PHARMAC
Pharmaceutical Management Agency

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15 June 2016

Dear Supplier

REQUEST FOR TENDER – SUPPLY OF VENLAFAXINE TO DHB HOSPITALS AND/OR TO COMMUNITY PHARMACIES

PHARMAC invites tenders for the supply of venlafaxine hydrochloride extended-release (venlafaxine) to DHB hospitals and/or to community pharmacies in New Zealand.

This request for tender (RFT) incorporates the following schedules:

(a) Schedule 1 sets out the definitions used in this RFT;

(b) Schedule 2 specifies the pharmaceuticals for which you may submit a Tender Bid in relation to community supply and/or hospital supply and provides background information to this RFT;

(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;

(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; and

(g) Schedule 7 sets out any other special terms.

Please note that some clauses included in this RFT may not be applicable to this tender. PHARMAC has decided to retain substantially all of the clauses included in the standard PHARMAC invitation to tender to keep the terms of this RFT as familiar as possible to potential suppliers. This may mean that some clauses are not applicable in the context of a particular tender (which should be evident from the context).

For the avoidance of doubt, references in this RFT to "Price" and "Subsidy" are references to the price at which a pharmaceutical would be listed on the Pharmaceutical Schedule.

If you wish to submit a Tender Bid in relation to community supply and/or hospital supply, you must submit it to PHARMAC via the Government Electronic Tenders Service (GETS) (www.gets.govt.nz) no later than **4pm** (New Zealand time) on **Monday 11 July 2016**.

If you have any inquiries about this RFT you should submit them via GETS or alternatively contact Matthew Wolfenden, Procurement Manager, by email procurement@pharmac.govt.nz. We look forward to receiving your tender.

Yours sincerely

Sarah Fitt

Sarah Fitt
Director of Operations

Contents

Schedule 1: Definitions and interpretation

1. Definitions

In this RFT:

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) Schedule Seven; and

(c) in relation to a Pharmaceutical with Sole Subsidised Supply Status, Schedule Five; or

(d) 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 Government Electronic Tenders Service (GETS) comprising the RFT;

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 on GETS in relation to this RFT;

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 RFT or in relation to your Tender Bid, including during all negotiations relating to your Tender Bid;

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;

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

Deadline means 4 pm (New Zealand time) on 11 July 2016;

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 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 on GETS in relation to this RFT, 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) 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) 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;

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;

Government Electronic Tenders Service or **GETS** means the electronic system operated by the Ministry for Business, Innovation and Employment available at https://www.gets.govt.nz/ExternalIndex.htm through which you are required to submit your Tender Bid(s);

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 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 2017; and

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

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

(f) 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;

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 to have stock of the Pharmaceutical available for supply or sale, and supply or sell the Pharmaceutical, at the Price from the 12th day of the month prior to the Start Date;

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;

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 2017; and

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

(c) the number of months during which the Hospital Supply Status Period applies during the twelve month period ending on 30 June 2019; and

(d) 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;

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

PCT means a Tender Item for which a "PCT" is indicated in the list in clause 2 of Schedule Two and on GETS in relation to this RFT;

Pharmaceutical means the relevant Tender Item 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; or

(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).

For the avoidance of doubt, references to 'your stock' in (a) to (e) 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 listed on the Pharmaceutical Schedule and 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 RFT, 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 RFT, 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;

RFT means this request for tender and includes the cover letter, each of the Schedules, each Appendix, and the information on GETS referred to in this request for tender;

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 Tender Submission Form submitted through GETS 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 the form and strength of a Chemical Entity (or entities, if applicable) 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 available on GETS and at www.pharmac.health.nz;

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 or a syringe);

Unit Price means the relevant Price specified for a pack 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 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 on GETS in relation to this RFT.

2. Interpretation

In the construction of this RFT, 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 RFT;

(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 on GETS in relation to this RFT 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 on 19 March 2017.

(b) Where PHARMAC has been advised of the existence of a patent prior to sending out this RFT, it has commented on this in the Background section on page 16 of this RFT.

(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 and hospital supply, are based on actual volumes for the year ending 30 June 2015.

(b) Market value figures, in relation to community and hospital supply, are expressed as the gross cost in the year ending 30 June 2015.

(c) The figures referred to in paragraphs (a) and (b) 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.

(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 and/or specified in Schedule Seven.

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 is as at 1 May 2016.

(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 May 2016. This information is also shown on GETS in relation to this RFT.

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 on GETS in relation to this RFT.

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 RFT.

1.8 Tender Items subject to existing subsidy protection arrangements

Where a Tender Item is subject to a contract with an ongoing period of subsidy and/or delisting protection as at the date of this RFT, it is indicated by a “ʊ” symbol in the list of products below. Accordingly, the subsidy for those Tender Items is fixed until 31 March 2017 so any new sole supply arrangements could only commence after that date.

1.9 Hospital only products

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

1.10 Community only Products

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

1.11 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.

1.12 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 on GETS in relation to this RFT.

1.13 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 as each line item in that Tender Item.

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, 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.

1.15 No Rebates considered

PHARMAC is not willing to consider Tender Bids that include rebates in respect of Tender Items as part of this RFT. Accordingly, you may not submit a bid for a Tender Item that includes a rebate.

1.16 Duration of Sole Supply Period and Hospital Supply Status Period

Without limiting PHARMAC's rights in any way, the standard duration of the Sole Supply Period and the Hospital Supply Status Period (as applicable) that PHARMAC would be willing to consider is a period of approximately three years.

2. List of products

Chemical Name	Presentation	DV Limit Φ	Distribution	FYE 2015	
				Units	Gross Cost
Venlafaxine	37.5 mg ʊ	1%	C	2,281,704	$609,577
			H	14,980	$2,855
Venlafaxine	75 mg ʊ	1%	C	9,691,591	$3,875,285
			H	60,412	$17,342
Venlafaxine	150 mg ʊ	1%	C	5,883,754	$3,773,212
			H	52,012	$19,259
Venlafaxine	225 mg ʊ	1%	C	244,130	$125,029
			H	3,080	$1,577

KEY

C Community Supply

H Hospital Supply

ʊ Subsidy and/or delisting protection applies until 31 March 2017

Φ DV Limit to apply (as per Clause 1.6 Schedule 2)

3. Background information

Current Situation

Venlafaxine is indicated for the treatment of major depression; generalised anxiety disorder; social anxiety disorder and panic disorder. Venlafaxine is also indicated for the prevention of relapse and recurrence of major depression where appropriate. It belongs to a class of medications for depression and anxiety called serotonin and noradrenaline reuptake inhibitors (SNRIs).

PHARMAC currently lists and fully funds the following presentations of venlafaxine hydrochloride extended-release in Section B and Section H of the Pharmaceutical Schedule. All presentations have subsidy and delisting protection until 31 March 2017. PHARMAC understands that Efexor XR is currently under patent NZ314442 which expires on 19 March 2017.

Chemical and presentation	Brand	Pack size	Current subsidy and price (ex-man, ex-GST)
Venlafaxine Tab 37.5 mg	Arrow-Venlafaxine XR	28	$5.06
Venlafaxine Tab 75 mg	Arrow-Venlafaxine XR	28	$6.44
Venlafaxine Tab 150 mg	Arrow-Venlafaxine XR	28	$8.86
Venlafaxine Tab 225 mg	Arrow-Venlafaxine XR	28	$14.34
Venlafaxine Cap 37.5 mg	Efexor XR	28	$5.69
Venlafaxine Cap 75 mg	Efexor XR	28	$11.40
Venlafaxine Cap 150 mg	Efexor XR	28	$13.98

Arrow-Venlafaxine XR is open listed, whereas Efexor XR is restricted via Special Authority (SA1061) for patients with treatment-resistant depression as follows:

> **Initial application** from a relevant specialist or vocationally registered general practitioner. Approvals valid for 2 years for applications meeting the following criteria:
>
> Both:
>
> 1. The patient has 'treatment-resistant' depression; and
> 2. Either:
>
> 2.1. The patient must have had a trial of two different antidepressants and have had an inadequate response from an adequate dose over an adequate period of time (usually at least four weeks); or
>
> 2.2. Both:
>
> 2.2.1. The patient is currently a hospital in-patient as a result of an acute depressive episode; and
>
> 2.2.2. The patient must have had a trial of one other antidepressant and have had an inadequate response from an adequate dose over an adequate period of time.
>
> **Renewal** from any medical practitioner. Approvals valid for 2 years where the patient has a high risk of relapse (prescriber determined).

Desired Outcome

PHARMAC is seeking bids for venlafaxine hydrochloride extended-release:

- capsules and/or tablets
    - 37.5 mg
    - 75 mg
    - 150 mg
    - 225 mg*
- for listing on the Pharmaceutical Schedule without any restrictions/Special Authority criteria;
- Sole Supply Status to run until 30 June 2020; and
- Hospital Supply Status with a DV Limit of 1% to run until 30 June 2020.

* Notwithstanding clause 2 of Schedule Three, you may at your option submit a Tender Bid for the 225 mg presentation, which would not prejudice any Tender Bid for the other presentations stated above. PHARMAC may award sole supply for venlafaxine hydrochloride extended-release capsules and/or tablets with a range made up of just the 37.5, 75 and 150 mg presentations. This would result in the 225 mg presentation being delisted.

Please note the Second Transition Period may be extended to six months instead of three months in accordance with clause 1.2 of Schedule Three and you should take this into account when submitting a Tender Bid.

For clarification, in accordance with clauses 2.3 to 2.6 of Schedule Three, you may submit:

- Individual Tender Bids;
- Aggregated Tender Bids;
- Combined Community/Hospital Tender Bids for each presentation, and
- Aggregated Combined Community/Hospital Tender Bids.

For the avoidance of doubt and in accordance with clause 1.16 of Schedule Two, PHARMAC is not willing to consider Tender Bids that include rebates in respect of Tender Items as part of this RFT. Accordingly, you may not submit a bid for a Tender Item that includes a rebate.

Schedule 3: Tender Process

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 12th day of the month prior to the Start Date);

(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 12th day of the month prior to the Start Date);

(ii) 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:

(i) 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; and

(iv) Schedule Seven,

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; and

(iv) Schedule Seven,

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; and

(D) Schedule Seven,

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; and

(D) Schedule Seven,

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, Schedule Six and Schedule Seven, 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 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 on GETS in relation to this RFT as being a Tender Item for which you may submit a Tender Bid for Sole Subsidised Supply 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 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 Supply Status.

(b) The Community Tender Bid referred to in paragraph (a)(i) above and the contract for Sole 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 Schedule Four, Schedule Five and Schedule Seven; 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 and on GETS in relation to this RFT 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 Schedule Four, Schedule Six and Schedule Seven; 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 RFT and PHARMAC will have regard to probity principles in this respect.

(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 RFT

PHARMAC may having regard to probity principles:

(a) amend this RFT at any time up to five business days before the Deadline; and/or

(b) terminate this RFT 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 must 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.

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 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) 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 within a single Tender Item (for example, two different brands or pack sizes);

(iii) 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.

2.10 Rebates

You may not submit a bid for a Tender Item that includes a rebate.

2.11 No alternative bids

PHARMAC will not consider any alternative bids submitted in response to this RFT other than Tender Bids of a type expressly contemplated and permitted by the above provisions in this clause 2.

3. What to include in your Tender Submission Form

3.1 Compulsory use of Tender Submission Form

(a) You must submit your Tender Bid using the GETS and attach a completed Tender Submission Form for each Tender Item for which you wish to submit a bid.

(b) Electronic versions of the Tender Submission Form are available on GETS and on PHARMAC's website at www.pharmac.govt.nz. A copy of the Tender Submission Form is attached to this RFT as Appendix A.

3.2 Information that must be supplied about you

In the Tender Submission Form, 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) the chemical, form, strength, brand name, pack size and type of packaging;

(b) 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

(ii) 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;

(c) whether it has all necessary Consents (and if not, what the status of registration is);

(d) the Lead Time for supply of the Tender Item;

(e) the name and location of:

(i) the manufacturer(s) of the finished product (and name and location of the packaging site, if different); and

(ii) the manufacturer(s) of the active ingredients; and

(iii) alternative manufacturers of the finished product and active ingredients (if any);

(f) 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 to PHARMAC via GETS. 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 GETS by no later than the Deadline; and

(b) be irrevocable and remain open for acceptance by PHARMAC until, as applicable:

(i) six months following the Deadline;

(ii) the date specified for a Tender Item in Schedule Two or on GETS in relation to this RFT; 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 (FFC) that from 1 July 2016 will form part of PHARMAC's then current Operating Policies and Procedures (OPPs), as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. Please note that the FFC reflect a change in the way in which PHARMAC makes decisions, replacing PHARMAC's existing Decision Criteria from 1 July. Please be aware of the FFC. More information on the FFC 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 Tender Bids which demonstrate "health outcomes", and those aspects of Tender Bids which demonstrate the impact on the "funding provided" for pharmaceuticals. Those Factors for Consideration which relate directly to these aspects will be given the greatest weight by the Evaluation Committee but all FFC are important.

The matters taken into account by the Evaluation Committee will, however, include:

(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 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

(ii) 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 RFT. If PHARMAC does elect to check your Tender Bid, it is not obliged to check all or any other Tender Bids for conformity. A Tender Bid will conform if it:

(i) is submitted via GETS by the Deadline;

(ii) is submitted on the Tender Submission Form 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 RFT.

(b) PHARMAC may, in its sole discretion:

(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 FFC 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:

(i) 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 having regard to probity principles to accept or reject any Tender Bid and, other than to the extent necessary to debrief an unsuccessful tenderer, is not obliged to give reasons for its decision.

(b) While it is PHARMAC's current intention, unless specified otherwise in Schedule Two or on GETS in relation to this RFT, 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 (following such consultation as PHARMAC considers necessary or appropriate) and this acceptance is notified to the successful tenderer.

(d) PHARMAC may take any action having regard to probity principles, including making any adjustments to the tender process that it considers appropriate (provided that it notifies tenderers materially affected by such adjustments), or do anything, that is incidental to the process described in this RFT, at any time during the process, except to the extent that such action is explicitly precluded by this RFT.

(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.

(c) Notwithstanding any other provision in this RFT, the contract referred to in clause 1.3 of this Schedule will be conditional upon:

(i) PHARMAC completing all consultation it considers necessary or appropriate (including consultation under its OPPs, with suppliers and with other interested parties), and in this regard PHARMAC reserves the right not to consult on the Price; and

(ii) following consultation, approval of its terms by PHARMAC's Board (or its delegate, where applicable).

(d) For the avoidance of doubt, and without limiting any of PHARMAC's rights under this RFT, if PHARMAC's Board (or its delegate) does not grant the approval referred to in paragraph (c) above, PHARMAC may initiate negotiations with any other supplier(s).

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 RFT. PHARMAC does not seek submissions for Back-up Supply Agreements in response to this RFT 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 RFT.

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 on GETS in relation to this RFT).

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, 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 or advisors to PHARMAC, 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 RFT you should submit them on GETS. 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 RFT 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.

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:

(i) 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 non-compliance 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 & IAMA (a body corporate incorporated in Australia, registered as an overseas company in New Zealand in accordance with Part 18 of the Companies Act 1993, trading as the Resolution Institute), and the Chair of LEADR & IAMA (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.

4.6 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.

4.7 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.

4.8 Amendments

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

4.9 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.

4.10 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.

4.11 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.

4.12 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.

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;

(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 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 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 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 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 Out-of-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;

(ii) 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 to a level above 10% without your prior agreement if it has a direction from Medsafe or its successor, or a recommendation from PTAC or its sub-committees, 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:

(i) 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 2017; or

(B) for a Pharmaceutical listed on or prior to 30 June 2017, the period commencing on 1 July 2017 and ending on 30 June 2018 or, for a Pharmaceutical listed after 30 June 2017, the initial period starting on the date that the Hospital Supply Status Period begins up to and including 30 June 2018; or

(C) 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 2018, the initial period starting on the date that the Hospital Supply Status Period begins up to and including 30 June 2019,

(D) 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 on GETS in relation to this RFT 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 ÷ 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:

(i) you will cease to have Hospital Supply Status for that form and strength of the Pharmaceutical;

(ii) 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);

(iii) 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;

(iv) 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

(v) 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 (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, 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.

2.3 Pharmacode

You agree to obtain and notify PHARMAC of the Pharmacode for the Pharmaceutical as soon as the Pharmacode is notified to you, and in any event before the date on which the Pharmaceutical is listed in Section H of the Pharmaceutical Schedule.

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 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 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 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 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.

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 air-freighting 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 either:

(i) 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; or

(ii) 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

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:

(i) 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:

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 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:

(i) 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.

Schedule 7: Special terms and conditions

1. **Not Applicable**

Appendix A: Tender Submission Form

An electronic version of this form is available on GETS or on PHARMAC's website at www.pharmac.govt.nz. You should expand the boxes as necessary.

[***Tenderer to insert date***]

Director of Operations
PHARMAC
C/- Matthew Wolfenden

By electronic transfer using GETS (https://www.gets.govt.nz)

Dear Sir

Tender bid for the supply of venlafaxine to DHB hospitals and/or to community pharmacies - commercial in confidence

In response to your request for tenders (**RFT**) dated 11 June 2016, we put forward the following tender bid in respect of venlafaxine.

Set out below is further information in support of our tender bid.

(a) Our contact details (i.e., who communications relating to the attached bid(s) should be made to):

Name of supplier	
Contact person	
Address	
Phone	
Facsimile	
Email address	

(b) Information about our company structure:

(c) Information about our management and technical skills:

(d) Information about our financial resources:

(e) Information about our, or our supplier's, existing supply commitments:

(f) Information about our quality assurance processes (where applicable):

(g) Information about our ability to ensure the continuity of supply of the Tender Item:

(h) Our proposed distribution and supply arrangements for the Tender Item

(i) Key features of our tender bid:

(j) Information about our previous supply performance and relevant expertise:

(k) Confirmation that there are no intellectual property barriers (including patent barriers) to our supply of this product in New Zealand, with additional information if required:

(l) Details of pharmaceutical presentation(s):

Chemical name	
Strength (e.g. 10 mg)	
Form (e.g. tablet or capsule)	
Brand name	
Pack size (e.g. 30 tablets)	
Packaging type (e.g. Blister pack)	
Date of market approval (please attach copy of Medsafe Gazette notice)	
OR Date of submission of dossier (please attach confirmation from Medsafe that dossier has been submitted)	
OR Expected date of dossier submission to Medsafe	
Insert any other consents required for pharmaceutical	
Lead time (Months)	
The manufacturer(s) of the finished product (and name and location of the packaging site, if different)	
The manufacturer(s) of the active ingredients	
Alternative manufacturers of the finished product and active ingredients (if any)	

(m) Subsidy/Price per pack ($NZ, GST exclusive):

Chemical	Supplier	Brand	Pack size	Strength	Type	Supply Market	Subsidy/Price per Pack ($ NZD)
Venlafaxine				37.5 mg	Individual	C	
					Individual	H	
				75 mg	Individual	C	
					Individual	H	
				150 mg	Individual	C	
					Individual	H	
				225 mg	Individual	C	
					Individual	H	
				37.5 mg	Combined	C & H	
				75 mg	Combined	C & H	
				150 mg	Combined	C & H	
				225 mg	Combined	C & H	
				37.5 mg	Aggregated 1	C	
				75 mg	Aggregated 1	C	
				150 mg	Aggregated 1	C	
				225 mg	Aggregated 1	C	
				37.5 mg	Aggregated 2	H	
				75 mg	Aggregated 2	H	
				150 mg	Aggregated 2	H	
				225 mg	Aggregated 2	H	
				37.5 mg	Aggregated Combined	C & H	
				75 mg	Aggregated Combined	C & H	
				150 mg	Aggregated Combined	C & H	
				225 mg	Aggregated Combined	C & H	

Note – Please duplicate table for alternative brand(s)

Signed for and on behalf of **<insert name of tenderer>** by

_____
<Insert name>
<Insert designation>

PHARMAC
Pharmaceutical Management Agency

Level 9, 40 Mercer Street, Wellington 6011
PO Box 10-254, Wellington 6143, New Zealand
Phone 64-4-460-4990
Fax 64-4-460-4995
Information line 0800 66 00 50
enquiry@pharmac.govt.nz
www.pharmac.govt.nz

5 August 2016

Lloyd Price
Country Manager
Mylan New Zealand Limited
2B George Bourke Drive
Mt Wellington
Auckland
New Zealand

By email – lloyd.price@mylan.co.nz

Dear Lloyd,

Alternative Brand Allowance for Venlafaxine

We refer to the Request for Tender – Supply of Venlafaxine to DHB Hospitals and/or to Community Pharmacies dated 15 June 2016 ("Tender").

In the event PHARMAC accepts your Aggregated Combined Community/Hospital Tender Bid and a contract is entered into on the terms and conditions set out in Schedule 3, clause 1.3 of the Tender, between Mylan New Zealand Limited ("Mylan") and PHARMAC ("Contract"), the parties have agreed the following additional condition shall form part of the Contract as a new clause 1 of Schedule 7:

1. **Alternative Brand Allowance**

   Notwithstanding the additional contract terms for Sole Supply Status for your brand of the Pharmaceutical as set out in clause 1 of Schedule 5 of the Tender, PHARMAC reserves the right to allow subsidised access to another supplier's brand of the Pharmaceutical ("Alternative Brand") during the Sole Supply Period in accordance with the following conditions:

   (a) The maximum number of patients who are treated with the Alternative Brand shall not exceed 100 patients during the Sole Supply Period ("Period"); and
   (b) Those patients identified above shall be eligible for treatment of the Alternative Brand for a maximum period of 12 months within the ("Period").

In the event a Contract is entered into between Mylan and PHARMAC it shall be conditional upon consultation and approval by PHARMAC's Board (or its delegate) in accordance with Schedule 3, clause 7.4 (c) of the Tender.

Terms used in this letter shall have the same meaning as the terms defined in the Tender, unless the context otherwise requires.

In the event of any conflict between the terms stated in this letter and the terms stated in the Tender, the terms stated in this letter shall prevail.

Except as expressly amended by this letter, the terms of the Tender are unchanged.

Acceptance

To confirm your acceptance of this letter, please sign and return the attached copy to PHARMAC by **4 pm** on **Monday 8 August 2016**.

Yours faithfully

Lisa Williams
Manager, Pharmaceutical Funding

Signed and agreed by **Mylan New Zealand Limited** by:

Name: Lloyd Price

Position: Country Manager

Date: 5/8/16

MINUTES

To Venlafaxine RFT Evaluation Committee

From Matthew Wolfenden

Subject Evaluation Meeting Minutes

Date Thursday 28 July 2016 – Hedley Room 1:30pm

Attendees:

- Geraldine MacGibbon — Senior TGM/Team Leader
- Brian Roulston — Contract Manager
- Jonathan Dawes — Legal Counsel
- Scott Metcalfe — Deputy Medical Director
- Peter Murray — Medical Advisor Registrar
- Janet Mackay — Manager, Implementation Programmes
- Brad van Bakel — Analyst
- Chloe Dimock — Procurement Manager 2nd

1. Links to Key Documents

- Procurement Plan A900065
- RFT Document A913950
- Analysis A930516
- Tablet Comparison A931095
- Stock Issues A453755
- Factors For Consideration A761407

2. Conflicts of Interest

Noted - No conflicts of interest were raised

3. Terms of reference and proposed process for evaluation

(a) Members of the Evaluation Committee – **Noted and Agreed**

Member	Role
Chair	• Provide key documents required for evaluation. • To set out the proposed process for evaluation and lead the Evaluation Committee discussion to reach a consensus on any final recommendation(s). • Finalise minutes of the Evaluation Committee meeting after panel review.
Legal Counsel	• To observe that the evaluation process is carried out in accordance with the RFX document, is consistent with PHARMAC's legal requirements and to advise on any legal issues as they arise during the evaluation process.
Evaluation Committee members	• Review key documents and summary of proposals. • Provide advice in areas of expertise (eg clinical, analytical, contract management). • Evaluate proposals and participate in Evaluation Committee discussion to reach a final consensus on any final recommendation(s). • Review minutes of the Evaluation Committee meeting.

*Note: Members of the Evaluation Committee and the Chair are expected to remain the same for any future Evaluation Committee meetings.

(b) Role of Evaluation Committee – **Noted and Agreed**

The key role of this Evaluation Committee ('Committee') is to review and evaluate proposals received in response to the Venlafaxine RFT that was issued on 15 June 2016 ('RFT'). The Committee is expected to reach a consensus and select its preferred proposal(s) if any, to be progressed to consultation stage.

In undertaking the evaluation, the Evaluation Committee will evaluate proposals 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 extent applicable. More 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 by the Evaluation Committee in evaluating proposals will include (**Clauses 5.1 & 5.2 of Schedule 3 of the RFT**):

- *Evidence of 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:*
- *financial resources;*
- *management and technical skills;*
- *existing supply commitments;*
- *previous supply performance;*
- *quality assurance processes, where applicable;*
- *the site of manufacture and packaging of the Pharmaceutical, and site of manufacture of the active ingredient;*
- *proposed distribution and supply arrangements for the Tender Item; and*
- *the Lead Time for supply of the Tender Item;*
- *the pack size of the Tender Item and the type of packaging;*
- *the price of the Tender Item;*
- *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;*
- *either:*
    - *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;*

- *the name and location of the manufacturer of the finished product and active ingredients of the Tender Item; and*
- *any other benefits to the Funder of selecting you as the supplier of the Tender Item.*

Together with:

- any advice from PTAC or its relevant sub-committee; and
- any advice from relevant clinicians and/or DHB staff.

(c) Objective of the Evaluation Committee meeting

The objective of the Evaluation Committee meeting is to:

- agree on the proposed process for evaluation;
- check for any non-conforming proposals and make recommendations on the appropriate course of action;
- agree on the selection of preferred proposal(s) on the basis of information currently available to the Evaluation Committee (ie financial analysis, supplier information and sub-committee advice);
- recommend, where appropriate to seek further advice from suppliers and/or other stakeholders;
- make any other recommendations within the terms of the RFT.

4. Background – Noted

Venlafaxine is used for the treatment of major depression; generalised anxiety disorder; social anxiety disorder and panic disorder. Venlafaxine is also indicated for the prevention of relapse and recurrence of major depression where appropriate. It belongs to a class of medications for depression and anxiety, called serotonin- noradrenaline reuptake inhibitors (SNRIs).

Venlafaxine hydrochloride was included in the December 2006 Invitation To Tender (ITT), which was the first time a competitive process had been run for the supply of this pharmaceutical. In July 2007 the Board declined to award a Tender for venlafaxine [redacted]

PHARMAC then issued an RFP for the supply of venlafaxine in July 2007. [redacted]

[redacted]

[redacted]

PHARMAC later listed the Arrow-Venlafaxine brand of venlafaxine extended-release tablets (supplied by Actavis), [redacted]

- Efexor XR is restricted via Special Authority for patients with treatment-resistant depression. Arrow-Venlafaxine XR is open listed. The RFT was for an open listed product ie no clinical restrictions would apply.
- There are two other registered brands of venlafaxine extended-release capsules (Rex and Mylan).
- The current annual expenditure is $8.4M in the Community (FYR ending 2015) – #18 medicine by cost (Jan 2016)
- $7.22M expenditure was for the Pfizer Efexor XR capsules and $1.16M was on the Actavis Arrow-Venlafaxine XR tablets.
- FY ending 2015 – Number of patients approximately 41,000 (29,000 Chronic = 70%)

[redacted]

Current Situation

PHARMAC currently lists and fully funds the following presentations of venlafaxine hydrochloride extended-release in Section B and Section H of the Pharmaceutical Schedule. All presentations have subsidy and delisting protection until 31 March 2017. PHARMAC understands that Efexor XR is currently under patent NZ314442 which expires on 19 March 2017.

Chemical and presentation	Brand	Pack size	Current subsidy and price (ex-man, ex-GST)
Venlafaxine Tab 37.5 mg	Arrow-Venlafaxine XR	28	$5.06
Venlafaxine Tab 75 mg	Arrow-Venlafaxine XR	28	$6.44
Venlafaxine Tab 150 mg	Arrow-Venlafaxine XR	28	$8.86
Venlafaxine Tab 225 mg	Arrow-Venlafaxine XR	28	$14.34
Venlafaxine Cap 37.5 mg	Efexor XR	28	$5.69
Venlafaxine Cap 75 mg	Efexor XR	28	$11.40
Venlafaxine Cap 150 mg	Efexor XR	28	$13.98

Arrow-Venlafaxine XR is open listed, whereas Efexor XR is restricted via Special Authority (SA1061) for patients with treatment-resistant depression.

Desired Outcome as Outlined in the RFT Document

"PHARMAC is seeking bids for venlafaxine hydrochloride extended-release:

- capsules and/or tablets
  - 37.5 mg
  - 75 mg
  - 150 mg
  - 225 mg*
- for listing on the Pharmaceutical Schedule without any restrictions/Special Authority criteria;
- Sole Supply Status to run until 30 June 2020; and
- Hospital Supply Status with a DV Limit of 1% to run until 30 June 2020.

* Notwithstanding clause 2 of Schedule Three, you may at your option submit a Tender Bid for the 225 mg presentation, which would not prejudice any Tender Bid for the other presentations stated above. PHARMAC may award sole supply for venlafaxine hydrochloride extended-release capsules and/or tablets with a range made up of just the 37.5, 75 and 150 mg presentations. This would result in the 225 mg presentation being delisted.

Please note the Second Transition Period may be extended to six months instead of three months in accordance with clause 1.2 of Schedule Three and you should take this into account when submitting a Tender Bid."

List of Products Tendered For

Chemical Name	Presentation	DV Limit Φ	Distribution	FYE 2015	
				Units	Gross Cost
Venlafaxine	37.5 mg ʊ	1%	C	2,281,704	$609,577
			H	14,980	$2,855
Venlafaxine	75 mg ʊ	1%	C	9,691,591	$3,875,285
			H	60,412	$17,342
Venlafaxine	150 mg ʊ	1%	C	5,883,754	$3,773,212
			H	52,012	$19,259
Venlafaxine	225 mg ʊ	1%	C	244,130	$125,029
			H	3,080	$1,577

KEY

ʊ	Subsidy and/or delisting protection applies until 31 March 2017
C	Community Supply
H	Hospital Supply
Φ	DV Limit to apply (as per Clause 1.6 Schedule 2)

5. Summary of Proposals Received

MW described the bids received to the Evaluation Committee – taking particular care to explain the variations of various bids taken into account during the analysis.

[redacted]

[redacted]

- **Mylan**
  - Two bids
  - 1st bid – "28s" listed 1 April 2017
  - 2nd bid – "90s" listed 1 April 2017

[redacted]

(a) Late, conditional and non-conforming proposals

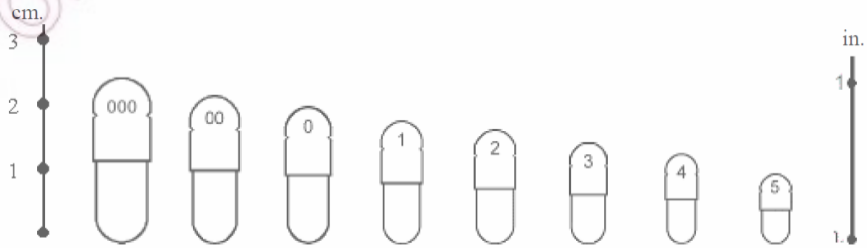

RELEASED UNDER THE
OFFICIAL INFORMATION ACT

(c) Analysis of proposals –

Agreed that PHARMAC staff would work with the preferred supplier to implement any potential new brand listing for 1 April 2017, including agreeing with the supplier that stock would need to be available to the market by 20 March 2017 rather than 12 March 2017.

6. Sample Comparison – Noted

Supplier	Strength	Presentation	Shape – Markings - Colour	Pack Size & Packaging	Shelf life	Excipients
[redacted]						
Mylan Enlafax XR	37.5 mg 75 mg 150 mg	Capsule	37.5 mg – White, No 0, capsules printed with "VEN" and "37.5" 75 mg – Flesh, No 0, capsules printed with "VEN" and "75" 150 mg – Scarlet , No 00, capsules printed with "VEN" and "150"	28 (7x4) & 90 (9 x10) Capsules Blister pack, PVC/PE/PVdC/ aluminium	36 months from date of manufacture stored at or below 25°C	Acetone, Ammonio methacrylate copolymer, Ethanol, Gelatin, Hypromellose, Basic Butylated Methacrylate Copolymer (Eudragit E100), Isopropyl alcohol, Magnesium stearate, Sodium laurilsulfate, Titanium dioxide. Iron oxide red – in 75 mg Erythrosine , Indigo carmine – in 150 mg
[redacted]						

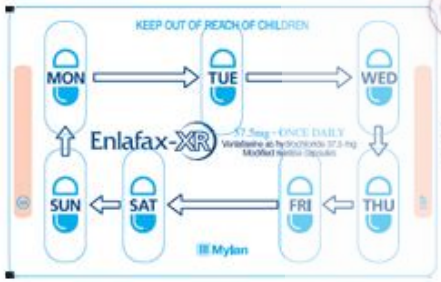


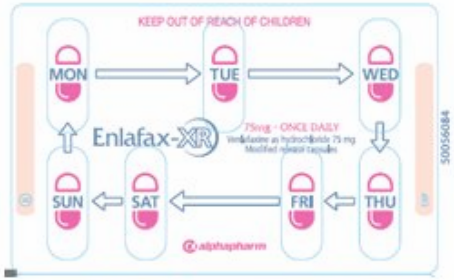
Mylan Enlafax XR – 28 cap

37.5 mg

75 mg

150 mg



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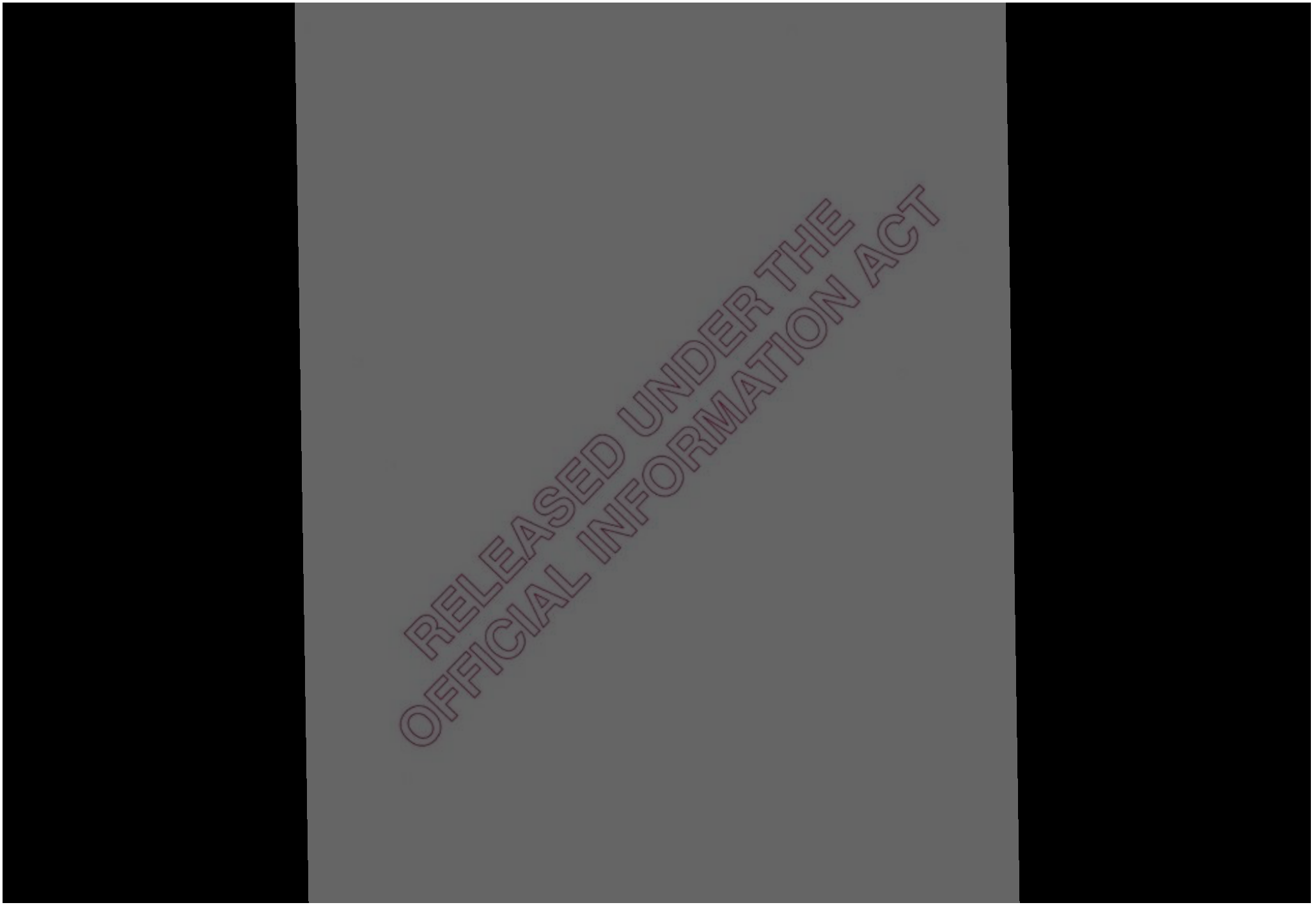

RELEASED UNDER THE
OFFICIAL INFORMATION ACT

The Evaluation Committee **Discussed** the sample comparison information and **Noted**:

[redacted]

- The visual appearances of the Mylan Enlafax XR capsules are similar in colour to Pfizer's Efexor XR brand. The Mylan 37.5 mg and 75 mg capsules are slightly larger due to the fact that they contain tablets rather than granules.
- The calendar style foil available on the Enlafax XR 28s was seen as desirable if there was to be a change from Efexor XR, mainly for reasons of ease of brand switch rather than for reasons of usefulness to patients.
    - On 19 July 2016, Mylan stated - The 90 pack would be a blister, comprising 9 strips of 10 capsules and that this would not be in a calendar pack configuration but that if a calendar pack configuration is seen as preferable / required, it could explore a 84 count blister pack.
    - Neither the 90 nor the 84 pack of Enlafax is currently registered with Medsafe and timeframes for 1 April 2017 listing would need to be considered and checked.

7. Potential Implementation Risks - Noted

Due to the nature and size of the patient group (40,000 patients mostly with treatment-resistant depression, of whom 29,000 have chronic need), the Committee considered that it is likely that any change in the medicines they use would have a greater impact when compared to short-term treatments where patients may be less likely to have significant brand loyalty (75% of venlafaxine patients use the listed originator brand despite it being more difficult for prescribers to prescribe it as it requires a Special Authority). The impact of change would be greater in this instance where the medicine is used for the treatment of depression.

Mitigation strategy - Noted

We could expect to undertake the following activities to mitigate some of the risks associated with change (if a change were the outcome of the RFT):

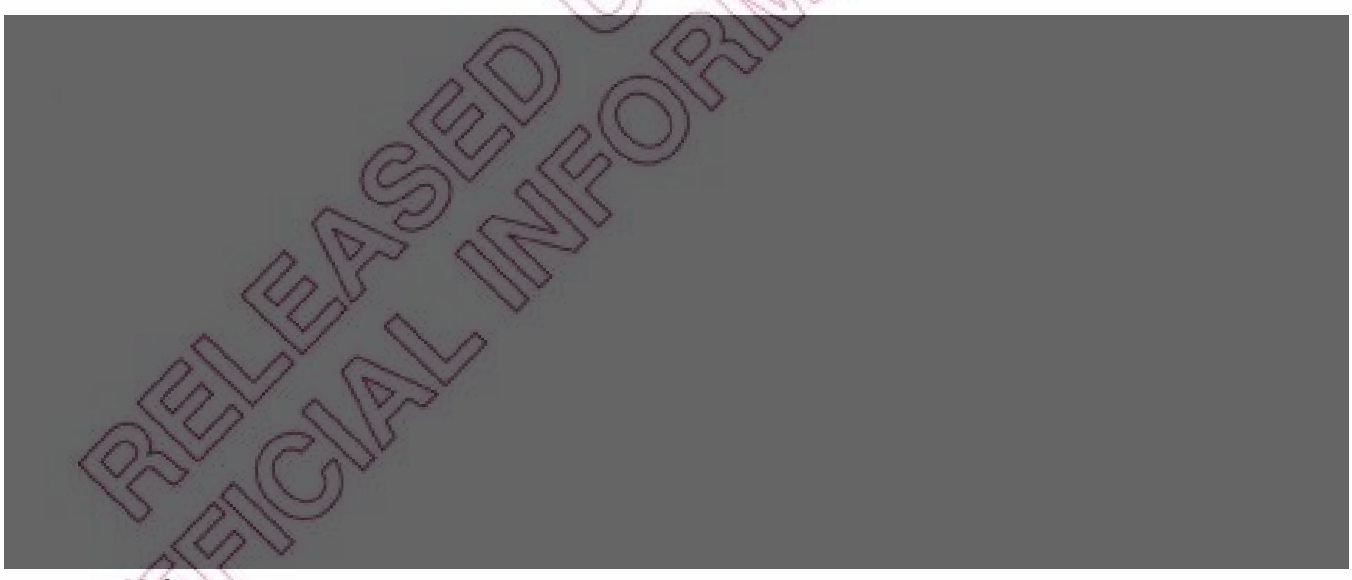
- provide an appropriate length of transition timeframe (i.e option of extended transition – note impact to any potential savings);
- continued access to originator brand for a small number of patients (if required);
- key messages and information resources about the change;
- other implementation activities as considered appropriate by the Engagement and Implementation directorate.

There is a high likelihood that pharmacies may see an increase in patient enquiries if a change in brand was implemented. If a change decision was progressed, we would assess whether to apply a brand switch fee to compensate for the extra time a pharmacist would have to spend with patients.

The Evaluation Committee **Discussed** the impact and implementation issues that would need to be addressed if the preferred bid would result in a brand switch. **Noting**:

- That the patient group could be a difficult one to switch and that a full implementation plan and programme would be needed – potentially similar to that of paroxetine hydrochloride (2007).
- That an extended (6 month) second transition period would not necessarily make the transition easier as patients tend to wait until the last month to switch whether it is a standard 3 month period or extended period.
- It may be necessary to enter into some post tender negotiations with any potential brand switch supplier to allow for a number (50-100) of patients who have particular difficulty switching from the Efexor XR brand to remain funded as part of an Alternative Brand Allowance clause. This could be effected using PHARMAC's existing 'wider discretion' individual patient consideration to assist a small number of patients in transitioning to any different brand over an additional 12 month period.
- Advice would be sought from the Mental Health Subcommittee with regard to implementation if the recommendation was a brand switch.
- A Brand Switch Fee was recommended.

8. Supplier Summary – Stock Issues in the last 12 months **– Noted**



- **Mylan**
  - Doxine (doxycycline)
  - imybe 10/40
  - rizatraptin
  - salbutamol (Respigen)
  - Isotane (Isotretinoin)
  - salbutamol (Respigen)
  - metronidazole (Trichazole)

MW gave an overview of the supplier histories of stock issues and BR added context to the severity of the stock issues. The Committee **Discussed** the matter and **Noted** the following:

- While Mylan has had a number of stock shortages recently, this is in the context of supplying a large number of pharmaceuticals (140+). Mylan is proactive and engaged with notifying and dealing with supply issues.

Stat Dispensing

The Committee **Discussed** the potential advantages of moving venlafaxine to stat dispensing and **Noted** the following:

- With the larger pack sizes offered (90 & 84) it may be appropriate to take this opportunity to switch dispensing to stat.
- It would be a benefit to patients both in terms of suitability and reduced transaction costs – such as travel.
- Overall saving to the Health Sector.
    - Savings to the Health Sector ~$500,000 per year from reduced dispensing fees.
    - Example of additional cost to PHARMAC CPB is based on Mylan 90s - $215,000 in 2018 then ~$165,000 per year. This is associated with some venlafaxine being dispensed stat that would otherwise not have been dispensed under monthly dispensings (from patients not picking up repeats)

Appendix One: Factors for Consideration

Evaluation Committee Recommendations
Venlafaxine Hydrochloride Extended Release – 37.5 mg, 75 mg, 150 mg

Selected Mylan New Zealand Limited's aggregated combined 90 capsule bid for its Enlafax XR brand of venlafaxine hydrochloride extended release as the best bid for the community and hospital markets;

noted that the key factors in selecting the tender from Mylan were:

- Mylan's bid offered the [redacted] savings over the proposed period of sole supply ending 30 June 2020 of [redacted]
- Mylan's Enlafax XR is a capsule presentation that would help when transitioning this patient group, most of whom are currently on a capsule presentation;
- the Committee was not aware of any outstanding supply issues that would prevent the award of the tender for venlafaxine hydrochloride extended release 37.5 mg, 75 mg, 150 mg to Mylan; and
- it was acceptable against all other criteria.

discussed Mylan's Enlafax XR capsules were similar in appearance to the incumbent Efexor XR capsules which would help when transitioning this patient group.

recommends undertaking post tender negotiations with Mylan to include the following, if there is no impact to the price per unit (capsule) or lead time:

- the addition of an Alternative Brand Allowance clause for 50-100 patients for a period of up to 12 months;
- a change in pack size to 84 capsules with the calendar pack foil – as this may help with transitioning patients.

recommends seeking specific clinical advice of the Mental Health Subcommittee of PTAC with regard to the implementation/brand switch and whether it has any concerns over moving to stat dispensing.

recommends moving to stat dispensing from the date of Sole Supply Status, unless the clinical feedback from the Subcommittee is opposed;

noted that the key factor for the stat dispensing recommendation was the overall saving to the Health Sector (DHBs).

Some Factors may be more or less relevant (or may not be relevant at all) depending on the type and nature of the decision being made and, therefore, judgement is always required. For further guidance on applying the Factors for Consideration, refer to A761407.

The need dimension

Need is about the disease, condition or illness. Within the 'need' dimension we consider the impact of the disease, condition or illness on the person, their family or whānau, wider society, and the broader New Zealand health system.

- The health need of the person
- The availability and suitability of existing medicines, medical devices and treatments
- The health need of others
- The impact on the Māori health areas of focus and Māori health outcomes
- The impact on the health outcomes of population groups experiencing health disparities
- The impact on Government health priorities

The Committee **Agreed** that these health needs would continue to be met should the recommendations be approved. The Committee **Noted** that if approved the 225 mg presentation would be removed but the dosage could quite easily be made up a couple of other ways (3x75 mg or 1x75 mg and 1x150 mg).

The health benefit dimension

Under this Factor, we will consider the health benefits (or harms) to the person receiving the medicine or medical device, the health benefits to their family, whānau and wider society, and the consequences for the broader health system.

- The health benefit to the person
- The health benefit to family, whānau and wider society
- Consequences for the health system

The Committee **Agreed** that these health benefits would be unchanged should the recommendations be approved.

The costs and savings dimension

This dimension focuses on the costs and savings that would result from a decision to fund the medicine or medical device. We consider the costs and savings to the person and their family, whānau and to wider society. The cost and savings to the health system covers both the cost and savings to the pharmaceutical budget and to the wider health system.

- Health-related costs and savings to the person

- Health-related costs and savings to the family, whānau and wider society
- Costs and savings to pharmaceutical expenditure
- Costs and savings to the rest of the health system

The Committee **Agreed** that there would be significant savings to the pharmaceutical expenditure and to the wider health system (namely DHBs) should the recommendations be approved.

The suitability dimension

This dimension considers the non-clinical features of a medicine or medical device that may still have an impact on health outcomes.

- The features of the medicine or medical device that impact on use by the person
- The features of the medicine or medical device that impact on use by family, whānau and wider society
- The features of the medicine or medical device that impact on use by the health workforce

The Committee **Agreed** that Mylan's bid was suitable and **noted** that should the recommendations be approved:

- Mylan's Enlafax XR is a capsule presentation that would help when transitioning this patient group, most of whom are currently on a capsule presentation;
- Mylan's Enlafax XR capsules were similar in appearance to the incumbent Efexor XR capsules which would help when transitioning this patient group; and
- Mylan's 90 (or 84) capsule pack size would benefit the large (>70%) chronic patient sub-group, as well as pharmacists when stat dispensing starts.

2. PHARMAC staff indicated in the RFT document that we may extend the second transition period to 6 months from the usual 3 month period. However our latest thinking is that a brand switch would be difficult regardless of the time period allowed for the second transition period and note that patients typically put off switching until the last possible moment either way. Do you believe that a 5 month transition period (2 months first transition period + 3 months second transition period as outlined below) is sufficient when combined with other implementation activities that PHARMAC would undertake? Note that each month of delay in the second transition period would equate to lost savings of approximately $500,000.

    - Listing Date 1 April 2017

      FIRST TRANSITION PERIOD – 2 Months
    - Reference Pricing Date 1 June 2017

      SECOND TRANSITION PERIOD – 3 Months
    - Sole Supply Date 1 September 2017

3. Do you have any concerns with regard to moving to stat (three months all at once) dispensing for venlafaxine? PHARMAC staff note that the majority of the currently listed SSRIs and all of the MAOIs are currently able to be dispensed under stat dispensing. In particular, would there be any safety concerns associated with stat dispensing of venlafaxine (ie any that would not apply to SSRIs or MAOIs)?

[redacted]

Many thanks for your help

Kind regards

Matt Wolfenden

Matthew Wolfenden BSc (Hons) | Procurement Manager

Hi Matt,
My answers:

1. No, I do not think that any additional advice will be necessary. [redacted]
2. I think that this should be done as quickly as possible. [redacted]
3. I support a change to 3 month dispensing of venlafaxine. With all medications there are safety concerns of overdose but these need to be managed by clinicians – as we do with many other agents.

[redacted]

Hello all

I agree [redacted]

Hi Matthew (et al)

I am in agreement with my colleagues. [redacted]

I think I understand what you mean by "stat" prescribing, but I would be keen to have this defined for my benefit.

My only thoughts with the transition period is that some patients will have only one appointment in a 3 month period - so if the prescriber misses that window to address the transition, the moment is lost. The key to help this would be strong pharmacy input to prime the medical discussion.

Venlafaxine is a more toxic drug in overdose than SSRIs, but as [redacted] points out, managing the risk of overdose is achieved by other clinical means.

[redacted]

[redacted]

Thank you for your response, please see clarification of “stat” dispensing below.

- Stat dispensing allows the patient to collect the full three month prescription all-at-once – without the need to go back to the pharmacy on a monthly basis – thus reducing the cost of dispensing fees on the Health Sector (DHBs) and reducing the transaction cost of travelling to the pharmacy for the patient.
- Stat dispensing is notified in the Pharmaceutical Schedule by an asterisk (*) next to the presentation.
- If the dispensing pharmacist believes the patient may benefit from monthly dispensing, then they should contact the prescriber to discuss. If the prescriber agrees that patient requires more frequent dispensing, then the prescription must be returned to the prescriber for the Close Control endorsement.

I hope that helps

Many thanks
Matt

Matthew Wolfenden BSc (Hons) | Procurement Manager

Agree [redacted]
[redacted]
My patients have transitioned years ago.
[redacted]

[redacted]

Hello

I concur with the others regarding generic venlafaxine a[redacted]
[redacted]

[redacted]
[redacted]
[redacted]
