofenac sodium					
Eye drops 1 mg per ml, 5 ml	113,465	\$313,163	\$2.7600	CH 1%	
Inj 25 mg per ml, 3 ml	26,032	\$68,724	\$2.6400	CH 1%	
Suppos 12.5 mg	7,110	\$1,450	\$0.2040	CH 1%	
Suppos 25 mg	6,527	\$1,593	\$0.2440	CH 1%	
Suppos 50 mg	74,024	\$31,238	\$0.4220	CH 1%	
Suppos 100 mg	113,130	\$79,191	\$0.7000	CH 1%	
Docetaxel					
Inj 20 mg				PCT H 1%	Preference for products where stability data >48 hours post-compounding
<u>lnj 80 mg</u>				PCT H 1%	Preference for products where stability data >48 hours post-compounding
Docusate Sodium					
<u>Tab 50 mg</u>	546,478	\$12,624	\$0.0231	CH 1%	
sole supply				#=	rebate *=part charge @=ASP +=patent

#=rebate *=part charge @=ASP +=patent

S	CHEDULE	TWO: PRO	DUCTS TO	BE TENDERED	
Chemical Name			Unit	DV	
Line Item	Units	Cost	Subsidy	Limit	Comments
Docusate Sodium					
<u>Tab 120 mg</u>	1,529,568	\$47,875	\$0.0313	CH 1%	
Donepezil hydrochloride					
Tab 5 mg	1,173,411	\$71,449	\$0.0609	CH 1%	
<u>Tab 10 mg</u>	1,076,455	\$125,708	\$0.1168	CH 1%	
Doxazosin mesylate					
Tab 2 mg	14,503,481	\$195,797	\$0.0135	CH 1%	
<u>Tab 4 mg</u>	11,171,780	\$216,062	\$0.0193	CH 1%	
Doxycycline hydrochloride					
Tab 20 - 40 mg				S	ot currently listed in the Pharmaceutical chedule. Any listing may be subject to pecial Authority restrictions
Tab 50 mg	476,359	\$46,050	\$0.0967	CH 1%	
<u>Tab 100 mg</u>	10,794,574	\$291,453	\$0.0270	CH 1%	
Econazole nitrate					
Crm 1% (pack size 30 g or less)	28,180	\$1,409	\$0.0500	CH 1%	
Emulsifying ointment					
Oint BP (pack size 200 g or less)				H 1%	
Oint BP (pack size greater than 200 g)	50,830,848	\$277,536	\$0.0055	CH 1%	
Ephedrine					
Inj 30 mg per ml, 1ml				H 1%	
Ergometrine maleate					
lnj 500 mcg per ml, 1 ml	1,726	\$32,690	\$18.9400	CH 1%	
Escitalopram					
Tab 10 mg	6,665,749	\$333,287	\$0.0500	CH 1%	
Tab 20 mg	2,619,080	\$224,481	\$0.0857	CH 1%	
Exemestane					
Tab 25 mg	238,130	\$115,095	\$0.4833	CH 1%	
Ezetimibe					
Tab 10 mg	6,181,785	\$690,320	\$0.1117	CH 1% S	pecial Authority restrictions may apply
Ezetimibe with simvastatin					
Tab 10 mg with simvastatin 10 mg	58,380	\$10,022	\$0.1717#	CH 1% S	pecial Authority restrictions may apply
Tab 10 mg with simvastatin 20 mg	87,596	\$17,957	\$0.2050#		pecial Authority restrictions may apply
Tab 10 mg with simvastatin 40 mg	220,568	\$52,568	\$0.2383#		pecial Authority restrictions may apply
Tab 10 mg with simvastatin 80 mg	177,506	\$48,223	\$0.2717#		pecial Authority restrictions may apply
	,	÷·•;			
Fentanyl Patch 12.5 mcg per hour	172,680	\$100,845	\$0.5840	CH 1%	
Patches 100 mcg per hour	172,000	ψ100,040	ψ0.00+0	CH 1%	
Patches 25 mcg per hour	142,392	\$104,231	\$0.7320	CH 1%	
Patches 50 mcg per hour	60,485	\$80,324	\$1.3280	CH 1%	
Patches 75 mcg per hour	19,091	\$35,051	\$1.8360	CH 1%	
Finasteride					
Tab 5 mg	3,295,497	\$228,477	\$0.0693		reference for a blister pack. May be ubject to Special Authority restrictions
Flucloxacillin sodium					
<u>Inj 250 mg</u>	44	\$39	\$0.8800	CH 1%	
<u>Inj 500 mg</u>	479	\$441	\$0.9200	CH 1%	
<u>lnj 1 g</u>	6,349	\$7,365	\$1.1600	CH 1%	
Fluconazole					
<u>Cap 50 mg</u>	119,580	\$14,904	\$0.1246	CH 1%	
<u>Cap 150 mg</u>	60,007	\$42,605	\$0.7100	CH 1%	
<u>Cap 200 mg</u>	64,705	\$22,392	\$0.3461	CH 1%	

S	SCHEDULE TWO: PRODUCTS TO BE TENDERED								
Chemical Name Line Item	Units	Cost	Unit Subsidy		DV Limi	t Comments			
Flucytosine Cap 500 mg				Н	1%				
Foscarnet sodium									
Inj 24 mg per ml, 250 ml				Н	1%				
Fosfomycin Powder for oral solution, 3 g sachet				СН	1%	Not currently listed in Section B of the Pharmaceutical Schedule. Any listing may be subject to Special Authoirty restrictions			
Fusidic acid									
Tab 250 mg	23,380	\$67,218	\$2.8750	СН	1%				
Gemcitabine hydrochloride									
Inj 200 mg				PCT H	1%	data >48 hours post-compounding			
Inj 1 g				PCT H	1%	Preference for products where stability data >48 hours post-compounding			
Gliclazide Tab 80 mg	25,593,536	\$588,651	\$0.0230	СН	1%				
Glucose [Dextrose]									
<u>lnj 50%, 10 ml</u>	10,285	\$56,568	\$5.5000	СН	1%				
<u>Inj 50%, 90 ml</u>	361	\$5,235	\$14.5000	СН	1%				
Glycerol				0.11					
<u>Liq BP</u>	1,661,665	\$12,330	\$0.0074	СН	1%	There may be a preference for pack size < 500 mL			
Glyceryl trinitrate									
<u>TDDS 25 mg, 5 mg per day</u>	88,377	\$46,339	\$0.5243	СН	1%				
<u>TDDS 50 mg, 10 mg per day</u>	40,154	\$24,922	\$0.6207	СН	1%				
Haloperidol decanoate									
Inj 100 mg per ml, 1 ml ampoule				н	1%				
Inj 50 mg per ml, 1 ml ampoule				Н	1%				
Hydrocortisone Powder	77,153	\$183,624	\$2.3800	СН	1%				
	77,155	φ103,024	<i>φ</i> 2.3600	CII	1 70				
Hydrocortisone Butyrate Oint 0.1% (pack size greater than 30 g)	2,862,100	\$196,054	\$0.0685	СН	1%				
Hydrocortisone with wool fat and minera		ψ100,004	ψ0.0000	011	170				
Lotn 1% with wool fat hydrous 3% and mineral oil	11,418,205	\$482,762	\$0.0423	СН	1%				
Ibuprofen									
lnj 10 mg per ml, 2 ml				Н	1%				
lnj 5 mg per ml, 2 ml				Н	1%				
<u>Tab 200 mg</u>	57,119,244	\$539,777	\$0.0095	СН	1%				
Imatinib mesilate									
Cap 400 mg	36,248	\$722,302	\$19.9267#	СН	1%	For non-GIST indications only			
<u>Cap 100 mg</u>	282,428	\$1,406,963	\$4.9817#	СН	1%	For non-GIST indications only			
Imipenem with cilastatin Inj 500 mg with cilastatin 500 mg				Н	1%				
Imiquimod									
<u>Crm 5%</u>	300,608	\$450,410	\$1.4983	СН	1%				
Iodine supplement									
Tab 150 mcg elemental	8,910,631	\$361,415	\$0.0406	СН	1%				
Ipratropium Bromide Aqueous nasal spray, 0.03%	671,955	\$176,946	\$0.2633	СН	1%				
Iron polymaltose	. ,	,		2.1.					
Inj 50 mg per ml, 2 ml	40,381	\$122,920	\$3.0440	СН	1%				

so	HEDULE	TWO: PRO	DDUCTS TO	BE TENDER	RED
Chemical Name Line Item	Units	Cost	Unit Subsidy	D' Lir	-
Isosorbide mononitrate			-		
<u>Tab 20 mg</u>	567,781	\$97,090	\$0.1710	CH 19	%
Tab long-acting 60 mg	8,464,073	\$798,416	\$0.0943	CH 19	%
Isotretinoin					
Cap 5 mg				CH 19	% Not currently listed in the Pharmaceutical Schedule. Any listing may be subject to Special Authority restrictions.
Itraconazole					
Oral liq 10 mg per ml	3,300	\$3,120	\$0.9453	CH 19	% Special Authority restrictions may apply
Ivermectin					
Cream 1%				CH 19	% Not currently listed in the Pharmaceutical Schedule.
Ketoconazole					
Shampoo 2%	5,215,400	\$155,940	\$0.0299	CH 19	%
Lamivudine					
<u>Oral liq 5 mg per ml</u>	12,180	\$13,703	\$1.1250	CH 19	, , , , , , , , , , , , , , , , , , , ,
<u>Oral liq 10 mg per ml</u>	3,120	\$1,332	\$0.4271	CH 19	, , , , , , , , , , , , , , , , , , , ,
<u>Tab 100 mg</u>	184,402	\$39,515	\$0.2143	CH 19	, , , , , , , , , , , , , , , , , , , ,
<u>Tab 150 mg</u>	9,368	\$8,197	\$0.8750	CH 19	% Special Authority restrictions may apply
Levodopa with Carbidopa					
Tab 100 mg with carbidopa 25 mg	7,548,917	\$1,509,783	\$0.2000	CH 19	
Tab 250 mg with carbidopa 25 mg	355,267	\$142,107	\$0.4000	CH 19	
Tab long-acting 200 mg with carbidopa 50 mg	2,053,565	\$975,443	\$0.4750	CH 19	% Pharmacokinetic data required
Levomepromazine	04.070	.	\$ 2,4222	0.11	
Tab 100 mg	94,372	\$41,486	\$0.4396	CH 19 CH 19	
Tab 25 mg	523,512	\$88,631	\$0.1693	Спі	70
Levonorgestrel Subdermal implant	11 717	¢1 565 077	¢122 6500#	CH 19	% For contraception. Confidential rebate
Subdemarinipiant	11,717	\$1,565,977	\$133.6500#	CH 19	applies. Sole Supply protection until 31/12/17
Lidocaine [lignocaine] hydrochloride					
Lidocaine [lignocaine] hydrochloride - Spray - 10 mg dose per spray				H 19	%
Oral [viscous] soln 2%	1,109,199	\$305,030	\$0.2750	CH 19	%
Lidocaine [lignocaine] hydrochloride with					
Soln 4% with adrenaline 0.1 % and tetracaine hydrochloride 0.5%, 5 ml			nyuroonioniae	CH 19	% Not currently listed in Section B of the Pharmaceutical Schedule
Lithium carbonate					
<u>Cap 250 mg</u>	1,955,948	\$184,250	\$0.0942	CH 19	%
Lodoxamide					
Eye drops 0.1%	301,830	\$262,894	\$0.8710	CH 19	%
Losartan				_	
<u>Tab 12.5 mg</u>	2,311,295	\$42,643	\$0.0185	CH 19	
Tab 25 mg	3,838,550	\$86,828	\$0.0226	CH 19	
Tab 50 mg	6,584,763 3 105 142	\$176,406 \$96,104	\$0.0268 \$0.0310	CH 19 CH 19	
<u>Tab 100 mg</u>	3,105,142	φ90,104	φυ.υδΤυ		/0
Losartan with hydrochlorothiazide Tab 50 mg with hydrochlorothiazide 12.5 mg	3,276,254	\$238,085	\$0.0727	СН 19	%
Loteprednol etabonate					
Eye drop 0.5% (pack size less than or equal to 5 ml)				CH 19	% Not currently listed in the Pharmaceutical Schedule.

SC		TWO: PRC	DUCTS TO	D BE TENDE	RE	D
Chemical Name			Unit	C	V	
Line Item	Units	Cost	Subsidy		mit	Comments
Macrogol 3350 with potassium chloride, s	odium bicarbo	onate and sod	ium chloride			
Powder for oral soln 6.563 g with potassium chloride 23.3 mg, sodium bicarbonate 89.3 mg and sodium chloride 175.4 mg				СН 1		Not currently listed in Section B of the Pharmaceutical Schedule
Powder for oral soln 13.125 g with potassium chloride 46.6 mg.sodium bicarbonate 178.5 mg and sodium chloride 350.7 mg	3,480,687	\$887,575	\$0.2550	СН 1	1%	
Magnesium sulphate						
<u>lnj 2 mmol per ml, 5ml</u>	12,107	\$15,315	\$1.2650	CH 1	%	
Mebendazole						
Oral liq 100 mg per 5 ml	30,787	\$4,474	\$0.1453	CH 1	1%	Units and unit subsidy expressed as 'per
Tab 100 mg	45,561	\$45,922	\$1.0079	СН 1	1%	ml'
	,					
Mebeverine hydrochloride Tab 135 mg	2,314,813	\$462,963	\$0.2000	CH 1	1%	
Mefloquine hydrochloride						
Tab 250 mg				H 1	1%	
Meropenem						
lnj 500 mg				H 1	%	
lnj 1 g				H 1	%	
Methadone hydrochloride Inj 10 mg per ml, 1 ml	28,524	\$173,996	\$6.1000	СН 1	1%	
	_0,0_1	<i>Q</i> 0,000	Q 011000		. , 0	
Methotrexate Inj 100 mg per ml, 10 ml				PCT C H 1		Preference for products where stability data >48 hours post-compounding
<u>Inj 100 mg per ml, 50 ml</u>				PCT C H 1	۱%	Preference for products where stability data >48 hours post-compounding
Methylprednisolone aceponate						
Crm 0.1%	558,315	\$184,244	\$0.3300	СН 1		There may be a preference for pack size of 30 g or less. There may be a preference for tubes
Oint 0.1%	359,175	\$118,528	\$0.3300	СН 1		There may be a preference for pack size of 30 g or less. There may be a preference for tubes
Metoclopramide hydrochloride						
Inj 5 mg per ml, 2 ml ampoule	216,568	\$97,456	\$0.4500	СН 1	1%	
Tab 10 mg	6,083,318	\$110,716	\$0.0182		1%	
	-,,	,, 		2		
Metronidazole Inj 5 mg per ml, 100ml				Н 1	1%	
Miconazole nitrate Crm 2% (15 g - 20 g pack)	2,374,170	\$87,061	\$0.0367	CH 1	1%	
Vaginal crm 2% with applicator	2,374,170	\$87,061 \$44,892	\$0.0367 \$0.0988			Single use applicators preferred
	10-1,000	ΨŦŦ,ΟΟΖ	ψ0.0000	511	. ,0	engle des applicators protorioù
Minocycline hydrochloride Cap 100 mg	185,152	¢25 771	\$0.1932	СН 1	1%	PHARMAC may choose to accort one or
	100,102	\$35,771	ΨU.1302			PHARMAC may choose to accept one or both presentations of minocycline capsules/tablets
Tab 50 mg	586,191	\$56,567	\$0.0965	CH 1		PHARMAC may choose to accept one or both presentations of minocycline capsules/tablets. Special Authority restrictions may apply
Morphine sulphate						
lnj 1 mg per ml, 100 ml bag				H 1	1%	
Inj 1 mg per ml, 10 ml syringe				H 1	1%	
Inj 1 mg per ml, 50 ml syringe				H 1	۱%	
<u>lnj 5 mg per ml, 1 ml ampoule</u>	75,196	\$187,689	\$2.4960	CH 1	۱%	
<u>Inj 10 mg per ml 1 ml ampoule</u>	195,698	\$355,779	\$1.8180	CH 1	1%	

SCHEDULE TWO: PRODUCTS TO BE TENDERED							
Chemical Name			Unit	DV			
Line Item	Units	Cost	Subsidy	Limit	Comments		
Morphine sulphate							
Inj 15 mg per ml, 1 ml ampoule	3,548	\$6,933	\$1.9540	CH 1%			
Inj 30 mg per ml, 1 ml ampoule	65,849	\$163,701	\$2.4860	CH 1%			
Tab immediate release 10 mg	3,021,906	\$846,134	\$0.2800	CH 1%			
Tab immediate release 20 mg	810,406	\$447,344	\$0.5520	CH 1%			
Naltrexone hydrochloride							
Tab 50 mg	141,083	\$357,409	\$2.5333	C H 1% Special	Authority restrictions may apply		
Naphazoline hydrochloride							
Eye drops 0.1%	104,175	\$28,822	\$0.2767	CH 1%			
Neostigmine metisulfate							
Inj 2.5 mg per ml, 1 ml	14,705	\$28,822	\$1.9600	CH 1%			
Nicotinic acid							
Tab 50 mg	864,020	\$34,215	\$0.0396	CH 1%			
<u>Tab 500 mg</u>	725,035	\$125,939	\$0.1737	CH 1%			
Nifedipine	0,000	,,000	,				
Tab long-acting 10 mg	697,939	\$206,122	\$0.2953	CH 1%			
Tab long-acting 20 mg	636,729	\$61,062	\$0.2955 \$0.0959	CH 1%			
Cap 5 mg	000,120	φ01,002	ψ0.0000	H 1%			
Tab long-acting 30 mg	516,262	\$64,533	\$0.1250	CH 1%			
Tab long-acting 60 mg	191,623	\$36,728	\$0.1917	CH 1%			
Nitazoxanide	,020	¢00,120	Q	• • • • • •			
Oral liq 100 mg per 5 ml				H 1%			
				11 170			
Nitrazepam	481,676	¢05 140	\$0.0522	CH 1%			
<u>Tab 5 mg</u>	401,070	\$25,143	\$0.05ZZ	UH 1%			
Nitrofurantoin Tab modified-release 50 mg				C H 1% Not curr Schedul	ently listed on the Pharmaceutical e		
Norfloxacin							
<u>Tab 400 mg</u>	200,997	\$27,135	\$0.1350	CH 1%			
Nystatin							
<u>Oral liq 100,000 u per ml</u>	1,636,128	\$173,839	\$0.1063	CH 1%			
Vaginal crm 100,000 u per 5 g with applicator(s)	148,425	\$9,321	\$0.0628	C H 1% Units an	d unit subsidy expressed as 'per g'		
Octreotide (somatostatin analogue)							
<u>lnj 50 mcg per ml, 1 ml</u>	3,472	\$9,374	\$2.7000	CH 1%			
<u>lnj 100 mcg per ml, 1 ml</u>	3,031	\$13,579	\$4.4800	CH 1%			
<u>lnj 500 mcg per ml, 1 ml</u>	1,717	\$30,700	\$17.8800	CH 1%			
Oestriol							
Crm 1 mg per g with applicator(s)	2,489,445	\$1,045,567	\$0.4200		or(s) should be mulitple use and a		
Desseries 500 mag	251 512	¢152.024	<u> </u>	measure			
Pessaries 500 mcg	351,513	\$153,024	\$0.4353	CH 1%			
Olanzapine	044.446	#40,405	#0.0005	011 404			
Orodispersible tab 5 mg	311,443	\$19,465 \$55,759	\$0.0625	CH 1%			
Orodispersible tab 10 mg	511,874	\$55,758 \$25,022	\$0.1089	CH 1% CH 1%			
<u>Tab 2.5 mg</u> Tab 5 mg	1,341,279	\$35,933 \$123,540	\$0.0268 \$0.0580	СН 1% СН 1%			
<u>Tab 5 mg</u> Tab 10 mg	2,096,386 2,807,496	\$123,540 \$255,679	\$0.0589 \$0.0911	CH 1% CH 1%			
<u>Tab 10 mg</u>	2,007,490	\$255,679	\$0.0911				
Omeprazole	E 00E 040	¢400.450	¢0.0040	011 40/			
<u>Cap 10 mg</u>	5,385,646	\$133,456 \$2,827,160	\$0.0248	CH 1%			
<u>Cap 20 mg</u>	87,446,947	\$2,827,160	\$0.0323	CH 1%			
<u>Cap 40 mg</u>	25,831,766	\$1,268,598	\$0.0491	CH 1%			
Ondansetron	4 007 046	¢400 704	#0.4000	011 404			
<u>Tab disp 4 mg</u>	1,687,012	\$168,701 \$115,572	\$0.1000	CH 1%			
<u>Tab disp 8 mg</u>	770,485	\$115,573	\$0.1500	CH 1%			
sole supply				#=rebate	*=part charge @=ASP +=patent		

5	SCHEDULE TWO: PRODUCTS TO BE TENDERED								
Chemical Name Line Item	Units	Cost	Unit Subsidy			D\ Lin	-		
Oxazepam									
Tab 10 mg	778,537	\$48,036	\$0.0617		С	H 19	6		
Tab 15 mg	270,348	\$23,061	\$0.0853		С	H 1%	6		
Paclitaxel									
Inj 30 mg				Р	СТІ	H 1%	6 Preference for products where stability data >48 hours post-compounding		
<u>lnj 100 mg</u>				Ρ	СТ	H 1%	% Preference for products where stability data >48 hours post-compounding		
<u>lnj 150 mg</u>				P	СТ І	H 1%	% Preference for products where stability data >48 hours post-compounding		
<u>Inj 300 mg</u>				P	СТ	H 1%	% Preference for products where stability data >48 hours post-compounding		
<u>Inj 600 mg</u>				P	СТ	H 1%	% Preference for products where stability data >48 hours post-compounding		
Pamidronate disodium									
Inj 3 mg per ml, 10 ml	569	\$3,869	\$6.8000		CI	H 1%	6		
<u>Inj 6 mg per ml, 10 ml</u>	198	\$2,614	\$13.2000		CI	H 1%	6		
<u>lnj 9 mg per ml, 10 ml</u>	326	\$6,259	\$19.2000		CI	H 1%	6		
Pancuronium bromide									
lnj 2 mg per ml, 2 ml					I	H 1%	6		
Paracetamol									
Tab 500 mg					I	H 1%	% Preference for a pack size smaller than 100		
Tab soluble 500 mg					I	H 1%	6		
lnj 10 mg per ml, 50 ml					I	H 1%	6		
lnj 10 mg per ml, 100 ml					I	H 1%	6		
<u>Oral liq 120 mg per 5 ml</u>	74,240,168	\$308,097	\$0.0042		CI	H 20%	% Preference may be given to products which include a measuring device		
<u>Oral liq 250 mg per 5 ml</u>	234,525,284	\$1,020,185	\$0.0044		C	H 20%	% Preference may be given to products which include a measuring device		
<u>Tab 500 mg</u>	363,982,616	\$3,082,933	\$0.0085		С				
Paracetamol with codeine									
Tab paracetamol 500 mg with codeine phosphate 8 mg	49,107,852	\$1,034,211	\$0.0211		CI	H 1%	6		
Paraffin (current access)									
White soft - 2,500 g			\$0.0081		CI	H 1%	6 PHARMAC would only award a tender for either current access or widened access. PHARMAC reserves the right to amend access		
White soft - 500 g			\$0.0072	*	C	H 1%	6 PHARMAC would only award a tender for either current access or widened access. PHARMAC reserves the right to amend access		
Paraffin (widened access)									
White soft - 2,500 g					CI	H 1%	6 PHARMAC would only award a tender for either current access or widened access. PHARMAC reserves the right to amend access		
White soft - 500 g					CI	H 1%	6 PHARMAC would only award a tender for either current access or widened access. PHARMAC reserves the right to amend access		
Paraffin liquid with wool fat liquid									
Eye oint 3% with wool fat liq 3%	83,563	\$86,666	\$1.0371		CI	H 1%	6		
Pegylated interferon alpha-2a									
Inj 135 mcg prefilled syringe			\$362.0000		CI	H 1%	6 PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.		

SCHEDULE TWO: PRODUCTS TO BE TENDERED

	IEDULE	TWO: PR	ODUCTS IC	BEIEND	EKE	U
Chemical Name Line Item	Units	Cost	Unit Subsidy		DV Limit	Comments
Pegylated interferon alpha-2a						
Inj 135 mcg prefilled syringe x 4 with ribavirin tab 200 mg x 168			\$1,975.0000	СН	1%	PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.
Inj 180 mcg prefilled syringe	272	\$61,200	\$225.0000#	СН	1%	PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.
Inj 180 mcg prefilled syringe x 4 with ribavirin tab 200 mg x 168	815	\$1,051,350	\$1,290.0000#	СН	1%	PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.
Pegylated interferon alpha-2b						
Inj 100 mcg				СН	1%	Not currently listed on the Pharmaceutical Schedule. PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.
inj 120 mcg				СН	1%	Not currently listed on the Pharmaceutical Schedule. PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.
Inj 150 mcg				СН	1%	Not currently listed on the Pharmaceutical Schedule. PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.
Inj 50 mcg				СН	1%	Not currently listed on the Pharmaceutical Schedule. PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.
Inj 80 mcg				СН	1%	Not currently listed on the Pharmaceutical Schedule. PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.
Pegylated interferon alpha-2b with ribavirin						
Inj 100 mcg x 4 with ribavirin cap 200 mg x 112				СН	1%	Not currently listed on the Pharmaceutical Schedule. PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.
Inj 120 mcg x 4 with ribavirin cap 200 mg x 140				СН	1%	Not currently listed on the Pharmaceutical Schedule. PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.
Inj 150 mcg x 4 with ribavirin cap 200 mg x 168				СН	1%	Not currently listed on the Pharmaceutical Schedule. PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.
Inj 50 mcg x 4 with ribavirin cap 200 mg x 112				СН	1%	Not currently listed on the Pharmaceutical Schedule. PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.

S	CHEDULE	TWO: PRO	DUCTS TO	BE TEND	DERE	D
Chemical Name Line Item	Units	Cost	Unit Subsidy		DV Limi	t Comments
Pegylated interferon alpha-2b with ribavi	rin					
Inj 80 mcg x 4 with ribavirin cap 200 mg x 168				СН	1%	Not currently listed on the Pharmaceutical Schedule. PHARMAC reserves the right to award one, some or all presentations across the range of pegylated interferon. May be subject to Special Authority restrictions.
Penicillamine						
Tab 125 mg	14,536	\$9,773	\$0.6723	СН	1%	
Tab 250 mg	51,883	\$57,134	\$1.1012	СН	1%	
Pentamidine isethionate Inj 300 mg				Н	1%	
Perindopril						
Tab 2 mg	304,555	\$38,069	\$0.1250	СН	1%	
<u>Tab 4 mg</u>	684,720	\$109,555	\$0.1600	СН	1%	
Permethrin						
<u>Crm 5%</u>	1,409,370	\$197,312	\$0.1400	СН	1%	
Lotion 5%	1,980,990	\$210,639	\$0.1063	СН	1%	
Pethidine hydrochloride						
<u>lnj 50 mg per ml, 1 ml</u>	5,655	\$6,232	\$1.1020	СН	1%	
<u>lnj 50 mg per ml, 2 ml</u>	22,517	\$26,255	\$1.1660	СН	1%	
Pilocarpine hydrochloride						
Eye drops 1%	16,395	\$4,656	\$0.2840	СН	1%	
Eye drops 2%	40,260	\$14,360	\$0.3567	СН	1%	
Eye drops 4%	28,350	\$15,101	\$0.5327	СН	1%	
Pivmecillinam						
Tab 200 mg				СН	1%	Not currently listed in Section B of the Pharmaceutical Schedule. Any listing may be subject to Special Authority restrictions
Poloxamer						
<u>Oral drops 10%</u>	281,370	\$35,453	\$0.1260	СН	1%	
Povidone lodine						
Oint 10%			#	Н	1%	
Pravastatin	0 700 0 44	A 044000	\$2.4450	0.11	4.07	
Tab 20 mg	2,733,241	\$314,323	\$0.1150	СН СН	1%	
Tab 40 mg	1,264,490	\$268,072	\$0.2120	Сп	1%	
Praziquantel	960	¢7 207	¢9 5000	<u>с н</u>	1%	
Tab 600 mg	862	\$7,327	\$8.5000	СН	1 70	
Prednisolone acetate Eye drops 0.12%	50,130	\$45,117	\$0.9000	СН	1%	
	50,150	ψ40,117	φ0.9000	OII	1 70	
Prednisone Tab 1 mg	11,280,568	\$240,953	\$0.0214	СН	1%	
Tab 2.5 mg	2,068,985	\$50,028	\$0.0214 \$0.0242	СН	1%	
Tab 20 mg	6,106,273	\$354,530	\$0.0581	СН	1%	
Tab 5 mg	12,559,146	\$278,562	\$0.0222	СН	1%	
Pregnancy tests - HCG urine						
Pregnancy test - HCG urine - Dipstick				С		Not currently listed on the Pharmaceutical Schedule. PHARMAC reserves the right to award one, some or all of the tenders for pregnancy tests - HCG urine
Pregnancy tests - HCG urine - Cassette	450,720	\$198,317	\$0.4400	С		PHARMAC reserves the right to award one, some or all of the tenders for pregnancy tests - HCG urine
Pregnancy tests - HCG urine - Midstream				С		Not currently listed on the Pharmaceutical Schedule. PHARMAC reserves the right to award one, some or all of the tenders for pregnancy tests - HCG urine

	SCHEDULE "	TWO: PRO	DUCTS TO	D BE TEND	ERE	Ð
Chemical Name Line Item	Units	Cost	Unit Subsidy		DV Limi	t Comments
Primaquine phosphate						
Tab 7.5 - 15 mg	1,116	\$2,332	\$2.0893	СН	1%	Tab 7.5 mg tablet is currently listed in Section B of the Pharamceutical Schedule. Units shown are for 7.5 mg tab. Special Authority restrictions may apply
Primidone						
Tab 25 mg				СН	1%	Not currently listed in Section B of the Pharmaceutical Schedule
Tab 50 mg				СН	1%	Not currently listed in Section B of the Pharmaceutical Schedule
Procaine penicillin						
<u>Inj 1.5 mega u</u>	1,474	\$36,408	\$24.7000	СН	1%	
Prochlorperazine	0.000.475	\$70.011	\$0.0105	0.11	4.07	
<u>Tab 5 mg</u>	3,636,475	\$70,911	\$0.0195	СН	1%	
Pyrazinamide	81,750	\$48,232	\$0.5900	СН	1%	
Tab 500 mg	61,750	φ40,232	Ф 0.5900	СП	170	
Pyridoxine hydrochloride Tab 25 mg	584,286	\$13,959	\$0.0239	СН	1%	
<u>Tab 50 mg</u>	1,704,589	\$39,376	\$0.0231	СН	1%	
Pyrimethamine	, ,					
Tab 25 mg	1,306	\$965	\$0.7390	СН	1%	Special Authority restrictions may apply
Quetiapine						
<u>Tab 100 mg</u>	3,546,298	\$165,506	\$0.0467	СН	1%	
<u>Tab 200 mg</u>	1,314,872	\$105,190	\$0.0800	СН	1%	
<u>Tab 25 mg</u>	17,318,246	\$404,035	\$0.0233	CH	1%	Preference for scored tablet
<u>Tab 300 mg</u>	423,096	\$56,411	\$0.1333	СН	1%	
Quinine dihydrochloride Inj 600 mg				Н	1%	
Quinine sulphate Tab 300 mg	1,051,258	\$130,167	\$0.1238	СН	1%	
Ranitidine						
lnj 25 mg per ml, 2 ml	4,967	\$8,692	\$1.7500	СН	1%	
Ranitidine hydrochloride						
<u>Oral liq 150 mg per 10 ml</u>	1,613,078	\$26,454	\$0.0164	СН	1%	
<u>Tab 150 mg</u> <u>Tab 300 mg</u>	7,863,565 2,474,555	\$161,989 \$72,900	\$0.0206 \$0.0295	СН СН	1% 1%	
Remifentanil hydrochloride	2,474,000	ψ12,300	ψ0.0200	011	170	
Inj 1 mg				Н	1%	
lnj 2 mg				Н	1%	
Ribavirin Tab 200 mg				СН	1%	Not currently listed on the Pharmaceutical Schedule. Any listing may be subject to Special Authority restrictions. PHARMAC may choose to accept one, some or all
Tab 400 mg				СН	1%	presentations of ribavirin tablets. Not currently listed on the Pharmaceutical Schedule. Any listing may be subject to Special Authority restrictions. PHARMAC may choose to accept one, some or all presentations of ribavirin tablets.
Tab 600 mg				СН	1%	
Rifampicin						
Cap 150 mg	57,637	\$32,133	\$0.5575	СН	1%	
<u>Cap 300 mg</u>	116,530	\$135,466	\$1.1625	СН	1%	
sole supply					#	=rebate *=part charge @=ASP +=patent

	SCHEDULE	TWO: PRO	ODUCTS TO	D BE TENDERED
Chemical Name Line Item	Units	Cost	Unit Subsidy	DV Limit Comments
Rifampicin				
Inj 600 mg				H 1%
<u>Oral liq 100 mg per 5 ml</u>	98,154	\$19,631	\$0.2000	C H 1%
<u>Tab 600 mg</u>	4,592	\$16,638	\$3.6233	C 1% Not currently listed in Section B of the Pharmaceutical Schedule
Rifaximin				
<u>Tab 200 mg - 550 mg</u>	21,900	\$244,420	\$11.1607	C H 1% Special Authority restrictions may apply. Tab 550 mg is currently listed on the Pharmaceutical Schedule. Units shown are for tab 550 mg
Risperidone				
lnj 25 mg per 2 ml	7,137	\$970,489	\$135.9800	C H 1% Depot injection. Special Authority restrictions may apply
Inj 37.5 mg per 2 ml	9,709	\$1,735,095	\$178.7100	C H 1% Depot injection. Special Authority restrictions may apply
lnj 50 mg per 2 ml	12,735	\$2,770,627	\$217.5600	C H 1% Depot injection. Special Authority restrictions may apply
Oral liquid 1 mg per ml	256,298	\$83,297	\$0.3250	C H 1%
<u>Tab 0.5 mg</u>	2,526,765	\$80,023	\$0.0317	CH 1%
Tab 1 mg	2,036,387	\$71,274	\$0.0350	C H 1%
<u>Tab 2 mg</u>	975,430	\$38,042	\$0.0390	C H 1%
<u>Tab 3 mg</u>	439,230	\$18,667	\$0.0425	C H 1%
<u>Tab 4 mg</u>	220,037	\$12,835	\$0.0583	CH 1%
Ritonavir				
Tab 100 mg	163,460	\$235,982	\$1.4437	CH 1%
Rizatriptan				
Tab orodispersible 10 mg	1,227,676	\$331,473	\$0.2700	C H 1%
Ropivacaine hydrochloride				
lnj 2 mg per ml, 10 ml				H 1%
lnj 2 mg per ml, 20 ml				H 1%
lnj 2 mg per ml, 100 ml				H 1%
lnj 2 mg per ml, 200 ml				H 1%
lnj 7.5 mg per ml, 10 ml				H 1%
lnj 7.5 mg per ml, 20 ml				H 1%
lnj 10 mg per ml, 10 ml				H 1%
lnj 10 mg per ml, 20 ml				H 1%
Silver Sulphadiazine				
Crm 1%, 50 g	537,400	\$132,200	\$0.2460	C H 1%
Simvastatin				
Tab 10 mg	5,429,329	\$57,334	\$0.0106	C H 1%
Tab 20 mg	25,732,837	\$460,360	\$0.0179	C H 1%
<u>Tab 40 mg</u>	23,387,379	\$735,299	\$0.0314	C H 1%
<u>Tab 80 mg</u>	1,738,220	\$152,772	\$0.0879	C H 1%
Sodium Citro-Tartrate				
Grans effervescent 4 g sachets	2,014,537	\$210,801	\$0.1046	C H 1%
Sodium nitroprusside				
Urinary Ketone Test strip	48,300	\$5,796	\$0.1200	C H 1%
Spiramycin				H 1%
Tab 500 mg				H 1%
Streptomycin sulphate Inj 400 mg per ml, 2.5 ml				H 1%
Sulfadiazine Sodium				
Tab 500 mg	3,620	\$18,617	\$5.1429	CH 1%

SCHEDULE TWO: PRODUCTS TO BE TENDERED								
Chemical Name			Unit		DV			
Line Item	Units	Cost	Subsidy		Limi	t Comments		
Sumatriptan								
Nasal spray				СН	1%	Not currently listed in Section B of the Pharmaceutical Schedule. May be subject to Special Authority restrictions		
Suxamethonium chloride								
Inj 50 mg per ml, 2 ml				Н	1%	There may be a preference for a pre-filled syringe		
Tar with triethanolamine lauryl sulphate	and fluorescein							
Soln 2.3% with triethanolamine lauryl sulphate and fluorescein sodium	37,684,854	\$253,242	\$0.0067	СН	1%			
Temazepam		• • • • • • •	Aa a a a a	0.11				
<u>Tab 10 mg</u>	3,442,395	\$174,874	\$0.0508	СН	1%			
Tenoxicam		* 40	A 0.0500	0.11	40/			
Inj 20 mg	1	\$10	\$9.9500	СН	1%			
Terbinafine Tab 250 mg	2,130,781	\$228,292	\$0.1071	СН	1%			
Testosterone	101 101	\$045.007	¢4,0000	0.11	4.07			
Transdermal patch 2.5 mg	161,421	\$215,227	\$1.3333	СН	1%	Special Authority restrictions may apply		
Testosterone cypionate Inj long-acting 100 mg per ml, 10 ml	1,394	\$106,641	\$76.5000	СН	1%			
	1,394	φ100,041	\$70.5000	CII	1 /0			
Thiamine Hydrochloride Tab 50 mg	5,407,646	\$303,910	\$0.0562	СН	1%			
-	0,407,040	φ000,010	ψ0.0002	UTI	170			
Ticarcillin with clavulanic acid Inj 3g with clavulanic acid 0.1 mg vial				Н	1%			
Tigecycline								
lnj 50 mg				Н	1%			
Timolol maleate	1 17 005	A 40 3 0 7	A A AAA	0.11	4.07			
Eye drops 0.25%	147,265	\$42,707	\$0.2900	СН	1%	For products containing BAK, PHARMAC reserves its right to list a BAK or preservative free product for a restricted market		
Eye drops 0.5%	142,220	\$41,244	\$0.2900	СН	1%	For products containing BAK, PHARMAC reserves its right to list a BAK or preservative free product for a restricted market		
Tobramycin								
Eye drops 0.3%	2,575	\$5,912	\$2.2960	СН	1%			
Eye oint 0.3%	1,554	\$4,640	\$2.9857	СН	1%			
Powder BP				н	1%			
lnj 100 mg per ml, 5 ml				Н	1%			
Tramadol hydrochloride	00 004 540	¢000.000	#0.0050	0.11	4.04			
<u>Cap 50 mg</u>	32,881,519	\$822,038	\$0.0250	СН	1%			
Inj 50 mg per ml, 1 ml				Н	1% 1%			
Inj 50 mg per ml, 2 ml <u>Tab sustained release 100 mg</u>	4,119,516	\$411,952	\$0.1000	н Сн	1% 1%			
Tab sustained release 100 mg	4,119,516 408,925	\$411,952 \$61,339	\$0.1000 \$0.1500	СН	1%			
Tab sustained release 200 mg	408,925 301,307	\$60,261	\$0.1300	СН	1%			
Triamcinolone acetonide	,007	,, _		5.11	. ,0			
0.1% in Dental Paste USP	117,255	\$124,994	\$1.0660	СН	1%			
Inj 10 mg per ml, 1 ml	4,338	\$18,046	\$4.1600	СН	1%	PHARMAC reserves its right to list a preservative free product for a restricted market		
<u>Inj 40 mg per ml, 1 ml</u>	75,295	\$769,515	\$10.2200	СН	1%	PHARMAC reserves its right to list a preservative free product for a restricted market		
<u>Crm 0.02%</u>	1,660,100	\$104,586	\$0.0630	СН	1%			
<u>Oint 0.02%</u>	904,000	\$57,404	\$0.0635	СН	1%			
	·							

SCHEDULE TWO: PRODUCTS TO BE TENDERED								
Chemical Name Line Item	Units	Cost	Unit Subsidy		DV Limi	t Comments		
Trimethoprim			-					
Oral liq				F	l 1%	Not currently listed on the Pharmaceutical Schedule		
Tab 100 mg				F	l 1%			
Trimethoprim with sulphamethoxazole [Co	o-trimoxazole]							
Inj 16 mg with sulphamethoxazole 80 mg per ml, 5 ml				F	1%			
Tab trimethoprim 80 mg and sulphamethoxazole 400 mg				F	1%			
Trimipramine maleate								
Cap 25 mg				CH	1%	Not currently listed on the Pharmaceutical Schedule		
Cap 50 mg				CH	l 1%	Not currently listed on the Pharmaceutical Schedule		
Tropicamide								
Eye drops 0.5%	1,080	\$515	\$0.4767	CH	1%	Single dose presentation would not be a DV Pharmaceutical		
Eye drops 1%	5,430	\$3,135	\$0.5773	CH	l 1%	Single dose presentation would not be a DV Pharmaceutical		
Ursodeoxycholic acid								
<u>Cap 250 mg - 300 mg</u>	499,692	\$266,836	\$0.5340	CH	l 1%	Cap 250 mg is currently listed on the Pharmaceutical Schedule. Units shown are for cap 250 mg. Special Authority restrictions may apply		
Vancomycin hydrochloride								
<u>lnj 500 mg</u>	5,515	\$14,560	\$2.6400	CH	l 1%			
Verapamil hydrochloride								
Tab 40 mg	248,467	\$17,418	\$0.0701	CH	l 1%			
Tab 80 mg	90,928	\$10,675	\$0.1174	CH	l 1%			
Tab long-acting 120 mg	1,790,895	\$108,886	\$0.0608	CH	1 1%			
Tab long-acting 240 mg	1,161,497	\$116,150	\$0.1000	CH	l 1%			
Zidovudine [AZT]								
lnj 10 mg per ml, 20 ml vial				CH	1%	Not currently listed in Section B of the Pharmaceutical Schedule		
Zidovudine [AZT] with lamivudine								
Tab 300 mg with lamivudine 150 mg	77,086	\$56,529	\$0.7333	CH	l 1%	Special Authority restrictions may apply		
Zinc								
Paste (pack size equal to or less than 50 g)				CH	1%	Not currently listed in the Pharmaceutical Schedule.		
Zinc and castor Oil Oint BP (pack size 30 g or less)				F	l 1%			
Zinc sulphate					. , 5			
Cap 50 mg elemental	1,189,967	\$130,896	\$0.1100	CH	l 1%			
Zolmitriptan								
Nasal Spray				CH	l 1%	Not currently listed in Section B of the Pharmaceutical Schedule. May be subject to Special Authority restrictions		

1. General

1.1 Sole Supply Period and Hospital Supply Status Period

- (a) Hospital Tender Bids are to be submitted on the basis that if your Hospital Tender Bid is accepted, you will have Hospital Supply Status for the particular Tender Item for the Hospital Supply Status Period.
- (b) Community Tender Bids are to be submitted on the basis that if your Community Tender Bid is accepted, you will have Sole Supply Status for the particular Tender Item for the Sole Supply Period.
- (c) Combined Community/Hospital Tender Bids are to be submitted on the basis that if your Combined Community/Hospital Tender Bid is accepted, you will have Hospital Supply Status for the particular Tender Item for the Hospital Supply Status Period and Sole Supply Status for the particular Tender Item for the Sole Supply Period.

1.2 **Transition Periods**

- (a) In relation to hospital supply:
 - (i) there will be two Transition Periods (the First Transition Period and the Final Transition Period) during which the successful tenderer's brand is to be available for supply and purchase by DHB Hospitals. Additionally, where the successful tenderer's brand of the Pharmaceutical is not listed immediately prior to the First Transition Period, the successful tenderer's brand must be available for supply and purchase by DHB Hospitals from the applicable dates specified in clause 3 of Schedule 6;
 - (ii) the First Transition Period is intended to allow for an orderly transition to the arrangements that will apply during the Hospital Supply Status Period;
 - (iii) the Final Transition Period is intended to allow for an orderly transition to any new arrangements following the end of the Hospital Supply Status Period;
 - (iv) DHB Hospitals may purchase DV Pharmaceuticals at any time within the First Transition Period and Final Transition Period without any requirement to comply with the DV Limit.
- (b) Subject to paragraph (d) below, in relation to community supply:
 - (i) there will be three Transition Periods (the First Transition Period, the Second Transition Period and the Final Transition Period) during which the successful tenderer's brand is to be available for supply and subsidised, but may not be the sole subsidised brand of that Tender Item. Additionally, where the successful tenderer's brand of the Pharmaceutical is not listed immediately prior to the First Transition Period, the successful tenderer's brand must be available for supply from the applicable dates specified in clause 3 of Schedule 5;
 - the First Transition Period and Second Transition Period are intended to allow for an orderly transition to the arrangements that will apply during the Sole Supply Period;

- (iii) the Final Transition Period is intended to allow for an orderly transition to any new arrangements following the end of the Sole Supply Period.
- (c) In relation to community and/or hospital supply, PHARMAC may, in its sole discretion:
 - determine a different commencement date for the First Transition Period and/or Second Transition Period, as applicable, including where it considers that a different commencement date is necessary to ensure appropriate stock management or appropriate supply of the Tender Item; and/or
 - (ii) extend the period of the First Transition Period and/or Second Transition Period, as applicable, by determining a different end date, and may do so before or after the commencement date of the relevant First Transition Period or Second Transition Period. For the avoidance of doubt, in the event that PHARMAC extends the Second Transition Period under this clause 1.2(c)(ii):
 - (A) the delisting of all other brands of that form and strength of the Chemical Entity is to be deferred until the actual commencement date of the Sole Supply Period, notwithstanding any date previously notified to suppliers by PHARMAC as being the intended date of delisting;
 - (B) all other brands of that form and strength of the Chemical Entity are to remain listed in accordance with the terms of any existing contract between PHARMAC and the particular pharmaceutical supplier in respect of the relevant brand(s) until such time as that supplier's brand of that form and strength of the Chemical Entity is actually delisted.
- (d) In relation to community supply, if the successful tenderer's brand is the only brand of the Tender Item listed on the Pharmaceutical Schedule as at the Market Notification Date, then the First Transition Period and clause 1.1(a) of Schedule Five will not apply and, subject to paragraph (c) above, the Second Transition Period is to begin on the first day of the second month following the date of such notification.
- (e) For the avoidance of doubt, any notification by PHARMAC of the delisting of all other brands of that form and strength of the Chemical Entity on the first day of the Sole Supply Period operates solely as advance notice of the intended delisting of those pharmaceuticals and does not constitute a notice of termination of any existing contract for the supply of those other brands.

1.3 Contract

If PHARMAC accepts your:

- (a) Community Tender Bid, then a contract on the terms and conditions set out in:
 - (i) your Tender Bid (incorporating any variations as a result of negotiations or discussions under clause 1.6 of this Schedule); and
 - (ii) Schedule Four; and
 - (iii) Schedule Five,

will be deemed to have been entered into between you and PHARMAC for Sole Supply Status for the relevant Pharmaceutical and, where applicable, its listing on the Pharmaceutical Schedule;

- (b) Hospital Tender Bid, then a contract on the terms and conditions set out in:
 - (i) your Tender Bid (incorporating any variations as a result of negotiations or discussions under clause 1.6 of this Schedule); and
 - (ii) Schedule Four; and
 - (iii) Schedule Six,

will be deemed to have been entered into between you and PHARMAC for Hospital Supply Status for the relevant Pharmaceutical and, where applicable, its listing on the Pharmaceutical Schedule;

- (c) Combined Community/Hospital Tender Bid, then:
 - (i) a contract on the terms and conditions set out in:
 - (A) your Tender Bid, to the extent applicable (incorporating any variations as a result of negotiations or discussions under clause 1.6 of this Schedule); and
 - (B) Schedule Four; and
 - (C) for the Community Tender Bid element of that Combined Community/Hospital Tender Bid, Schedule Five,

will be deemed to have been entered into between you and PHARMAC for Sole Supply Status for the relevant Pharmaceutical and, where applicable, its listing on the Pharmaceutical Schedule; and

- (ii) a separate contract on the terms and conditions set out in:
 - (A) your Tender Bid, to the extent applicable (incorporating any variations as a result of negotiations or discussions under clause 1.6 of this Schedule); and
 - (B) Schedule Four; and
 - (C) for the Hospital Tender Bid element of that Combined Community/Hospital Tender Bid, Schedule Six,

will be deemed to have been entered into between you and PHARMAC for Hospital Supply Status for the relevant Pharmaceutical and, where applicable, its listing on the Pharmaceutical Schedule.

For the avoidance of doubt, the terms and conditions specified in Schedule Four, Schedule Five and Schedule Six, as applicable, apply from the date when PHARMAC notifies you in accordance with clause 7.2 of this Schedule of its acceptance of your Tender Bid, and do not apply solely for the Sole Supply Period or Hospital Supply Status Period, as applicable.

1.4 Extension of Hospital Supply Status to include Sole Subsidised Supply Status

(a) You acknowledge and agree that if your Hospital Tender Bid is for a Tender Item that is specified in the product list in clause 2 of Schedule Two and the Electronic Portal as being a Tender Item for which you may submit a Tender Bid for Sole Subsidised Supply

Schedule 3

Status, you may agree (such consent not to be unreasonably withheld), if so requested by PHARMAC:

- (i) if PHARMAC has not yet accepted a Hospital Tender Bid for the particular Tender Item, to extend your Tender Bid to cover community supply; or
- (ii) if PHARMAC has accepted your Hospital Tender Bid for the particular Tender Item, to supply the Tender Item for use in the community under Sole Subsidised Supply Status as soon as practicable after such requirement is notified to you, and in any case no later than three months after that notification, under a separate contract for Sole Subsidised Supply Status.
- (b) The Community Tender Bid referred to in paragraph (a)(i) above and the contract for Sole Subsidised Supply Status referred to in paragraph (a)(ii) above will be:
 - (i) at a price that is equal to the Price specified for that Pharmaceutical in your Hospital Tender Bid; and
 - (ii) on the other terms and conditions set out in your Hospital Tender Bid (incorporating any variations as a result of negotiations or discussions under clause 1.6 of this Schedule), as applicable; and
 - (iii) for supply in accordance with Schedules Four and Five; and
 - (iv) for such quantities of the Pharmaceutical as are required for use in the community.
- (c) This clause confers a benefit on, and is enforceable by, the Funder in accordance with the Contracts (Privity) Act 1982.

1.5 Extension of Sole Supply Status to include Hospital Supply Status

- (a) You acknowledge and agree that if your Community Tender Bid is for a Tender Item that is specified in the product list in clause 2 of Schedule Two as being a Tender Item for which you may submit a Tender Bid for Hospital Supply Status, you may agree (such consent not to be unreasonably withheld), if so required by PHARMAC:
 - (i) if PHARMAC has not yet accepted a Community Tender Bid for the particular Tender Item, to extend your Tender Bid to cover hospital supply; or
 - (ii) if PHARMAC has accepted your Community Tender Bid for the particular Tender Item, to supply the Tender Item for use in DHB Hospitals under Hospital Supply Status as soon as practicable after such requirement is notified to you, and in any case no later than three months after that notification, under a separate contract for Hospital Supply Status.
- (b) The Hospital Tender Bid referred to in paragraph (a)(i) above and the contract for Hospital Supply Status referred to in paragraph (a)(ii) above will be:
 - (i) at a price that is equal to the Price specified for that Pharmaceutical in your Community Tender Bid; and
 - (ii) on the other terms and conditions set out in your Community Tender Bid (incorporating any variations as a result of negotiations or discussions under clause 1.6 of this Schedule), as applicable; and

- (iii) for supply in accordance with Schedules Four and Six; and
- (iv) for such quantities of the Pharmaceutical as are required for use in DHB Hospitals.
- (c) This clause confers a benefit on, and is enforceable by, DHB Hospitals in accordance with the Contracts (Privity) Act 1982.

1.6 **PHARMAC may initiate limited negotiations**

- (a) Notwithstanding clause 2.7 of this Schedule, PHARMAC may, in its sole discretion, initiate negotiations or discussions with you in relation to your Tender Bid about:
 - (i) any of the terms and conditions to apply if your Tender Bid is accepted;
 - (ii) the proposed packaging or pack size of the Tender Item;
 - (iii) your ability to ensure continued availability of the Tender Item throughout the Hospital Supply Status Period and/or Sole Supply Period, as applicable;
 - (iv) the price of the Tender Item, but only where PHARMAC determines, in its sole discretion, that an increased price for the Tender Item may be necessary for practicality of supply of the Tender Item (for example, because of particular packaging requirements);
 - (v) DV Limits and/or DV Pharmaceuticals, in relation to hospital supply;
 - (vi) the Lead Time and/or the Start Date; or
 - (vii) any other matter that PHARMAC considers necessary or appropriate.
- (b) If PHARMAC initiates negotiations or discussions with you under paragraph (a), and as a result there is a change to any of the terms and conditions relating to the supply of a Tender Item, PHARMAC is not obliged to inform the other tenderers of that change, nor give those tenderers an opportunity to amend their bid for that Tender Item, unless the change is one which would result in the terms and conditions being materially different in scope from those set out in this Invitation.
- (c) The initiation and pursuit of any negotiations or discussions under this clause shall not constitute a counter-offer and your original Tender Bid will remain open for acceptance in accordance with clause 4.2(b) of this Schedule in the absence of agreement on any variation to that Tender Bid.

1.7 **Termination and amendment of Invitation**

PHARMAC may:

- (a) amend this Invitation at any time up to five business days before the Deadline; and/or
- (b) terminate this Invitation at any time before the acceptance of any Tender Bid by giving five business days' written notice.

2. Information about submitting a Tender Bid

2.1 **Choice of forms and strengths**

Where a Tender Item includes different forms and strengths of a Chemical Entity or entities, your Tender Bid may, but does not need to, include all of the forms and strengths of the Chemical Entity or entities contained in that Tender Item.

2.2 Consents not yet held

You may submit a Tender Bid for a Tender Item where your brand of the Tender Item is yet to obtain all necessary Consents. In those circumstances, you may be required to demonstrate your ability to obtain those consents within a time frame acceptable to PHARMAC. For example, you may be required to demonstrate that you have the dossier for that brand of the Tender Item ready to submit to Medsafe within one month of such a request being made by PHARMAC. For the avoidance of doubt where your brand of the Tender Item is yet to obtain all necessary Consents, any time period to obtain those Consents shall be exclusive of the Lead Time indicated on your Tender Bid.

2.3 Individual Tender Bids

You may submit more than one bid for a Tender Item (for example, you may submit separate bids for different pack sizes (or other equivalent grouping for a Medical Device) of a Tender Item).

2.4 Aggregated Tender Bids

- (a) You may, in addition to submitting a separate Tender Bid for each Tender Item, submit an Aggregated Tender Bid, provided that:
 - (i) in the case of a pharmaceutical that is not a Medical Device, each brand contained in an Aggregated Tender Bid is only a different form and strength of the same Chemical Entity;
 - (ii) you may not aggregate across different chemical entities when submitting a Tender Bid;
 - (iii) you may not aggregate within a single Tender Item (for example, two different brands or pack sizes);
 - (iv) you must also submit a separate Community Tender Bid and/or Hospital Tender Bid, as applicable, for each particular Tender Item.
- (b) Where a Tender Item includes different forms and strengths of a Chemical Entity or different entities (for example, a two-part injection), and you bid for the whole Tender Item, that is not an Aggregated Tender Bid.

2.5 **Combined Community/Hospital Tender Bids**

You may submit a Combined Community/Hospital Tender Bid, provided that you must also submit a separate Community Tender Bid and a separate Hospital Tender Bid for each Tender Item in respect of which you submit a Combined Community/Hospital Tender Bid.

2.6 Aggregated Combined Community/Hospital Tender Bids

You may submit a Tender Bid that is both an Aggregated Tender Bid and a Combined Community/Hospital Tender Bid, provided that you comply with clauses 2.4 and 2.5 above.

2.7 **No conditions**

You cannot make a conditional Tender Bid nor qualify a Tender Bid in any way.

2.8 Separate offers

PHARMAC will treat each Tender Bid as a separate offer.

2.9 **Tender Bid prices**

You must submit, for each Tender Bid, a single price in New Zealand dollars (exclusive of GST), which will be the Price at which you will supply the Tender Item.

3. What to include in your Offer Letter and Tender Submission Form

3.1 **Compulsory use of Offer Letter and Tender Submission Form**

- (a) You must submit your Tender Bid using the Electronic Portal and attach the Offer Letter and a completed Tender Submission Form for each Tender Item for which you wish to submit a bid.
- (b) An electronic version of the Offer Letter is available on the Electronic Portal.

3.2 Information that must be supplied about you

In the Offer Letter, you must supply the following information about you:

- (a) your company structure;
- (b) your management and technical skills;
- (c) your financial resources;
- (d) your (or your supplier's) existing supply commitments;
- (e) your (or your supplier's) previous supply performance; and
- (f) your quality assurance processes, where applicable.

3.3 Information that must be supplied about the Tender Item

In your Tender Submission Form, you must supply the following information about the Tender Item:

(a) in the case of a pharmaceutical that is not a Medical Device, the chemical, form, strength, brand name, pack size and type of packaging;

- (b) for any Medical Device:
 - (i) the brand name, pack size (or other equivalent grouping) and type of packaging;
 - details of the Tender Item(s) and any associated services available in relation to the Tender item(s), including training, education and product support;
 - (iii) confirmation that the Tender Item(s) that you are submitting a Tender Bid in respect of meet the relevant standards and regulatory requirements for its intended use;
 - (iv) information on current usage of and expenditure on the Tender Item(s) by DHBs;
 - (v) confirmation that you have a business continuity plan with a brief summary of the plan;
 - (vi) demonstration of experience and knowledge within the healthcare sector, and specifically DHB Hospitals;
 - (vii) the WAND registration number of the Tender Item(s); and
 - (viii) the name of the sponsor of the Tender Item for the purpose of the Medicines (Database of Medical Devices) Regulations 2003;
- (c) a single price in New Zealand dollars (exclusive of GST) at which you will supply the Tender Item:
 - (i) to wholesalers and other distributors during the Sole Supply Period in respect of a Community Tender Bid; or
 - to, at a DHB Hospital's discretion, Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), in respect of a Hospital Tender Bid;
- (d) whether it has all necessary Consents (and if not, what the status of registration is);
- (e) the Lead Time for supply of the Tender Item;
- (f) the name and location of:
 - (i) the manufacturer(s) of the finished product (and name and location of the packaging site, if different); and
 - the manufacturer(s) of the active ingredients (not required in respect of Medical Devices); and
 - (iii) alternative manufacturers of the finished product and active ingredients (if any) (not required in respect of Medical Devices);
- (g) your proposed distribution and supply arrangements for the Tender Item.

3.4 **PHARMAC** may request further information

- (a) PHARMAC may request such further information as it considers necessary from or about you for the purposes of clarifying or evaluating your Tender Bid, including (but not limited to):
 - (i) information about your credit status;
 - (ii) information on the price of a Tender Item, but only where PHARMAC requires clarification to confirm the exact price being offered, or where PHARMAC initiates negotiations with you under clause 1.6 of this Schedule;
 - (iii) where a Tender Item is a controlled drug, information about the form in which the Tender Item will be supplied, in which case you must supply that information within 10 business days of PHARMAC requesting the information; and
 - (iv) a sample pack or container of the Tender Item (and if you intend supplying it in a different form from that sample pack or container, information about the form in which it will be supplied), in which case you must supply that sample pack or container or information within 10 business days of PHARMAC requesting it.
- (b) If PHARMAC requests further information from or about you it is not obliged to request the same or any other information from or about any other party.

4. How to submit a Tender Bid

4.1 Submission of Tender Bids

All Tender Bids must be submitted via the Electronic Portal. Tender Bids or any copies of Tender Bids should not be delivered in person, by courier, by post, by facsimile or by email to PHARMAC.

4.2 Key dates

Your Tender Bid must:

- (a) be submitted via the Electronic Portal by no later than the Deadline; and
- (b) be irrevocable and remain open for acceptance by PHARMAC until, as applicable:
 - (i) Friday, 31 July 2017;
 - (ii) the date specified for a Tender Item in Schedule Two or on the Electronic Portal (if any); or
 - (iii) if PHARMAC so requests at any time, such later date as you agree in writing.

5. Evaluation

5.1 **Process of evaluation**

The Evaluation Committee, taking such regulatory, legal, medical and other advice as it considers appropriate, will evaluate all conforming Tender Bids that have been checked for

conformity under clause 6(a) of this Schedule, and any non-conforming Tender Bids that are admitted for consideration under clause 6(b) of this Schedule.

5.2 Matters for evaluation

The Evaluation Committee will evaluate Tender Bids in light of PHARMAC's statutory objective which is "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided". In doing so the Evaluation Committee will be guided by the Factors for Consideration (Factors) that form part of PHARMAC's then current Operating Policies and Procedures (OPPs), as published on PHARMAC's website (www.pharmac.govt.nz), to the applicable. More extent information on the Factors can be found at www.pharmac.health.nz/factors-for-consideration.

The requirement for PHARMAC to pursue its statutory objective means that particular emphasis will be given to those aspects of proposals which demonstrate "health outcomes", and those aspects of proposals which demonstrate the impact on the "funding provided" for pharmaceuticals. Those Factors which relate directly to these aspects will be given the greatest weight by the Evaluation Committee but all Factors are important.

The information to be taken into account in applying the Factors by the Evaluation Committee will include, in particular:

- (a) your ability to ensure continued availability of the Tender Item throughout the Sole Supply Period and/or Hospital Supply Status Period and each of the Transition Periods, as applicable, taking into account each of the following separate points:
 - (i) your financial resources;
 - (ii) your management and technical skills;
 - (iii) your, or your supplier's, existing supply commitments;
 - (iv) your, or your supplier's, previous supply performance;
 - (v) your quality assurance processes, where applicable;
 - (vi) the site of manufacture and packaging of the Pharmaceutical, and site of manufacture of the active ingredient;
 - (vii) your proposed distribution and supply arrangements for the Tender Item; and
 - (viii) the Lead Time for supply of the Tender Item;
- (b) the pack size (or other relevant grouping for a Medical Device) of the Tender Item and the type of packaging;
- (c) the price of the Tender Item;
- (d) the amount and timing of savings, including non-pharmaceutical savings accruing to the Funder or PHARMAC during the Hospital Supply Status Period and/or the Second Transition Period and the Sole Supply Period, as applicable;
- (e) either:

- (i) evidence that you have obtained, and still have, market approval for your brand of the Tender Item, and all necessary Consents; or
- evidence that will enable the Evaluation Committee to form a view on the likelihood and timing of your brand of the Tender Item gaining all necessary Consents;
- (f) the name and location of the manufacturer of the finished product and active ingredients of the Tender Item; and
- (g) any other benefits to the Funder of selecting you as the supplier of the Tender Item.

6. **Conformity**

- (a) PHARMAC may, in its sole discretion, check your Tender Bid for conformity with this Invitation. If PHARMAC does elect to check your Tender Bid, it is not obliged to check all or any other Tender Bids for conformity, provided that in PHARMAC's judgment this would not be unfair to you in comparison to any other party. A Tender Bid will conform if it:
 - (i) is submitted via the Electronic Portal by the Deadline;
 - (ii) is submitted on the Tender Submission Form and an Offer Letter is attached;
 - (iii) has no conditions or qualifications attached;
 - (iv) includes all information required under clauses 3.2 and 3.3 of this Schedule; and
 - (v) otherwise complies, both as to form and substance, with the requirements of this Invitation.
- (b) PHARMAC may, in its sole discretion, provided that in PHARMAC's judgment this would not be unfair to you in comparison to any other party:
 - (i) exclude any non-conforming Tender Bid from consideration; or
 - (ii) consider, and accept, any non-conforming Tender Bid.

7. Decision

7.1 Decision on acceptance of Tender Bid

- (a) The Evaluation Committee will make a recommendation as to which Tender Bid should be accepted to PHARMAC's Board of Directors (or its delegate under Delegated Authority pursuant to Section 73 of the Crown Entities Act 2004, where applicable).
- (b) PHARMAC's Board of Directors (or its delegate, where applicable) will have the sole discretion to decide whether or not to accept a Tender Bid for any Tender Item.
- (c) PHARMAC's Board of Directors (or its delegate, where applicable):
 - (i) will use the Factors in PHARMAC's then current OPPs as applicable, in deciding whether or not to accept a Tender Bid for any Tender Item; and

(ii) is not obliged to act in accordance with any recommendation of the Evaluation Committee.

7.2 Notification of acceptance

- (a) Once PHARMAC's Board of Directors (or its delegate, where applicable) has decided under clause 7.1 above which Tender Bid (if any) to accept for a Tender Item, PHARMAC will, within a reasonable period of time, notify the successful tenderer in writing that it has been successful and in addition:
 - subject to paragraph (b) below, if the successful Tender Bid is unconditionally accepted, PHARMAC will, within a reasonable period of time, notify each unsuccessful tenderer in writing of the identity of the successful tenderer; or
 - (ii) subject to paragraph (b) below, if the successful Tender Bid is conditionally accepted, PHARMAC will, within a reasonable period of time of that tender becoming unconditionally accepted, notify each unsuccessful tenderer in writing of the identity of the successful tenderer.
- (b) If for any reason you do not receive written notification from PHARMAC in accordance with paragraph (a) above, you will be deemed to have received the required notification on the date that each Tender Item you bid for is notified in the Pharmaceutical Schedule.

7.3 PHARMAC's rights reserved

- (a) PHARMAC reserves the right to accept or reject any Tender Bid.
- (b) While it is PHARMAC's current intention, unless specified otherwise in Schedule Two or the Electronic Portal, to enter into an agreement to award Hospital Supply Status and/or Sole Supply Status for each Tender Item, PHARMAC will not in any circumstances be bound to accept any or all Tender Bids and, in particular, PHARMAC will not be bound to accept the lowest or any other Tender Bid for a Tender Item.
- (c) Acceptance only occurs if, and when, PHARMAC's Board of Directors (or its delegate, where applicable) resolves to accept a Tender Bid and this acceptance is notified to the successful tenderer.
- (d) PHARMAC may take any action, including making any adjustments to the tender process that it considers appropriate, acting reasonably (provided that it notifies tenderers materially affected by such adjustments).
- (e) PHARMAC may, at any time, suspend or cancel in whole or in part, this tender process in order to fulfil its public law obligations through consultation, or otherwise. In this situation PHARMAC may (without limitation) ask you to adapt and resubmit your Tender Bid in light of consultation, or alternatively we may request that new Tender Bids be submitted (or in the case of a suspension PHARMAC may also resume the tender process without further change following the end of the period of suspension).

7.4 Conditional acceptance

(a) Where the successful tenderer's brand of a Tender Item is yet to receive all necessary Consents:

- (i) the contract referred to in clause 1.3 of this Schedule will be conditional upon such Consents being received within a time period specified by PHARMAC; and
- (ii) PHARMAC may terminate the contract if such Consents have not been obtained, or in PHARMAC's view are unlikely to be obtained, within the period specified by PHARMAC.
- (b) Acceptance of a Tender Bid by PHARMAC's Board of Directors (or its delegate, where applicable), and the contract referred to in clause 1.3 of this Schedule may be conditional upon you satisfying PHARMAC that you will have sufficient stock of the Tender Item available to commence supply as at a date reasonably determined by PHARMAC.

8. Back-up supply

Back-up Supply Agreements

- (a) PHARMAC may at any time negotiate a Back-up Supply Agreement with another supplier for any Tender Item.
- (b) PHARMAC may, at its sole discretion, seek proposals for Back-up Supply Agreements under a separate process to this Invitation to Tender. PHARMAC does not seek submissions for Back-up Supply Agreements in response to this Invitation to Tender and is not obliged to consider proposals or bids for back-up supply submitted as part of the tender process.

9. Dealing with information

9.1 **Confidentiality**

Subject to clause 9.2 below, all Confidential Information is confidential to us and our employees, legal advisers, electronic procurement providers and other consultants (including PTAC and its sub-committees), the Ministry of Health, DHBs and the Funder. You acknowledge that it may be necessary or appropriate for PHARMAC to disclose Confidential Information:

- (a) pursuant to the Official Information Act 1982; or
- (b) in publicly notifying any acceptance of your Tender Bid; or
- (c) otherwise pursuant to PHARMAC's public law or any other legal obligations.

PHARMAC may consult with you before deciding whether to disclose Confidential Information for the purposes described in paragraphs (a) and (c) above, in order to ascertain any objections you may have to the disclosure of any of the Confidential Information. You acknowledge, however, that it is for PHARMAC to decide, in its absolute discretion, whether it is necessary or appropriate to disclose information for any of the above purposes, provided that PHARMAC shall act in good faith in disclosing any Confidential Information. Outside the circumstances described in paragraphs (a) and (c) above, Confidential Information must not be disclosed by either of us (or by our employees, legal advisers and other consultants) unless:

(d) the information is publicly available without any cause attributable to the disclosing party; or

- (e) the other party has been reasonably informed prior to disclosure, and the disclosure is:
 - (i) for the purposes of this Agreement; or
 - (ii) required by law; or
 - (iii) in a form, and of content, agreed to by us.

For the avoidance of doubt, information released by PHARMAC in accordance with paragraphs (a) to (c) above ceases to be Confidential Information and you agree that PHARMAC may release that information again at any time in future without consulting with you or obtaining your prior agreement.

9.2 **Use of information**

Generalised aggregated information regarding your Tender Bid that does not identify you or that cannot reasonably be expected to identify you or lead to the connection of you with your Tender Bid is not Confidential Information and PHARMAC may use and publish such information as it sees fit.

10. Miscellaneous

10.1 **Process contract**

In submitting a Tender Bid, you agree that you and PHARMAC are contractually bound to follow the process and comply with the obligations expressly contained in this Invitation.

10.2 Costs

PHARMAC is not liable in any way whatsoever for any direct or indirect costs incurred, or loss (including loss of profit) or damage sustained, by you in respect, or arising out, of this tendering process or the obtaining or granting of Hospital Supply Status and/or Sole Supply Status, as applicable, for your supply of the Tender Item including, without limitation, costs of obtaining all necessary Consents for any Tender Item.

10.3 No reliance

Your Tender Bid is submitted in reliance on your own knowledge, skill and independent advice, and not in reliance on any representations made by PHARMAC (including for these purposes the sales and market information (if any) provided in Schedule Two or the Electronic Portal).

10.4 No further liability

PHARMAC is not, in any event, liable in contract, tort or any other way whatsoever for any direct or indirect loss (including loss of profit), damage or cost of any kind incurred by you or any other person in relation to this tendering process.

10.5 No lobbying

(a) You are not to initiate any communication with PHARMAC or its advisors, the Minister of Health (or any Associate Ministers), the Ministry of Health (including its operating unit Medsafe), or a District Health Board or any of their officers or directors, at any time with a view to influencing the outcome of the tendering process. (b) Failure to comply with this clause will entitle PHARMAC, in its sole discretion, to disqualify you from this tendering process.

10.6 Enquiries

If you have any enquiries about this Invitation you should contact Tim Nuthall or Katie Brownless at PHARMAC. Any additional information that PHARMAC gives to you as a result of your enquiry will also be given by PHARMAC to other potential tenderers, if PHARMAC determines that such information is material.

10.7 Jurisdiction and governing law

We each submit to the exclusive jurisdiction of the New Zealand courts and agree that this Invitation is governed by New Zealand law.

Schedule 4: Contract terms for both Sole Supply Status and Hospital Supply Status

1. General

1.1 **Operating Policies and Procedures**

- (a) You acknowledge that:
 - (i) PHARMAC is required to pursue the objectives, carry out the functions, and otherwise comply with the statutory obligations, prescribed for PHARMAC in the New Zealand Public Health and Disability Act 2000;
 - (ii) PHARMAC is subject to other statutory and public law obligations, which govern PHARMAC's decision-making processes;
 - (iii) PHARMAC has OPPs which provide guidance on the way in which PHARMAC carries out its statutory responsibilities in relation to the management of the Pharmaceutical Schedule;
 - (iv) PHARMAC's OPPs may be amended or updated from time to time, following consultation with relevant groups;
 - (v) the actions which PHARMAC may take under its OPPs include (without limitation):
 - (A) listing new pharmaceuticals;
 - (B) changing guidelines or restrictions on the purchasing, prescribing and dispensing of listed pharmaceuticals;
 - (C) changing the subsidy levels and/or market dynamics for pharmaceuticals as a result of PHARMAC adopting one of the strategies set out in the OPPs or by any other means;
 - (D) amending the basis on which pharmaceuticals are classified into therapeutic groups and sub-groups;
 - (E) delisting pharmaceuticals, or delisting all or part of a therapeutic group or sub-group;
 - (vi) any action taken by PHARMAC pursuant to its OPPs may impact on the listing of the Pharmaceutical.
- (b) PHARMAC agrees not to apply, amend or update its OPPs in order to avoid any of PHARMAC's obligations under this Agreement.

1.2 Amendments to Pharmaceutical Schedule

PHARMAC will consult with you before amending the Pharmaceutical Schedule if a proposed amendment would have a material adverse effect on the listing of the Pharmaceutical.

1.3 **Product identification codes**

You agree to obtain and notify PHARMAC by submitting a notification of product changes form of the Pharmacode, the GTIN and the CTPP for the Pharmaceutical as soon as these are notified to you, and in any event no later than the earlier of:

- (a) 10 business days following the Market Notification Date; or
- (b) the 5th day of the month immediately prior to the Start Date.

For the avoidance of doubt, this requirement does not apply in relation to any Pharmaceutical that is a Medical Device.

2. Crown Direction

- (a) You acknowledge that PHARMAC must comply with any Crown Direction.
- (b) PHARMAC may terminate or amend the Agreement, or impose restrictions on the prescribing or dispensing of a Pharmaceutical, at any time during the Sole Supply Period or the Hospital Supply Status Period (as applicable) or the Transition Periods, if the termination, amendment or imposition of restrictions is required to give effect to a Crown Direction.
- (c) In the event that a Crown Direction is issued to PHARMAC that requires an amendment to be made to this Agreement to give effect to that direction:
 - PHARMAC will give you as much notice as practicable of the Crown Direction and of any amendments to this Agreement that are required to give effect to that direction;
 - (ii) the Agreement will be deemed to be amended so as to give effect to the Crown Direction from the date when such direction is due to take effect; and
 - (iii) you may terminate this Agreement on not less than six months' written notice to PHARMAC where the effect of the amendment required under sub-paragraph (ii) above is such that it is no longer viable, financially or otherwise, for you to continue supplying the Pharmaceutical or to perform your obligations under this Agreement.

3. Audit

- (a) PHARMAC may, from time to time, review your records and any other information you hold that relates to this Agreement with regard to stock levels, registration information and supply issues, for the purposes of auditing your compliance with this Agreement. In these circumstances, PHARMAC, in consultation with you, will determine the terms and manner of any such audit, which as a minimum, must include the following:
 - (i) the audit will be conducted by an auditor authorised by PHARMAC;
 - (ii) you agree to co-operate fully with PHARMAC and provide PHARMAC and the auditor with all reasonable assistance to ensure that any audit conducted under this clause is fully and properly completed to PHARMAC's satisfaction, including:

- (A) allowing the auditor access to your premises, records and other information you hold that relates to this Agreement with regard to stock levels, registration information and supply issues, for the purposes of, and during the course of, conducting the audit;
- (B) answering promptly any questions from PHARMAC or the auditor concerning any aspect of your compliance with this Agreement.
- (iii) PHARMAC will give you 10 business days' notice of its intention to conduct an audit under this clause and will ensure that the conduct of any such audit, and access in terms of sub-paragraph (A) above, does not unreasonably disrupt your business operations.
- (b) PHARMAC will notify you in writing if an audit under this clause reveals any noncompliance with this Agreement. You agree to remedy any non-compliance within 10 business days of receiving such notice from PHARMAC or such other period as agreed with PHARMAC.
- (c) In relation to Hospital Supply Status, PHARMAC will use its best endeavours to audit compliance by DHB Hospitals with the DV Limits and related requirements set out under this Agreement.

4. Miscellaneous

4.1 Litigation support

If this Agreement or its terms (including the basis on which the Pharmaceutical is listed):

- (a) give rise to proceedings being issued against PHARMAC; or
- (b) result in PHARMAC being made a party to any proceedings issued by a third party,

you will give PHARMAC all assistance it reasonably requires to gather evidence (including expert medical and clinical evidence) for the purpose of those proceedings.

4.2 **Dispute resolution**

If there is a dispute between us arising out of, or in connection with, this Agreement, neither of us is to commence any proceedings relating to that dispute until the following procedure has been complied with:

- (a) the party claiming a dispute has arisen must give written notice to the other party specifying the nature of the dispute;
- (b) we will endeavour, in good faith, to resolve the dispute referred to in the notice by using informal dispute resolution techniques;
- (c) if we do not agree on a dispute resolution technique within 14 days after the date notice of a dispute was given, the dispute is to be mediated according to the standard mediation agreement of LEADR New Zealand Incorporated (Lawyers Engaged in Alternative Dispute Resolution), and the Chair of LEADR (or the Chair's nominee) will select the mediator and determine the mediator's remuneration;

- (d) a party seeking urgent interlocutory relief may, by notice to the other party, elect not to comply with the provisions of this clause, but only to the extent of the relief sought, and only for the period required to dispose of the application for interlocutory relief; and
- (e) pending resolution of the dispute, this Agreement will remain in full effect without prejudicing our respective rights and remedies.

For the avoidance of doubt you acknowledge and agree that where a dispute arises in respect of hospital supply, PHARMAC may elect to involve any relevant DHB in any part, or all, of the above procedure.

4.3 **Advertising**

You must ensure that any Advertisement aimed at consumers of pharmaceuticals which you procure to be published, or in any way participate or assist in publishing, does not breach any applicable:

- (a) statute or regulation, including the Fair Trading Act 1986, Medicines Act 1981 and Medicines Regulations 1984; or
- (b) industry standard, including the Advertising Standards Authority Codes of Practice and Medicines New Zealand Code of Practice.

For the purposes of this clause:

- (c) "Advertisement" means any words, whether written, printed or spoken, any pictorial representation or design, any sounds or visual images, or combination of sounds and visual images, or any other form of communication used or appearing to be used to promote:
 - (i) the sale of a Pharmaceutical; or
 - (ii) the use of a method of treatment involving a Pharmaceutical; and
- (d) references to a statute, regulation or industry standard include that statute, regulation or industry standard as amended or replaced from time to time.

4.4 **No derogation**

For the avoidance of doubt, the express provision of a remedy for, or consequence of, breach of any term of this Agreement does not derogate from any other legal right or remedy available to PHARMAC under this Agreement or otherwise in respect of such breach.

4.5 **No waiver**

A failure or delay by either of us to exercise any right arising under this Agreement is not a waiver of that right, and a waiver of a breach of this Agreement is not a waiver of any other breach.

4.5 Agreement prevails

Where any of your terms of supply, whether recorded on your invoices or in credit arrangements entered into or elsewhere, conflict with or detract from any of the terms of this Agreement, the terms of this Agreement will prevail and will apply to the exclusion of any of your terms or documentation.

4.6 Entire agreement

This Agreement:

- (a) is the entire agreement between us regarding the terms on which the Pharmaceutical is, as applicable:
 - (i) listed in Section B of the Pharmaceutical Schedule and subsidised by the Funder; and/or
 - (ii) listed in Section H of the Pharmaceutical Schedule and purchased by DHB Hospitals; and
- (b) supersedes and extinguishes, from the Start Date, all prior agreements and understandings between us, and between you and any District Health Board regarding supply of the Pharmaceutical to DHB Hospitals.

4.7 Amendments

Amendments to this Agreement are only effective if in writing and signed by both of us.

4.8 Assignment

You will not permit any part of this Agreement to be transferred, assigned or sub-contracted (either directly or due to a change of ownership or control) without PHARMAC's prior written consent (such consent not to be unreasonably withheld). Any such consent may be given subject to such reasonable conditions as PHARMAC sees fit but no such consent will relieve you from any liability or obligation under the terms of the Agreement, and you will continue to be responsible for the acts, defaults and neglects of your transferee, assignee or sub-contractor.

4.9 Further assurances

We both agree to execute any further documents and do any further acts within our power as may be reasonably necessary from time to time to give effect to the terms and intentions of this Agreement.

4.10 Contracts Privity

- (a) For the purposes of the Contracts (Privity) Act 1982, we both acknowledge that your obligations in this Agreement constitute promises which confer or are intended to confer a benefit on the Funder and related persons and/or DHB Hospitals and related persons (as applicable), and are enforceable at the suit of the Funder, any such DHB Hospitals or any related persons.
- (b) Except as expressly provided in paragraph (a) above, the parties do not intend to create rights in, or grant remedies to, any third party as a beneficiary of this Agreement, and all the provisions of this Agreement shall be for the sole and exclusive benefit of the parties.
- (c) For the avoidance of doubt, you acknowledge that PHARMAC may pursue damages or any other claim (including injunctive or other such relief) under this Agreement on its own account and/or on behalf of the Funder and/or DHB Hospitals (as applicable), in respect of any form of loss or damage incurred by PHARMAC and/or the Funder and/or DHB Hospitals.

4.11 Jurisdiction and governing law

We each submit to the exclusive jurisdiction of the New Zealand courts and agree that this Agreement is governed by New Zealand law.

51

Schedule 5: Additional contract terms for Sole Supply Status

1. Effect of Sole Supply Status

1.1 Subsidy arrangements

- (a) Subject to clause 3.1 of this Schedule, the Pharmaceutical will be subsidised, and you must supply it, during the First Transition Period at the Price. If any other brands of the Chemical Entity are listed on the Pharmaceutical Schedule, those brands will continue to be subsidised for the First Transition Period at the subsidy applicable to those brands immediately before the commencement of the First Transition Period.
- (b) The subsidy payable for all other brands of that form and strength of the Chemical Entity that are listed will be changed to the Price on the first day of the Second Transition Period, unless the Price exceeds the subsidy applicable to those brands immediately prior to the First Transition Period, in which case the subsidy will remain unchanged.
- (c) All other brands of that form and strength of the Chemical Entity will be delisted on the first day of the Sole Supply Period, with the result that you will have Sole Supply Status for that form and strength of the Chemical Entity during the Sole Supply Period.
- (d) The Pharmaceutical will continue to be fully subsidised, and you must continue to supply it, at the Price throughout the Second Transition Period and, subject to PHARMAC's other rights under this Agreement in relation to the Pharmaceutical, throughout the Sole Supply Period.
- (e) Subject to PHARMAC's other rights under this Agreement in relation to the Pharmaceutical, the Pharmaceutical will not be delisted during the Final Transition Period.

1.2 Exclusivity for the Sole Supply Period

- (a) Subject to PHARMAC's other rights under this Agreement in relation to the Pharmaceutical, PHARMAC will not subsidise another supplier's brand of the Pharmaceutical on the Pharmaceutical Schedule at any time during the Sole Supply Period.
- (b) This clause does not prohibit PHARMAC from entering into negotiations or arrangements with, or inviting tenders from, other suppliers to be the sole subsidised supplier of any forms and strengths of the Chemical Entity, if such supply commences after the end of the Sole Supply Period.
- (c) For the avoidance of doubt, PHARMAC may lower the subsidy applicable to a Pharmaceutical during the Final Transition Period as it sees fit, including lowering the subsidy of a Pharmaceutical as a result of the implementation of new tender arrangements.

1.3 Withdrawal of Sole Supply Status

(a) PHARMAC may withdraw Sole Supply Status in relation to your supply of the Pharmaceutical (in which case clauses 1.1 and 1.2 of this Schedule will no longer apply), by written notice to you at any time during the Sole Supply Period or (in anticipation) during the First Transition Period or the Second Transition Period if:

- (i) you have failed to notify PHARMAC as required under clause 5.1 of this Schedule;
- (ii) you are unable to supply the Pharmaceutical in accordance with this Agreement for a period of 30 days;
- (iii) any Consent for the Pharmaceutical is withdrawn; or
- (iv) you otherwise fail to supply the Pharmaceutical in accordance with this Agreement.
- (b) In the event that PHARMAC exercises its rights under clause 1.3(a) above in relation to a Pharmaceutical, it may also withdraw Sole Supply Status in relation to your supply of all forms and strengths of that Pharmaceutical (in which case clauses 1.1 and 1.2 of this Schedule will no longer apply), following a recommendation from its clinical advisors, either by the written notice provided under clause 1.3(a) above or by further written notice to you at any time during the Sole Supply Period or (in anticipation) during the First Transition Period or the Second Transition Period.
- (c) Any withdrawal of Sole Supply Status is without prejudice to PHARMAC's rights under clauses 5.2 and 5.3 of this Schedule.

1.4 **Suspension of Sole Supply Status**

- (a) If, at any time during the Sole Supply Period or (in anticipation) during the First Transition Period or the Second Transition Period, you are unable to meet demand for the Pharmaceutical, or you notify PHARMAC under clause 5.1 of this Schedule of a Potential Out-of-Stock Event, or you otherwise fail to supply the Pharmaceutical in accordance with this Agreement, PHARMAC may suspend Sole Supply Status in relation to your supply of the Pharmaceutical for the period of such inability.
- (b) In the event that PHARMAC exercises its rights under clause 1.4(a) above in relation to a Pharmaceutical, it may also suspend Sole Supply Status in relation to your supply of all forms and strengths of that Pharmaceutical, following a recommendation from its clinical advisors, either by the written notice provided under clause 1.4(a) above or by further written notice to you at any time during the Sole Supply Period or (in anticipation) during the First Transition Period or the Second Transition Period.
- (c) Any suspension of Sole Supply Status is without prejudice to PHARMAC's rights under clauses 5.2 and 5.3 of this Schedule.
- (d) PHARMAC may, at any time, in its sole discretion, notify you of the date on which the suspension of Sole Supply Status under this clause 1.4 ceases and on which date:
 - (i) Sole Supply Status is to be re-implemented in respect of the Pharmaceutical; or
 - (ii) Sole Supply Status is to be withdrawn in accordance with clause 1.3 of this Schedule.

1.5 Subsidy arrangements after the End Date

(a) Subject to paragraphs (b) and (c) below, the Pharmaceutical is to continue to be the subject of a listing agreement between you and PHARMAC with effect from the End Date, and accordingly:

- (i) you will cease to have Sole Supply Status for that form and strength of the Chemical Entity; and
- (ii) the Pharmaceutical will remain listed in Section B of the Pharmaceutical Schedule subject to PHARMAC's standard terms of supply for pharmaceuticals used in the community (as recorded in the then current general listing terms Annex of PHARMAC's standard community contract template).
- (iii) you may increase the price ex-manufacturer (exclusive of GST) at which you supply the Pharmaceutical to wholesalers and other such distributors on giving PHARMAC six months' written notice of that price increase. You may provide PHARMAC with this written notice at any time after, but not before, the End Date;
- (iv) if PHARMAC does not increase the subsidy for the Pharmaceutical to the new price notified under paragraph (a)(iii) above, you may withdraw the Pharmaceutical from supply on not less than six months' prior written notice;
- (v) if PHARMAC does increase the subsidy for the Pharmaceutical to the new price notified under paragraph (a)(iii) above, you may withdraw the Pharmaceutical from supply on not less than two years' prior written notice (except where the withdrawal is for reasons that PHARMAC considers to be wholly outside of your control, in which case you must first provide to PHARMAC such information as it may require from you in order to satisfy it, in its sole discretion, that you are required to withdraw supply); and
- (vi) if at the time of providing notice under paragraph (a)(v) above, you advise PHARMAC that you are required to purchase a significant quantity of extra stock of the Pharmaceutical to enable you to continue to supply for the two-year period, and you advise PHARMAC of the total cost of that stock, PHARMAC will either:
 - (A) use reasonable endeavours to enter into an agreement to reimburse you for stock that remains unsold at the end of that two-year period; or
 - (B) release you from your obligations to supply under this paragraph (a).
- (b) PHARMAC may at its sole discretion, with effect from the End Date:
 - (i) require that the Pharmaceutical does not continue to be the subject of a listing agreement, in which case PHARMAC will give you written notice not less than three months prior to the End Date; and/or
 - (ii) apply any of the strategies under PHARMAC's then current OPPs to the Pharmaceutical (including delisting the Pharmaceutical after the Final Transition Period).
- (c) In the event PHARMAC applies any of the strategies described in paragraph (b)(ii) above, you may withdraw the Pharmaceutical from supply on not less than six months' prior written notice. You may provide PHARMAC with this written notice at any time after, but not before, the date that the particular strategy takes effect in the Pharmaceutical Schedule.
- (d) Where a Pharmaceutical is designated an ASP, PHARMAC will provide at least four months written notice of another supplier's brand of the Pharmaceutical being listed on the Pharmaceutical Schedule.

2. Consents

2.1 Warranty and indemnity that Consents are held

You warrant that you have, and will maintain, all necessary Consents. If a Consent is not held by you or is withdrawn or the Pharmaceutical is no longer approved for the treatment of any indication for which it is subsidised, then:

- (a) PHARMAC is entitled to terminate this Agreement by 14 days' written notice to you; and
- (b) whether or not PHARMAC terminates this Agreement under paragraph (a) above, you are to indemnify the Funder for any additional costs incurred by it (or by PHARMAC on its behalf) as a result of that failure to hold all necessary Consents. This clause confers a benefit on (and is enforceable by) the Funder in accordance with the Contracts (Privity) Act 1982.

2.2 Changed medicine notification

If the Ministry of Health issues a changed medicine notification in relation to a Pharmaceutical, and as a result a variant of the Pharmaceutical (the "**CMN Pharmaceutical**") is approved:

- (a) you must immediately notify PHARMAC; and
- (b) PHARMAC may take such action as it considers appropriate in relation to that Pharmaceutical or the CMN Pharmaceutical including (but not limited to):
 - (i) withdrawing Sole Supply Status for the Pharmaceutical;
 - (ii) reviewing the terms of listing of that Pharmaceutical; and
 - (iii) determining whether, and the extent to which, the Funder may subsidise the CMN Pharmaceutical.

3. Price

3.1 **Price change**

- (a) Subject to clause 3.1 (b) (ii) and clause 3.1 (b) (iii) of this Schedule your brand of the Pharmaceutical must be available for supply and you must supply the Pharmaceutical, at the Price from the 12th day of the month prior to the Start Date, and the Pharmaceutical will be subsidised at the Price from the Start Date.
- (b) In the event your brand of the Pharmaceutical is currently listed on the Pharmaceutical Schedule at the beginning of the First Transition Period:
 - (i) you must ensure that wholesalers and other such distributors change the price at which they supply the Pharmaceutical to the Price on the 12th day of the month prior to the Start Date, and you shall provide price support to wholesalers and other such distributors for a maximum 4 weeks stock on hand (or such other level of stock as agreed between you and PHARMAC) of the Pharmaceutical held at wholesalers and other such distributors, provided that such wholesalers and other such distributors can provide you with stock on hand reports upon request; or

- (ii) your brand of the Pharmaceutical must be available for supply and you must supply the Pharmaceutical, at the Price from the 1st day of the month prior to the Start Date, and the Pharmaceutical will be subsidised at the Price from the Start Date which is conditional upon you having at least 2 months Lead Time for the Pharmaceutical; and
- (iii) notwithstanding clauses 3.1 (b) (i) or (b) (ii) above, PHARMAC may agree a process with you, that results in your brand of the Pharmaceutical, which includes a rebate, must be available for supply and you must supply the Pharmaceutical, at the Price from the 22nd day of the month prior to the Start Date, and you shall provide price support to wholesalers and other such distributors for a maximum 4 weeks stock on hand (or such other level of stock as agreed between you and PHARMAC) of the Pharmaceutical held at wholesalers and other such distributors, provided that such wholesalers and other such distributors can provide you with stock on hand reports upon request.

For the avoidance of doubt if you do not notify PHARMAC in your Tender Bid in the electronic portal which of the options stated in clauses 3.1 (b) (i) or (b) (ii) above apply to the Pharmaceutical, clause (b) (i) above shall apply.

(c) You shall upon request by PHARMAC, provide information on how you intend to manage the price changes stated in clauses 3.1 (b) (i) to b (iii) above. PHARMAC may, at its sole discretion, publish this information at the time the Tender Item is notified in the Pharmaceutical Schedule in accordance with clause 7.2 of Schedule 3.

3.2 Supply Price

During each of the Second Transition Period, the Sole Supply Period and the Final Transition Period, the price at which the Pharmaceutical is supplied by you must not exceed the Price.

3.3 Warranty that Pharmaceutical is supplied at not less than cost price

You warrant that the price at which you are required to supply the Pharmaceutical under this Agreement is greater than the cost price of the Pharmaceutical (including, without limitation, the costs of manufacturing the Pharmaceutical and of supplying it to you for supply in New Zealand).

3.4 No reference pricing during Sole Supply Period

The subsidy payable for the Pharmaceutical will not be reduced as a result of a reduction in the reference price for the therapeutic sub-group of which it is a member during the Sole Supply Period. For the avoidance of doubt, PHARMAC will not be prevented from applying its reference pricing mechanisms to the Pharmaceutical to reduce the subsidy payable for it from the End Date.

3.5 Unsold stock following delisting

You acknowledge and agree that the price at which you are required to supply any Pharmaceutical under this Agreement incorporates, if applicable, any costs incurred by you associated with unsold stock of the Pharmaceutical held by you or any wholesaler or other distributor, after the Pharmaceutical has been delisted or after notification that it will be delisted.

4. Shelf-life of Pharmaceutical

- (a) You will not supply the Pharmaceutical to wholesalers, or other such distributors, or pharmacies if:
 - (i) the remaining shelf-life of the Pharmaceutical is less than six months; or
 - (ii) where the total shelf-life of the Pharmaceutical is less than six months, the remaining shelf-life is less than 75% of the Pharmaceutical's total shelf-life,

without prior written agreement from PHARMAC.

(b) If you have an agreement with PHARMAC to supply the Pharmaceutical, where the total shelf-life of the Pharmaceutical is less than six months and the remaining shelf-life is less than 75% of the Pharmaceutical's total shelf-life, and a particular wholesaler, or other such distributor, or pharmacy does not distribute or dispense that Pharmaceutical before its expiry or use-by date, you agree to allow that wholesaler, or other such distributor, or pharmacy to return the Pharmaceutical to you and to provide that wholesaler, or other such distributor, or pharmacy with a credit for the Pharmaceutical.

5. **Out-of-stock arrangements**

5.1 Notification of Potential Out-of-Stock Event and supply of Alternative Pharmaceutical

- (a) You must notify PHARMAC in writing as soon as you have reasonable cause to believe at any time that you will fail to supply the Pharmaceutical in accordance with this Agreement and, in any event, you must notify PHARMAC if at any time a Potential Outof-Stock Event occurs, including during the Sole Supply Period or the First Transition Period or the Second Transition Period, in which case PHARMAC may suspend Sole Supply Status in relation to your supply of the Pharmaceutical.
- (b) If a Potential Out-of-Stock Event occurs, or your failure to supply the Pharmaceutical in accordance with this Agreement will result in insufficient stock of the Pharmaceutical being available, then at PHARMAC's option:
 - (i) PHARMAC may implement an arrangement with another supplier to supply an Alternative Pharmaceutical (including an arrangement for back-up supply); or
 - (ii) you must use your best endeavours to procure wholesalers and other such distributors to supply, as soon as practicable, an Alternative Pharmaceutical to pharmacies at the Price, and PHARMAC will subsidise the Alternative Pharmaceutical at the Price.

5.2 General indemnity

You agree to indemnify the Funder if you fail to supply the Pharmaceutical in accordance with this Agreement (other than for reasons that PHARMAC reasonably considers, following discussion with you, to be wholly outside your control) whether as a result of:

- (a) your inability to meet demand for supply of the Pharmaceutical;
- (b) your withdrawal of the Pharmaceutical from supply;
- (c) any failure to have and maintain a Consent as specified in clause 2 of this Schedule;

- (d) any failure to notify PHARMAC in accordance with clause 5.1 above; or
- (e) for any other reason.

This indemnity:

- (f) covers all additional costs, including without limitation all costs (if any) incurred in securing and subsidising an Alternative Pharmaceutical, incurred by the Funder (or by PHARMAC on its behalf) as a result of your failure that are additional to any costs specified in clause 5.3; and
- (g) confers a benefit on (and is enforceable by) the Funder in accordance with the Contracts (Privity) Act 1982.

5.3 Liquidated damages

- (a) If you fail to supply the Pharmaceutical in accordance with this Agreement (other than for reasons that PHARMAC reasonably considers, following discussion with you, to be wholly outside your control) and:
 - (i) you have not notified PHARMAC under clause 5.1 of this Schedule, then without prejudice to PHARMAC's rights under clause 5.2:
 - (A) subject to paragraph (e) below, you must pay to PHARMAC (for the benefit of PHARMAC and the Funder) liquidated damages for the administrative and/or operational costs incurred by PHARMAC as a result of your failure to supply in the amount of \$50,000 per Pharmaceutical in respect of which you failed to notify PHARMAC; and
 - (B) PHARMAC may withdraw Sole Supply Status in relation to your supply of the Pharmaceutical under clause 1.3 of this Schedule; or
 - (ii) you have notified PHARMAC under clause 5.1 of this Schedule, then without prejudice to PHARMAC's rights under clause 5.2:
 - (A) you are not liable to pay any liquidated damages under this clause 5.3; and
 - (B) if you fail to supply the Pharmaceutical in accordance with this Agreement for more than 30 days, PHARMAC may withdraw Sole Supply Status in relation to your supply of the Pharmaceutical under clause 1.3 of this Schedule.
- (b) If, having notified PHARMAC under clause 5.1 of this Schedule, you remain able to, and you continue to, supply the Pharmaceutical, or an Alternative Pharmaceutical in accordance with clause 5.1(b)(ii) of this Schedule, such that there is no interruption to supply of the Pharmaceutical or of the Alternative Pharmaceutical in accordance with this Agreement, you will not be liable for any costs unless PHARMAC, in its sole discretion, has considered it necessary to enter into an arrangement with an alternative supplier under which PHARMAC has agreed to make a payment to that supplier to ensure continuity of supply, in which case you must indemnify the Funder or PHARMAC for that payment. Such indemnity will be limited to an amount of \$10,000.
- (c) You acknowledge and agree that:
 - (i) the amounts of liquidated damages in this clause represent a reasonable estimate of the administrative and operational costs incurred by PHARMAC (including the

use of staff and loss of opportunity as a result of use of staff time, and communication costs), the estimate being based on PHARMAC's previous experience; and

(ii) the amounts referred to as liquidated damages are not intended to include any penalty element nor any amount for costs relating to the securing of an Alternative Pharmaceutical, or the subsidisation of an Alternative Pharmaceutical,

provided that PHARMAC may, in its sole discretion, require you to pay less than the amount specified as liquidated damages if it is satisfied that the actual costs in the particular circumstances are less than the relevant amount so specified.

- (d) Where a Pharmaceutical in respect of which you are liable to pay liquidated damages pursuant to clause 5.3(a)(i)(A) above also has Hospital Supply Status and where you would otherwise be liable to pay the same amount of liquidated damages in respect of any corresponding failure under the terms of such Hospital Supply Status, you will only be required to pay liquidated damages of \$50,000 in total in respect of both supply failures.
- (e) All amounts referred to in this clause are plus GST.

5.4 **Failure to supply**

References in this clause 5 and elsewhere in this Schedule to your failure or inability to supply the Pharmaceutical in accordance with this Agreement, or your inability to meet demand for the Pharmaceutical, or insufficient stock of the Pharmaceutical being available, include, but are not limited to, circumstances where:

- (a) no stock of the Pharmaceutical is physically held by you or on your behalf in New Zealand;
- (b) the only stock of the Pharmaceutical physically held by you or on your behalf in New Zealand is stock to which clause 4(a)(i) or (ii) of this Schedule applies and no agreement has been reached with PHARMAC in terms of clause 4(a) of this Schedule;
- (c) you fail, directly or indirectly, to ensure that all orders for the Pharmaceutical are filled (without restricting quantities that may be ordered), including in particular where, for reasons attributable (wholly or partly) to you, not all patients for whom the Pharmaceutical is prescribed receive the full amount of the Pharmaceutical they require, or to which they are entitled, under their prescriptions, within the required time frames for dispensing under the then current contract, or notice under section 88 of the New Zealand Public Health and Disability Act 2000, in respect of pharmacy services;
- (d) you fail to supply the Pharmaceutical on and from the Start Date.

5.5 **Default interest and recovery costs**

If payment of any amount required to be paid by you under this clause 5 is not made by you, in full, by the due date for payment of that amount as notified to you in writing by PHARMAC, then:

(a) interest will accrue in such sum as remains unpaid at a rate per annum equal to the relevant SME overdraft rate (weighted average rate) of the Reserve Bank of New Zealand plus five percentage points, calculated and compounded on a daily basis, from the due date until such time as the sum due (including interest) is paid in full. This

obligation to pay default interest is to arise without the need for a notice or demand from PHARMAC for such default interest; and

(b) PHARMAC may take any action, including legal action, without first needing to implement the dispute resolution procedure contained in clause 4.2 of Schedule Four, to recover that amount and you agree to pay to PHARMAC actual enforcement costs incurred in relation to that action.

6. Termination and restrictions

6.1 Termination and restrictions for clinical reasons

PHARMAC reserves the right, but only after consultation with you and a relevant medical adviser (being either the Ministry of Health, PTAC or its sub-committees), to:

- (a) terminate this Agreement at any time during the Sole Supply Period or the First Transition Period or the Second Transition Period if the medical adviser determines for clinical reasons that it is no longer appropriate to have either:
 - (i) a sole subsidised supplier of that form and strength of the Chemical Entity; or
 - (ii) the Pharmaceutical as the sole subsidised brand; and/or
- (b) impose at any time during the Sole Supply Period or the Transition Periods restrictions on the prescribing or dispensing of a Pharmaceutical if those restrictions are necessary for clinical reasons.

6.2 **Termination following an audit**

PHARMAC may terminate the Agreement, or withdraw Sole Supply Status in relation to a Pharmaceutical, at any time during the Sole Supply Period or the Transition Periods, if you fail to remedy any area of non-compliance in accordance with clause 3(b) of Schedule Four.

7. Guarantee

- (a) PHARMAC may require an entity acceptable to it to provide a guarantee (in a form satisfactory to PHARMAC) of your performance obligations under clauses 5.2 and 5.3 of this Schedule including, without limitation, the payment of any sum payable under the indemnity or as liquidated damages pursuant to those clauses for any failure to supply the Pharmaceutical in accordance with this Agreement during the Sole Supply Period.
- (b) The guarantor's liability under such a guarantee will be limited to a total of \$100,000 per Chemical Entity for all claims made by PHARMAC under the guarantee.

Schedule 6: Additional contract terms for Hospital Supply Status

1. Effect of Hospital Supply Status

1.1 **Pricing arrangements**

- (a) Subject to PHARMAC's other rights under this Agreement and clause 3.1 of this Schedule, on and from the Start Date, during the remainder of the First Transition Period and during the Hospital Supply Status Period, the Pharmaceutical is to be:
 - (i) listed at the Price set out in Section H of the Pharmaceutical Schedule;
 - sold by you to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), at the Price.
- (b) Where the Pharmaceutical is included in an order by a DHB Hospital for pharmaceuticals where the total value (excluding GST) of the order is less than \$1,000, you may invoice the DHB Hospital, in accordance with clause 4.1 below, for the cost of freight for that particular order. For the avoidance of doubt, this clause 1.1(b) does not entitle you to invoice a DHB Hospital for any other costs in relation to the particular order.
- (c) Subject to PHARMAC's other rights under this Agreement in relation to the Pharmaceutical (including under clause 1.6 of this Schedule), and provided that there are no Alternative Pharmaceuticals listed in Section H of the Pharmaceutical Schedule at the start of the Final Transition Period, the Pharmaceutical:
 - (i) is to continue to be listed, sold and purchased at the Price referred to in clauses 1.1(a)(i) and (ii) above during the Final Transition Period and beyond; and
 - (ii) is not to be delisted during the Final Transition Period.

1.2 **Supplier for Hospital Supply Status Period**

- (a) Subject to:
 - (i) PHARMAC's other rights under this Agreement in relation to the Pharmaceutical; and
 - (ii) clauses 1.4 and 1.5 of this Schedule relating to the DV Limit for the Pharmaceutical,

your brand of the Pharmaceutical will be the brand listed in Section H of the Pharmaceutical Schedule, and purchased by DHB Hospitals at any time during the Hospital Supply Status Period, as the brand having Hospital Supply Status.

(b) This clause does not prohibit PHARMAC (on behalf of DHB Hospitals) from entering into negotiations or arrangements with, or inviting tenders from, other suppliers to be the supplier of any forms and strengths of the particular Pharmaceutical with Hospital Supply Status, or a relevant Alternative Pharmaceutical having a status equivalent to Hospital Supply Status, if notification of such an arrangement (once finalised) occurs, and such supply commences, after the end of the Hospital Supply Status Period.

1.3 **DV Pharmaceuticals**

- (a) PHARMAC may amend the relevant list of DV Pharmaceuticals specified in Section H of the Pharmaceutical Schedule, from time to time, in accordance with this clause 1.3, whereby:
 - (i) PHARMAC is only to remove a pharmaceutical listed as a DV Pharmaceutical if PHARMAC:
 - (A) has first obtained your agreement; or
 - (B) has a direction from Medsafe or its successor, or a recommendation from PTAC or its sub-committees, based on a significant clinical issue;
 - (ii) PHARMAC may add a pharmaceutical to the relevant list of DV Pharmaceuticals specified in Section H of the Pharmaceutical Schedule if such pharmaceutical is identified as a DV Pharmaceutical during the Hospital Supply Status Period or the First Transition Period by PHARMAC following a recommendation from PTAC or its sub-committees.
- (b) PHARMAC must consult with you prior to the removal of any pharmaceutical from the relevant list of DV Pharmaceuticals specified in Section H of the Pharmaceutical Schedule.

1.4 **DV Limit**

- (a) PHARMAC may, from time to time during the Hospital Supply Status Period or the First Transition Period, amend the DV Limit of the Pharmaceutical following what PHARMAC considers to be appropriate consultation with PTAC or its sub-committees, provided that PHARMAC may only increase the DV Limit without your prior agreement if it has a direction from Medsafe or its successor, or a recommendation from PTAC or its subcommittees, based on a significant clinical issue.
- (b) Subject to clause 1.5 of this Schedule you acknowledge and agree that while you have Hospital Supply Status:
 - DHB Hospitals may purchase DV Pharmaceuticals at any time within the First Transition Period and Final Transition Period without any requirement to comply with the DV Limit;
 - (ii) provided that DHB Hospitals collectively do not exceed the National DV Limit for the relevant Pharmaceutical, a DHB Hospital may purchase DV Pharmaceuticals at any time within the Hospital Supply Status Period;
 - (iii) without derogating from any other rights available to PHARMAC or DHB Hospitals under this Agreement or otherwise, if you fail to supply the Pharmaceutical in accordance with this Agreement (other than for a reason that PHARMAC reasonably considers, following discussion with you, to be wholly outside your control) within the Hospital Supply Status Period, then the relevant DHB Hospital is not required to comply with the DV Limit for the Pharmaceutical during that period of non-supply and the calendar month during which that non-supply occurred will be excluded in any review of the DV Limit in accordance with clause 1.5 below;
 - (iv) if a DHB Hospital's usage of any DV Pharmaceuticals, in percentage terms, reaches or exceeds the percentage at which the Individual DV Limit is set for the relevant Pharmaceutical, that DHB Hospital may negotiate with you to agree to

vary the application of the Individual DV Limit to the DHB Hospital in respect of particular patients with exceptional needs.

1.5 **DV Limit Compliance**

- (a) For the purposes of this clause 1.5:
 - (i) "Relevant Period" means:
 - (A) the initial period starting on the day that the Hospital Supply Status Period begins up to and including 30 June 2018; or
 - (B) for a Pharmaceutical listed on or prior to 30 June 2018, the period commencing on 1 July 2018 and ending on 30 June 2019 or, for a Pharmaceutical listed after 30 June 2019, the initial period starting on the date that the Hospital Supply Status Period begins up to and including 30 June 2019; or
 - (C) for a Pharmaceutical listed on or prior to 30 June 2019, the period commencing on 1 July 2019 and ending on 30 June 2020, or, for a Pharmaceutical listed after 30 June 2019, the initial period starting on the date that the Hospital Supply Status Period begins up to and including 30 June 2020,

provided that for the purposes of carrying out the calculations in this clause 1.5 any calendar months that fall within those periods when there is any failure to supply the Pharmaceutical in accordance with this Agreement will be excluded.

(ii) **"Actual National DV Limit Indicator"** means, for a particular Pharmaceutical in any Relevant Period, such sum, expressed as a percentage, as is equal to:

(Total DV Pharmaceuticals Volume ÷ (Total DV Pharmaceuticals Volume + Total Pharmaceutical Volume)) x 100;

- (iii) "Total DV Pharmaceuticals Volume" means, for a particular Pharmaceutical in any Relevant Period, the total number of Units of all DV Pharmaceuticals of the relevant Pharmaceutical with Hospital Supply Status purchased by DHB Hospitals, as calculated by PHARMAC, following your request in accordance with clause 1.5(b) below, on the basis of the data extracted by PHARMAC from the electronic records used by it; and
- (iv) "Total Pharmaceutical Volume" means, for a particular Pharmaceutical with Hospital Supply Status in any Relevant Period, the total number of Units of that Pharmaceutical purchased by DHB Hospitals, as calculated by PHARMAC following your request in accordance with clause 1.5(b) below, on the basis of the data extracted by PHARMAC from the electronic records used by it.
- (b) If you reasonably believe that DHB Hospitals' percentage usage of DV Pharmaceuticals collectively exceeds the National DV Limit for a particular Pharmaceutical, you may at any time, but not more often than three-monthly, request that PHARMAC carry out calculations in accordance with the procedure set out in this clause 1.5 for the proportion of the Relevant Period that has passed to the date of your request, and PHARMAC may, in its discretion, agree to carry out the calculations for the Total DV Pharmaceuticals Volume, the Total Pharmaceutical Volume and the Actual National DV Limit Indicator, provided that if PHARMAC refuses to carry out such calculations, it will provide you with the reasons for refusing to do so.

- (c) It is acknowledged, for the avoidance of doubt, that if the Actual National DV Limit Indicator is less than the National DV Limit specified for the relevant Chemical Entity in Schedule Two and the Electronic Portal then, regardless of whether an individual DHB Hospital's percentage usage of DV Pharmaceuticals has exceeded the Individual DV Limit percentage for that Pharmaceutical, PHARMAC may decide, in its sole discretion, not to take any further action.
- (d) If the Actual National DV Limit Indicator is greater than the National DV Limit, PHARMAC will use its best endeavours to identify which individual DHB Hospitals' percentage usage of DV Pharmaceuticals have exceeded the Individual DV Limit percentage for that Pharmaceutical. You acknowledge that if PHARMAC cannot do this on the basis of information held by it, it may be necessary to obtain any further information you can provide. If neither of us can establish or quantify non-compliance by an individual DHB Hospital with the Individual DV Limit, then you acknowledge that PHARMAC may not be able to calculate for you, and you may not be able to obtain, financial compensation under clause 1.5(f)(ii) below. In that event you acknowledge, for the avoidance of doubt, that PHARMAC is not liable to pay any financial compensation on behalf of the relevant DHB.
- (e) If an individual DHB Hospital's percentage usage of DV Pharmaceuticals has exceeded the Individual DV Limit percentage for that Pharmaceutical as a result of DV Pharmaceutical usage that has been agreed to by you in accordance with clause 1.4(b)(iv) above then PHARMAC will not take any further action.
- (f) Subject to paragraph (e) above, PHARMAC will address the issue of non-compliance with any individual DHB Hospital or DHB Hospitals identified in accordance with paragraph (d) above by:
 - (i) using its best endeavours to ensure that the relevant DHB Hospital complies with the DV Limit for that Pharmaceutical in the remainder of that Relevant Period (if applicable) and in any subsequent Relevant Period or Relevant Periods; and/or
 - (ii) following the end of a Relevant Period, and only once in respect of any Relevant Period, determining what financial compensation is payable by that DHB for its contribution towards exceeding the National DV Limit (where PHARMAC is able to quantify this based on the information available to it), being the greater amount of \$1,000 or such sum as is equal to:

DHB Deviation x Adjusted Price

where:

- (A) "Adjusted Price" means the Unit Price, for a particular Pharmaceutical in any Relevant Period, divided by two;
- (B) **"DHB Deviation"** is equal to:

(Total Contribution for $DHB_x \div Total$ Contribution for Exceeding DHBs) x Total DV Pharmaceuticals Volume in Excess of DV Limit

where:

"Total Contribution for DHB_x" means, for:

(a) a particular Pharmaceutical; and

(b) a particular DHB Hospital,

in any Relevant Period, the total number of Units of all DV Pharmaceuticals of the relevant Pharmaceutical with Hospital Supply Status purchased by that DHB Hospital minus the number of Units of DV Pharmaceuticals that corresponds to the percentage of the Individual Total Market Volume represented by the Individual DV Limit percentage for that Pharmaceutical, as calculated by PHARMAC for such Relevant Period on the basis of the data extracted by PHARMAC from the electronic records used by it;

"Total Contribution for Exceeding DHBs" means, for a particular Pharmaceutical in any Relevant Period, the sum of the Total Contribution for DHB_x for each DHB Hospital identified by PHARMAC in accordance with paragraph (d) above as exceeding the Individual DV Limit for that Relevant Period, as calculated by PHARMAC for such Relevant Period on the basis of the data extracted by PHARMAC from the electronic records used by it;

"Total DV Pharmaceuticals Volume in Excess of DV Limit" means, for a particular Pharmaceutical in any Relevant Period, the total number of Units of all DV Pharmaceuticals of the relevant Pharmaceutical with Hospital Supply Status purchased by DHB Hospitals in excess of the National DV Limit for that Relevant Period, as calculated by PHARMAC on the basis of the data extracted by PHARMAC from the electronic records used by it;

- (iii) PHARMAC will notify you and the relevant DHB in writing of any DV Limit compensation payable in accordance with clause 1.5(f)(ii) above. You may then invoice the relevant DHB for the amount of DV Limit compensation payable, as calculated and notified to you by PHARMAC. You must provide to PHARMAC a copy of any such invoice, and evidence of any payment received from the DHB in respect of that invoice, within 10 business days of sending such invoice or receiving such payment, respectively.
- (iv) If you have not received the amount of any DV Limit compensation payable in accordance with clause 1.5(f)(ii) above from the DHB within 60 business days of invoicing the DHB for the amount owing, then you may take such further actions (other than ceasing to supply) directly with the DHB as you consider appropriate to recover the amount owing to you. In that event you acknowledge, for the avoidance of doubt, that PHARMAC is not liable to pay any financial compensation on behalf of the relevant DHB.
- (v) For the avoidance of doubt, for the purposes of calculating the Total DV Pharmaceuticals Volume, the Total Contribution for DHB_x and the Total DV Pharmaceuticals Volume in Excess of DV Limit in this clause 1.5, if a pharmaceutical is added to, or removed from, the list of DV Pharmaceuticals during the Relevant Period in accordance with clause 1.3 of this Schedule, then only the number of Units of that pharmaceutical purchased by DHB Hospitals during the portion of the Relevant Period in which that pharmaceutical was a DV Pharmaceutical are to be included in those calculations.

1.6 **Supply arrangements after the End Date**

(a) Subject to paragraphs (b) and (c) below, the Pharmaceutical is to continue to be the subject of a listing agreement between you and PHARMAC with effect from the End Date, and accordingly:

- you will cease to have Hospital Supply Status for that form and strength of the Pharmaceutical (in the case of any Pharmaceutical that is not a Medical Device); or
- (ii) you will cease to have Hospital Supply Status in respect of an item conforming to the individual specifications described for the item in the product list in clause 2 of Schedule Two which the Pharmaceutical was listed as conforming with (in the case of any Pharmaceutical that is a Medical Device); and
- (iii) the Pharmaceutical will remain listed in Section H of the Pharmaceutical Schedule subject to PHARMAC's standard terms of supply for pharmaceuticals used in DHB Hospitals (as recorded in the then current general listing terms Annex of PHARMAC's standard hospital contract template);
- (iv) you may increase the price (exclusive of GST) at which you supply the Pharmaceutical to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), on giving PHARMAC six months' written notice of that price increase. You may provide PHARMAC with this written notice at any time after, but not before, the End Date;
- (v) you may withdraw the Pharmaceutical from supply on not less than two years' prior written notice (except where the withdrawal is for reasons that PHARMAC considers to be wholly outside of your control, in which case you must first provide to PHARMAC such information as it may require from you in order to satisfy it, in its sole discretion, that you are required to withdraw supply); and
- (vi) if at the time of providing notice under paragraph (a)(iv) above, you advise PHARMAC that you are required to purchase a significant quantity of extra stock of the Pharmaceutical to enable you to continue to supply for the two-year period, and you advise PHARMAC of the total cost of that stock, PHARMAC will either:
 - (A) use reasonable endeavours to enter into an agreement to reimburse you for stock that remains unsold at the end of that two-year period; or
 - (B) release you from your obligations to supply under this paragraph (a).
- (b) PHARMAC may, at its sole discretion, with effect from the End Date:
 - (i) require that the Pharmaceutical does not continue to be the subject of a listing agreement, in which case PHARMAC will give you written notice not less than three months prior to the End Date; and/or
 - (ii) apply any of the strategies under PHARMAC's then current OPPs to the Pharmaceutical (including delisting the Pharmaceutical after the Final Transition Period).
- (c) In the event PHARMAC applies any of the strategies described in paragraph (b)(ii) above, you may withdraw the Pharmaceutical from supply on not less than six months' prior written notice. You may provide PHARMAC with this written notice at any time after, but not before, the date that the particular strategy takes effect in the Pharmaceutical Schedule.

1.7 Withdrawal of Hospital Supply Status

- (a) PHARMAC may withdraw Hospital Supply Status in relation to your supply of the Pharmaceutical (in which case clauses 1.1, 1.2 and 1.3 of this Schedule will no longer apply), by written notice to you at any time during the Hospital Supply Status Period or (in anticipation) during the First Transition Period if:
 - (i) you have failed to notify PHARMAC as required under clause 7.1 of this Schedule;
 - (ii) you fail, for a period of 30 days, to supply the Pharmaceutical in accordance with this Agreement to any of the DHB Hospitals including to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding);
 - (iii) any Consent for the Pharmaceutical required under clause 2 of this Schedule is withdrawn;
 - (iv) you have failed to comply with clause 6 of this Schedule on more than one occasion; or
 - (v) you otherwise fail to supply the Pharmaceutical in accordance with this Agreement.
- (b) In the event that PHARMAC exercises its rights under clause 1.7(a) above in relation to a Pharmaceutical, it may also withdraw Hospital Supply Status in relation to your supply of all forms and strengths of that Pharmaceutical (or your supply of all other Medical Devices under this Agreement, where PHARMAC has exercised its rights under clause 1.7(a) above in respect of a Medical Device) (in which case clauses 1.1, 1.2 and 1.3 of this Schedule will no longer apply), following a recommendation from its clinical advisors, either by the written notice provided under clause 1.7(a) above or by further written notice to you at any time during the Hospital Supply Period or (in anticipation) during the First Transition Period.
- (c) Any withdrawal of Hospital Supply Status is without prejudice to PHARMAC's rights under clauses 7.2 and 7.3 of this Schedule.

1.8 **Suspension of Hospital Supply Status**

- (a) If, at any time during the Hospital Supply Status Period or (in anticipation) during the First Transition Period, you are unable to meet demand for the Pharmaceutical, or you notify PHARMAC under clause 7.1 of this Schedule of a Potential Out-of-Stock Event, or you otherwise fail to supply the Pharmaceutical in accordance with this Agreement, then:
 - (i) PHARMAC may suspend Hospital Supply Status in relation to your supply of the Pharmaceutical for the period of such inability; and
 - (ii) DHB Hospitals may purchase DV Pharmaceuticals during the period when Hospital Supply Status is suspended without the requirement to comply with the DV Limit for the relevant Pharmaceutical.
- (b) In the event that PHARMAC exercises its rights under clause 1.8(a) above in relation to a Pharmaceutical, it may also suspend Hospital Supply Status in relation to your supply of all forms and strengths of that Pharmaceutical (or your supply of all other Medical Devices under this Agreement, where PHARMAC has exercised its rights under clause

1.8(a) above in respect of a Medical Device), following a recommendation from its clinical advisors, either by the written notice provided under clause 1.8(a) above or by further written notice to you at any time during the Hospital Supply Period or (in anticipation) during the First Transition Period.

- (c) Any suspension of Hospital Supply Status is without prejudice to PHARMAC's rights under clauses 7.2 and 7.3 of this Schedule.
- (d) PHARMAC may, at any time, in its sole discretion, notify you of the date on which the suspension of Hospital Supply Status under this clause 1.8 ceases and on which date:
 - (i) Hospital Supply Status is to be re-implemented in respect of the Pharmaceutical; or
 - (ii) Hospital Supply Status is to be withdrawn in accordance with clause 1.7 of this Schedule.

2. Consents

2.1 Warranty and indemnity that Consents are held

You warrant that you have, and will maintain, all necessary Consents. If a Consent is not held by you or is withdrawn or the Pharmaceutical is no longer approved for the treatment of any indication for which it is listed in Section H of the Pharmaceutical Schedule, then:

- (a) PHARMAC is entitled to terminate this Agreement by 14 days' written notice to you; and
- (b) whether or not PHARMAC terminates this Agreement under paragraph (a) above, you are to indemnify the Funder for any additional costs incurred by it (or by PHARMAC on its behalf) as a result of that failure to hold all necessary Consents. This clause confers a benefit on (and is enforceable by) the Funder in accordance with the Contracts (Privity) Act 1982.

2.2 Changed medicine notification

If the Ministry of Health issues a changed medicine notification in relation to a Pharmaceutical, and as a result a variant of the Pharmaceutical (the "**CMN Pharmaceutical**") is approved:

- (a) you must immediately notify PHARMAC; and
- (b) PHARMAC may take such action as it considers appropriate in relation to that Pharmaceutical or the CMN Pharmaceutical including (but not limited to):
 - (i) withdrawing Hospital Supply Status for the Pharmaceutical;
 - (ii) reviewing the terms of listing of that Pharmaceutical; and
 - (iii) determining whether, and the extent to which, DHB Hospitals may purchase the CMN Pharmaceutical.

3. Price

3.1 **Price change**

- (a) Subject to clause 3.1(b)(ii) and clause 3.1(b)(iii) of this Schedule, you must change the price at which you supply the Pharmaceutical to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), to the Price with effect from the 12th day of the month prior to the Start Date. If your brand of the Pharmaceutical is not listed on the Pharmaceutical Schedule at the beginning of the First Transition Period, it must be available for supply or sale, and you must supply or sell it, at the Price on and from the 12th day of the month prior to the Start Date.
- (b) In the event your brand of the Pharmaceutical is currently listed on the Pharmaceutical Schedule at the beginning of the First Transition Period:
 - (i) you must ensure that wholesalers and other such distributors change the price at which they supply the Pharmaceutical to the Price on the 12th day of the month prior to the Start Date, and you shall provide price support to wholesalers and other such distributors for a maximum 4 weeks stock on hand (or such other level of stock as agreed between you and PHARMAC) of the Pharmaceutical held at wholesalers and other such distributors, provided that such wholesalers and other such distributors can provide you with stock on hand reports upon request; or
 - (ii) your brand of the Pharmaceutical must be available for supply and you must supply the Pharmaceutical, at the Price from the 1st day of the month prior to the Start Date, and the Pharmaceutical will be subsidised at the Price from the Start Date which is conditional upon you having at least 2 months Lead Time for the Pharmaceutical; and
 - (iii) notwithstanding clauses 3.1(b)(i) or (b)(ii) above, PHARMAC may agree a process with you, that results in your brand of the Pharmaceutical, which includes a rebate, must be available for supply and you must supply the Pharmaceutical, at the Price from the 22nd day of the month prior to the Start Date, and you shall provide price support to wholesalers and other such distributors for a maximum 4 weeks stock on hand (or such other level of stock as agreed between you and PHARMAC) of the Pharmaceutical held at wholesalers and other such distributors, provided that such wholesalers and other such distributors can provide you with stock on hand reports upon request.

For the avoidance of doubt if you do not notify PHARMAC in your Tender Bid in the electronic portal which of the options stated in clauses 3.1(b)(i) or (b)(ii) above apply to the Pharmaceutical, clause (b)(i) above shall apply.

(c) You shall upon request by PHARMAC, provide information on how you intend to manage the price changes stated in clauses 3.1(b)(i) to b(iii) above. PHARMAC may, at its sole discretion, publish this information at the time the Tender Item is notified in the Pharmaceutical Schedule in accordance with clause 7.2 of Schedule 3.

3.2 Supply price

Subject to clause 3.1 of this Schedule, during each of the First Transition Period, the Hospital Supply Status Period and the Final Transition Period, if applicable in accordance with clause 1.1(b) of this Schedule, the price at which the Pharmaceutical is supplied by you to, at a DHB

Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), must not exceed the Price.

3.3 **Supply at lower price**

Notwithstanding clauses 3.1 and 3.2 above but subject to clause 3.4 below, you may supply the Pharmaceutical to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding) at a price lower than the Price, provided that where you decide to supply the Pharmaceutical in respect of any one or more DHB Hospital(s) at a price lower than the Price, you must supply the Pharmaceutical at the same lower price to all DHB Hospitals in respect of which you supply the Pharmaceutical, in which case that lower price will be deemed to be the Price of that Pharmaceutical for the purposes of this Agreement.

3.4 Warranty that Pharmaceutical is supplied at not less than cost price

You warrant that the Price at which you are required to supply the Pharmaceutical under this Agreement is greater than the cost price of the Pharmaceutical (including, without limitation, the costs of manufacturing the Pharmaceutical and of supplying it to you for supply in New Zealand).

3.5 **Unsold stock following delisting**

You acknowledge and agree that the price at which you are required to supply any Pharmaceutical under this Agreement incorporates, if applicable, any costs incurred by you associated with unsold stock of the Pharmaceutical held by you or any wholesaler or other distributor, after the Pharmaceutical has been delisted or after notification that it will be delisted.

4. Invoicing and Payment

4.1 Invoice

You are to invoice DHB Hospitals at the end of each month, but no later than the tenth day following the month to which the invoice in respect of the Pharmaceutical relates, specifying for the Pharmaceutical supplied during that month:

- (a) your delivery note reference number;
- (b) the particular DHB's purchase order reference number (if applicable);
- (c) the net amount payable in respect of the Pharmaceutical supplied to that DHB in accordance with this Agreement;
- (d) full details in respect of the Pharmaceutical supplied to that DHB in accordance with this Agreement, including the:
 - (i) DHB's item codes;
 - (ii) quantity of the Pharmaceutical supplied;
 - (iii) price of the Pharmaceutical;

- (iv) cost of freight for orders that included the Pharmaceutical (only where applicable under clause 1.1(b) above);
- (v) total cost for the total amount of the Pharmaceutical supplied; and
- (e) any other information that DHB Hospital requires you to supply.
- (f) The provisions of Clause 4.1 do not apply to the extent that both parties have agreed to alternative or varied invoicing arrangements in respect of a particular Pharmaceutical.

4.2 Payment

- (a) Provided that the Pharmaceutical has been supplied in accordance with this Agreement, and the particular DHB receives an invoice in accordance with clause 4.1 above, payment by the DHB Hospital to you of the amount required to be paid by it is expected to occur:
 - (i) by electronic funds transfer or such other method of payment as is designated by that DHB Hospital;
 - (ii) on the 20th day of the month following the month to which the invoice for the Pharmaceutical relates, or, if the 20th day of the month is not a business day, then on the next business day following the 20th of the month.
- (b) Where you invoice a DHB Hospital later than the tenth day following the month to which the invoice in respect of the Pharmaceutical relates then, provided that the Pharmaceutical has been supplied in accordance with this Agreement, and the invoice otherwise accords with clause 4.1 above, payment by the DHB Hospital to you of the amount required to be paid by it is expected to occur:
 - (iii) by electronic funds transfer or such other method of payment as is designated by that DHB Hospital;
 - (iv) on the 20th day of the month following the month in which you invoice the DHB for the Pharmaceutical, or, if the 20th day of the month is not a business day, then on the next business day following the 20th of the month.

4.3 Future payment

- (a) A particular DHB Hospital's failure to dispute any invoice prior to payment does not prejudice that DHB Hospital's right subsequently to dispute the correctness of such an invoice, nor its ability to recover any amount of overpayment from you.
- (b) A DHB Hospital may withhold, deduct or set off the amount of any overpayment or any amount recoverable by that DHB Hospital from you under this Agreement from any future amount owing to you.

4.4 **Contracts Privity**

This clause 4 confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contracts (Privity) Act 1982.

5. Emergency and disaster supply

In the event of an emergency or disaster affecting any DHB Hospital, or an emergency or disaster on a national level, you will use your best endeavours to provide such quantities of the Pharmaceutical as are required by the relevant DHB Hospital(s). Your obligations under this clause include, but are not limited to, using your best endeavours to:

- (a) source the Pharmaceutical from other suppliers and distributors within New Zealand; and
- (b) source the Pharmaceutical or a pharmaceutical that is the same brand as the Pharmaceutical from any overseas manufacturer, supplier or distributor, and airfreighting that stock to New Zealand (for which the relevant DHB Hospital will meet all reasonable costs) for supply, either under Medsafe's explicit consent to import, sell or distribute the Pharmaceutical or under section 29 of the Medicines Act 1981, to DHB Hospitals.

6. Defective and short-dated Pharmaceuticals

6.1 **Pharmaceutical recall**

- (a) In the event that you are required by the Ministry of Health or any other authorities to recall the Pharmaceutical or a particular batch of the Pharmaceutical, you will notify PHARMAC and the relevant DHB Hospitals immediately you become aware of the need to recall the Pharmaceutical or that batch of the Pharmaceutical.
- (b) You will use your best endeavours to provide replacement Pharmaceuticals to DHB Hospitals as soon as possible.
- (c) If you fail to provide replacement Pharmaceuticals or an Alternative Pharmaceutical within what DHBs consider to be a reasonable time frame, then DHB Hospital(s) may purchase an Alternative Pharmaceutical elsewhere. Any reasonable additional costs incurred by DHB Hospital(s) in purchasing such an Alternative Pharmaceutical will be met by you on demand by PHARMAC or the DHB Hospital(s) and will be recoverable from you as a debt due to PHARMAC and to the DHB Hospital(s), as applicable.
- (d) In the event that the Pharmaceutical or a particular batch of the Pharmaceutical is recalled as contemplated by paragraph (a) above, you shall immediately refund to the relevant DHB Hospitals all money paid by them to you for or on account of the Pharmaceutical or that batch of the Pharmaceutical and such money will be recoverable from you as a debt due to the relevant DHB Hospitals, unless you have provided a replacement Pharmaceutical to the relevant DHB Hospitals' satisfaction.
- (e) This clause confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contracts (Privity) Act 1982.

6.2 **Shelf-life of Pharmaceutical**

- (a) You will not supply the Pharmaceutical if:
 - (i) the remaining shelf-life of the Pharmaceutical is less than six months; or
 - (ii) where the total shelf-life of the Pharmaceutical is less than six months, the remaining shelf-life is less than 75% of the Pharmaceutical's total shelf-life,

without prior agreement from the relevant DHB Hospital.

- (b) If you have an agreement with the relevant DHB Hospital to supply the Pharmaceutical, where the total shelf-life of the Pharmaceutical is less than six months and the remaining shelf-life is less than 75% of the Pharmaceutical's total shelf-life, and that DHB Hospital does not use the Pharmaceutical before its expiry or use-by date, you agree to allow that DHB Hospital to return the Pharmaceutical to you and to provide that DHB Hospital with a credit for the Pharmaceutical.
- (c) This clause confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contracts (Privity) Act 1982.

7. Out-of-stock arrangements

7.1 Notification of Potential Out-of-Stock Event and supply of Alternative Pharmaceutical

- (a) You must notify PHARMAC in writing as soon as you have reasonable cause to believe at any time that you will fail to supply the Pharmaceutical in accordance with this Agreement and, in any event, you must notify PHARMAC and the relevant DHB Hospitals if at any time a Potential Out-of-Stock Event occurs, including during the Hospital Supply Period or the First Transition Period.
- (b) If a Potential Out-of-Stock Event occurs, or your failure to supply the Pharmaceutical in accordance with this Agreement will result in insufficient stock of the Pharmaceutical being available, then at PHARMAC's option:
 - (i) PHARMAC may implement an arrangement with another supplier to supply an Alternative Pharmaceutical (including an arrangement for back-up supply); and/or
 - (ii) you must use your best endeavours to procure, as soon as practicable, an Alternative Pharmaceutical for supply to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), at the Price, and if you are unable to do so you will pay to DHB Hospitals any additional costs incurred by DHB Hospitals as a result of the purchase price for the Alternative Pharmaceutical being higher than the Price.

7.2 General indemnity

You agree to indemnify DHB Hospitals and PHARMAC if you fail to supply the Pharmaceutical in accordance with this Agreement (other than for reasons that PHARMAC reasonably considers, following discussion with you, to be wholly outside your control) whether as a result of:

- (a) your inability to meet demand for supply of the Pharmaceutical;
- (b) your withdrawal of the Pharmaceutical from supply;
- (c) any failure to have and maintain a Consent as specified in clause 2 of this Schedule;
- (d) any failure to notify PHARMAC in accordance with clause 7.1 above; or
- (e) for any other reason.

This indemnity:

- (f) covers all additional costs, including without limitation all costs (if any) incurred in securing and purchasing an Alternative Pharmaceutical, incurred by DHB Hospitals (or by PHARMAC on their behalf) as a result of your failure that are additional to any costs specified in clause 7.3; and
- (g) confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contracts (Privity) Act 1982.

7.3 Liquidated damages

- (a) If you fail to supply the Pharmaceutical in accordance with this Agreement (other than for reasons that PHARMAC reasonably considers, following discussion with you, to be wholly outside your control) and:
 - (i) you have not notified PHARMAC and the relevant DHB Hospitals under clause 7.1 of this Schedule, then without prejudice to PHARMAC's and the relevant DHB Hospitals' rights under clause 7.2 above, but subject to paragraph (e) below, you must pay to PHARMAC (for the benefit of PHARMAC and DHB Hospitals) liquidated damages for the administrative and/or operational costs incurred by PHARMAC and DHB Hospitals as a result of your failure to supply in the amount of \$50,000 per Pharmaceutical in respect of which you failed to notify PHARMAC; or
 - (ii) you have notified PHARMAC and the relevant DHB Hospitals under clause 7.1 of this Schedule, then without prejudice to PHARMAC's and the relevant DHB Hospitals' rights under clause 7.2 above you are not liable to pay any liquidated damages under this clause 7.3.
- (b) If, having notified PHARMAC and the relevant DHB Hospitals under clause 7.1 of this Schedule, you remain able to, and you continue to, supply the Pharmaceutical, or an Alternative Pharmaceutical in accordance with clause 7.1(b)(ii) of this Schedule, such that there is no interruption to supply of the Pharmaceutical or of the Alternative Pharmaceutical in accordance with this Agreement, you will not be liable for any costs unless PHARMAC, in its sole discretion, has considered it necessary to enter into an arrangement with an alternative supplier under which PHARMAC or the relevant DHB Hospitals have agreed to make a payment to that supplier to ensure continuity of supply, in which case you must indemnify the relevant DHB Hospitals and PHARMAC for that payment. Such indemnity will be limited to an amount of \$10,000 per Pharmaceutical.
- (c) You acknowledge and agree that:
 - (i) the amounts of liquidated damages in this clause represent a reasonable estimate of the administrative and operational costs incurred by PHARMAC and DHB Hospitals (including the use of staff and loss of opportunity as a result of use of staff time, and communication costs), the estimate being based on PHARMAC's and DHB Hospitals' previous experience; and
 - (ii) the amounts referred to as liquidated damages are not intended to include any penalty element nor any amount for costs relating to the securing of an Alternative Pharmaceutical, or the purchasing of an Alternative Pharmaceutical,

provided that PHARMAC may, in its sole discretion, require you to pay less than the amount specified as liquidated damages if it is satisfied that the actual costs in the particular circumstances are less than the relevant amount so specified.

- (d) Where a Pharmaceutical in respect of which you are liable to pay liquidated damages pursuant to clause 7.3(a)(i) above also has Sole Supply Status and where you would otherwise be liable to pay the same amount of liquidated damages in respect of any corresponding failure under the terms of such Sole Supply Status, you will only be required to pay liquidated damages of \$50,000 in total in respect of both supply failures.
- (e) All amounts referred to in this clause are plus GST.

7.4 Failure to supply

References in this clause 7 and elsewhere in this Schedule to your failure or inability to supply the Pharmaceutical in accordance with this Agreement, or your inability to meet demand for supply of the Pharmaceutical, or insufficient stock of the Pharmaceutical being available, include, but are not limited to, circumstances where:

- (a) no stock of the Pharmaceutical is physically held by you or on your behalf in New Zealand;
- (b) the only stock of the Pharmaceutical physically held by you or on your behalf in New Zealand is stock to which clause 6.2(a)(i) or (ii) of this Schedule applies and no agreement has been reached with the relevant DHB Hospital in terms of clause 6.2(a) of this Schedule;
- (c) you fail, directly or indirectly, to ensure that all orders for the Pharmaceutical are filled (without restricting quantities that may be ordered), including in particular where not all patients for whom the Pharmaceutical is prescribed receive the full amount of the Pharmaceutical they require, or to which they are entitled, under their prescriptions, without delay;
- (d) you fail to supply the Pharmaceutical on and from the Start Date.

7.5 Default interest and recovery costs

If payment of any amount required to be paid by you under this clause 7 is not made by you, in full, by the due date for payment of that amount as notified to you in writing by PHARMAC, then:

- (a) interest will accrue in such sum as remains unpaid at a rate per annum equal to the relevant SME overdraft rate (weighted average rate) of the Reserve Bank of New Zealand plus five percentage points, calculated and compounded on a daily basis, from the due date until such time as the sum due (including interest) is paid in full. This obligation to pay default interest is to arise without the need for a notice or demand from PHARMAC for such default interest; and
- (b) PHARMAC may take any action, including legal action, without first needing to implement the dispute resolution procedure contained in clause 4.2 of Schedule Four, to recover that amount and you agree to pay to PHARMAC actual enforcement costs incurred in relation to that action.

8. Termination and restrictions

8.1 Termination and restrictions for clinical reasons

PHARMAC reserves the right, but only after consultation with you and a relevant medical adviser (being either the Ministry of Health, PTAC or a sub-committee of PTAC), to:

- (a) terminate this Agreement at any time during the Hospital Supply Status Period or the First Transition Period if the medical adviser determines for clinical reasons that it is no longer appropriate to have:
 - (i) in the case of any Pharmaceutical that is not a Medical Device, any Pharmaceutical, including the Pharmaceutical or any relevant Alternative Pharmaceutical, having Hospital Supply Status of that form and strength of the Pharmaceutical with Hospital Supply Status;
 - (ii) in the case of any Pharmaceutical that is a Medical Device, any Pharmaceutical, including the Pharmaceutical or any relevant Alternative Pharmaceutical, having Hospital Supply Status; or
 - (iii) the Pharmaceutical as the brand having Hospital Supply Status; and/or
- (b) impose at any time during the Hospital Supply Status Period or the Transition Periods restrictions on the prescribing or dispensing of a Pharmaceutical if those restrictions are necessary for clinical reasons.

8.2 **Termination following an audit**

PHARMAC may terminate the Agreement, or withdraw Hospital Supply Status in relation to, or revise DV Limits for, a Pharmaceutical, at any time during the Hospital Supply Status Period or the Transition Periods, if you fail to remedy any area of non-compliance in accordance with clause 3(b) of Schedule Four.

9. Guarantee

- (a) PHARMAC may require an entity acceptable to it to provide a guarantee (in a form satisfactory to PHARMAC) of your performance obligations under clauses 7.2 and 7.3 of this Schedule including, without limitation, the payment of any sum payable under the indemnity or as liquidated damages pursuant to those clauses for any failure to supply the Pharmaceutical in accordance with this Agreement during the Hospital Supply Status Period.
- (b) The guarantor's liability under such a guarantee will be limited to a total of \$100,000 per Pharmaceutical for all claims made by PHARMAC under the guarantee.

10. Access by PHARMAC to price and volume data

- (a) You acknowledge that PHARMAC and its agents will require access to price and volume data held by you and DHB Hospitals in respect of the Pharmaceutical covered by this Agreement to assist PHARMAC to carry out its statutory function in relation to managing the purchasing of hospital pharmaceuticals on behalf of DHBs.
- (b) Notwithstanding any other provisions in this Agreement, including clauses 9.1 and 9.2 of Schedule Three regarding confidential information, you agree that where the circumstances in this clause apply, a DHB Hospital may provide PHARMAC and its agents with any price and volume data held by that DHB Hospital in respect of a Pharmaceutical covered by this Agreement and PHARMAC and its agents may provide such data on DHBs.
- (c) You agree that within 10 business days following any request from PHARMAC, you will provide PHARMAC with volume data in respect of the Pharmaceutical covered by this Agreement for each month of the period specified in that request.

11. **PCTs**

7.1

11.1 Listing in Section B of the Pharmaceutical Schedule

- (a) Where the Pharmaceutical is a PCT, you acknowledge and agree that PHARMAC may list the Pharmaceutical in Section B of the Pharmaceutical Schedule:
 - (i) at a price that is equal to (or subject to your agreement, less than) the Price;
 - (ii) subject to the rules and restrictions applying to PCTs in Sections A to G of the Pharmaceutical Schedule.
- (b) If PHARMAC lists the Pharmaceutical in Section B of the Pharmaceutical Schedule pursuant to paragraph (a) above, you acknowledge and agree that:
 - such listing will be for reasons relating to claiming and will not, unless otherwise advised in writing by PHARMAC, enable you to supply the Pharmaceutical for use in the community;
 - (ii) listing of the Pharmaceutical in Section B will, at PHARMAC's option, be additional to or instead of listing in Part II of Section H;
 - (iii) references to the "listing" of the Pharmaceutical will, where applicable, be to the listing of the Pharmaceutical in Section B of the Pharmaceutical Schedule (and references to "list", "listed", "delist", "delisted", and "delisting" are to be interpreted accordingly); and
 - (iv) the standard terms of listing of the Pharmaceutical in Section B of the Pharmaceutical Schedule will, except to the extent otherwise advised in writing by PHARMAC, be the terms set out in Schedule Four and this Schedule, and for that purpose all references in Schedule Four and this Schedule to "Section H" will be deemed to be references to "Section B".
- (c) This clause confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contracts (Privity) Act 1982.
- (d) Where the Pharmaceutical is a PCT, clause 7.1 of this Schedule will be deleted and replaced by the following:
 - Notification of Potential Out-of-Stock Event and supply of Alternative Pharmaceutical.
 - (a) You must notify PHARMAC in writing as soon as you have reasonable cause to believe that you will fail to supply a Pharmaceutical in accordance with this Agreement and, in any event, you must notify PHARMAC and the relevant DHB Hospitals if at any time a Potential Out-of-Stock Event occurs, including during the Hospital Supply Period or the First Transaction Period.
 - (b) If you fail to supply a Pharmaceutical in accordance with this Agreement for more than 1 business day to any DHB Hospital, then:
 - you must use your best endeavours to procure, within what the relevant DHB Hospitals consider to be a reasonable period of time, an Alternative Pharmaceutical for supply to, at a DHB

Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding) at the Price; and

- (ii) if you fail to procure an Alternative Pharmaceutical at the Price in accordance with sub-clause (i) above (other than for reasons that PHARMAC reasonably considers, following discussion with you, to be wholly outside your control) then, at PHARMAC's option:
 - (A) you must pay to PHARMAC (for the benefit of PHARMAC and DHB Hospitals) any additional costs that PHARMAC incurs or that the relevant DHB Hospitals incur as a result of the purchase of the Alternative Pharmaceutical; or
 - (B) PHARMAC may implement an arrangement with another supplier to supply an Alternative Pharmaceutical (including an arrangement for back-up supply), and you must pay to PHARMAC (for the benefit of PHARMAC and DHB Hospitals) any additional costs that PHARMAC incurs or that the relevant DHB Hospitals incur as a result of the purchase of the Alternative Pharmaceutical.
- (c) This clause confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contracts (Privity) Act 1982.