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16 August 2018

Dear Supplier

REQUEST FOR TENDER – SUPPLY OF KNEE-LENGTH COMPRESSION HOSIERY AND DONNING AIDS TO DHB HOSPITALS, FOR THE TREATMENT AND PREVENTION OF VENOUS LEG ULCERS.

PHARMAC invites tenders for the supply of knee-length compression hosiery and donning aids (Compression Hosiery Products) to DHB Hospitals in New Zealand, for the treatment and prevention of venous leg ulcers.

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 Compression Hosiery Products for which you may submit a Tender Bid in relation to hospital supply and provides background information regarding 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 hospital supply;
- (d) Schedule 4 sets out terms that will apply if your Tender Bid in relation to hospital supply is awarded;
- (e) Schedule 5 sets out the additional terms that will apply if your Tender Bid in relation to hospital supply is awarded; and
- (f) Schedule 6 sets out any other special terms that will apply if your Tender Bid is submitted and accepted on the basis of such terms applying.

Please also note the addition of Schedule 6, which sets out any terms not generally found in PHARMAC's standard invitation to tender.

This RFT invites tenders for the supply of Medical Devices (which are defined within the scope of "pharmaceuticals" as defined in the New Zealand Public Health and Disability Act 2000) but only in a hospital supply setting.

If you wish to submit a Tender Bid in relation to hospital supply of Compression Hosiery Products, you must submit it to PHARMAC via the Government Electronic Tenders Service (GETS) no later than **4pm** on **11 September 2018** (New Zealand time).

If you have any queries about this RFT please submit these via GETS

We look forward to receiving your Tender Bid.

Yours sincerely

AN

Lisa Williams Director of Operations

Contents

Sch	edule 1: Definitions and interpretation4			
1.	Definitions4			
2.	Interpretation7			
Sch	edule 2: Products to be tendered8			
1.	Information about Tender Items8			
2.	List of Compression Hosiery Products in scope of RFT9			
3.	Background information10			
Sch	edule 3: Tender Process11			
1.	General11			
2.	Information about submitting a Tender Bid12			
3.	What to include in your Tender Submission Form12			
4.	How to submit a Tender Bid14			
5.	Evaluation15			
6.	Conformity16			
7.	Decision16			
8.	Dealing with information18			
9.	Miscellaneous			
Sch	edule 4: Contract terms for Hospital Supply20			
1.	General20			
2.	Crown Direction			
3.	Audit21			
4.	Miscellaneous			
Sch	Schedule 5: Additional contract terms for Hospital Supply			

4.	Emergency and disaster supply	28
5.	Defective and short-dated Pharmaceuticals	28
6.	Out-of-stock arrangements	29
7.	Termination and restrictions	32
8.	Guarantee	32
9.	Access by PHARMAC to price and volume data	32
Sch	edule 6: Special terms and conditions	33
Tend	der Submission Form	34

Schedule 1: Definitions and interpretation

1. Definitions

In this RFT:

Aggregated Tender Bid means a Tender Bid for more than one Tender Item, which PHARMAC is to consider in aggregate;

Agreement means:

- (a) Schedule Four;
- (b) Schedule Five; and
- (c) Schedule Six,

and includes, to the extent applicable, the other Schedules and the information on GETS comprising the RFT;

Alternative Pharmaceutical means an alternative brand of a Pharmaceutical that PHARMAC or the DHB Hospital considers to be an acceptable substitute for that Pharmaceutical;

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 Tender Items must have WAND registration, have any applicable international compliance certificates and meet Medical Compression Hosiery Quality Assurance RAL-GZ 387/1 (January 2008 edition);

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

Deadline means 4 PM on 11 September 2018 (New Zealand time);

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

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

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

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

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

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 <u>https://www.gets.govt.nz/ExternalIndex.htm</u> through which you are required to submit your Tender Bid(s);

GTIN means the Global Trade Item Number for a Pharmaceutical;

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 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 2.1 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;

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

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

Pharmaceutical means the relevant Tender Item for which you have submitted, and PHARMAC has accepted on behalf of the Funder, a Tender Bid;

Potential Out-of-Stock Event means:

- (a) 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
- (b) forecast sales demand in respect of the next two-month period is greater than your stock of the Pharmaceutical; or
- (c) 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
- (d) your stock of the Pharmaceutical in New Zealand is insufficient to enable you to fully fill all orders as they are received (without restricting quantities that may be ordered); or
- (e) in relation to New Zealand manufactured products if either:
 - (i) forecast sales demand in respect of the next two-month period is greater than your stock of the Pharmaceutical; or
 - (ii) you have insufficient stock to enable you to fully fill all orders as they are received; or

(iii) your stock of the active pharmaceutical ingredient taking into account manufacturing and stock on hand falls below two months stock for the Pharmaceutical in New Zealand.

For the avoidance of doubt, references to 'your stock' in (a) to (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 in relation to hospital supply, at a DHB Hospital's discretion, any Designated Delivery Points, 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;

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;

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

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 1.2 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;

Tender Item means the Medical Device 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, attached to this RFT as Appendix A and available on GETS;

Unit means an individual unit of a Tender Item; and

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).

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 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).

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 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.

1.3 **Pack size for use by DHB Hospitals**

In pairs for off-the-shelf compression hosiery or as single Tender Items for made-to-measure compression hosiery.

2. List of Compression Hosiery Products in scope of RFT

Tender Item	Presentation
Knee length Compression Hosiery (standard off- he-shelf product)	Circular knit weave
	Flat knit weave
	With or without grip tops
	Pressure classes I, II, III and IV
	Range of sizes, leg length, foot lengths etc
	Open/closed toe
	Range of colours
nee length Compression Hosiery (made-to- easure)	Circular knit weave
	Flat knit weave
	With or without grip tops
	Pressure classes I, II, III and IV
	Range of colours
	Sizes – made-to-measure for leg & foot length, circumference etc
Donning aids	Range of stocking donning aids

All Tender Items supplied must comply with an internationally approved standard for compression hosiery, for example but not limited to RAL-GZ 387/1 (January 2008 edition).

Compression hosiery would be proposed to be listed with the following restrictions:

- Initiation by a vascular surgeon, vascular nurse, outpatient clinic nurse or district health nurse;
- Patient has or is at risk of venous leg ulcers (VLU); and
- 3 pairs will be funded per year ongoing (for the duration of treatment) with option for another 3 pairs in first year if comfort is impacting on adherence.

Donning aids would be proposed to be listed with the following rules:

- Initiation by a vascular surgeon, vascular nurse, outpatient clinic nurse or district health nurse;
- Patient has or is at risk of VLU; and
- A maximum of 1 donning aid funded per patient and no more than 1 per treatment duration unless current donning aid no longer suitable.

Tender Items considered out of scope of this RFT for Compression Hosiery Products:

- Anti-embolism hosiery;
- Upper thigh length compression hosiery;
- Compression arm and hand wear;

- Light weight compression stockings and support stockings;
- Lymphedema hosiery garments;
- Liners;
- Non-medical support hosiery;
- Compression bandages / wraps;
- Ulcer Kits;
- Ulcer wound dressings, creams;
- Adjustable Velcro Devices;
- Sequential Continuous Contraction Devices;
- VTE prevention therapy; and
- Negative Pressure Wound Therapy and accessories.

3. Background information

PHARMAC is the New Zealand government agency that decides which pharmaceuticals to publicly fund in order to get the best health outcomes from within available funding. All funded products that are subsidised by the Government are listed in the Pharmaceutical Schedule. Schedule H, Part II, of the Pharmaceutical Schedule lists pharmaceuticals that must be made available in DHB Hospitals.

This is the first time that PHARMAC has issued an RFT to consider the funding of Compression Hosiery Products. The purpose of issuing this RFT is to seek tenders for the listing of Compression Hosiery Products in Part II of Section H of the Pharmaceutical Schedule so that all patients with VLU would have equitable access to funded Compression Hosiery Products for the treatment and prevention of VLU.

PHARMAC recognises that the use of the Tender Items touches a wide group of health professionals; therefore, in the event an Agreement is entered into with a supplier, as an outcome of this RFT process, and the Tender Items are listed in Part II of Section H of the Pharmaceutical Schedule:

- (i) the listing shall be non-exclusive and will include pricing details of the Tender Items;
- (ii) DHB Hospitals will be required to procure the Tender Items from a contracted supplier under the terms of the Agreement;
- (iii) it is anticipated that multiple suppliers of the Tender Items will be listed, where appropriate; and
- (iv) any resultant Agreement will be between the suppliers and PHARMAC. DHBs will be able to procure under the Agreement, effective from the Start Date, and will not be required to individually approve the Agreement for it to come into effect.

Schedule 3: Tender Process

1. General

1.1 Contract

If PHARMAC accepts your 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 1.2 of this Schedule); and
- (ii) Schedule Four; and
- (iii) Schedule Five; and
- (iv) Schedule Six (as applicable),

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

For the avoidance of doubt, the terms and conditions specified in Schedule Four, Schedule Five and Schedule Six, as applicable, apply from the date when PHARMAC notifies you in accordance with clause 7.2 of this Schedule of its acceptance of your Tender Bid.

1.2 **PHARMAC** may initiate limited negotiations

- (a) Notwithstanding clause 2.2 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) your ability to ensure continued availability of the Tender Item;
 - (iii) the Lead Time and/or the Start Date; or
 - (iv) 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.
- (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.

1.3 **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

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(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 Individual Tender Bids

You may submit more than one Tender Bid for a Tender Item.

2.2 **No conditions**

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

2.3 Separate offers

PHARMAC will treat each Tender Bid as a separate offer.

2.4 **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.

2.5 **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 and Attachment 1 (Compression Hosiery Product Details Spreadsheet)

(a) You must submit your Tender Bid using GETS and attach a completed Compression Hosiery Tender Submission Form.

Electronic versions of the Tender Submission Form are available on GETS and on PHARMAC's website at <u>www.pharmac.health.nz</u>. A copy of the Tender Submission Form is attached to this RFT as Appendix A.

(b) You must submit details of all types and sizes of your Compression Hosiery Products by completing Attachment 1 Compression Hosiery Product Details.

Electronic version of Attachment 1 Compression Hosiery Product Details spreadsheet is available on GETS and on PHARMAC's website at, <u>www.pharmac.health.nz</u>).

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) comprehensive description of your clinician education and training resources;
- (d) comprehensive description of your patient education resources;
- (e) your current supply arrangements, and proposed distribution and supply arrangements for your Compression Hosiery Products, including but not limited to:
 - (i) your status as to whether you are a manufacturer or distributor of the Compression Hosiery Products;
 - (ii) the terms of any distribution agreement, if you are not the manufacturer, for example the duration and exclusivity of the distribution agreement; and
 - (iii) information regarding freight or delivery cost to DHBs;
- (f) Lead Time for the supply of each of the Tender Item offered, including made-to-measure hosiery; and
- (g) Price in \$NZ (exclusive of GST) for Tender Items (please insert pricing as per format in Attachment 1 Compression Hosiery Product Details).

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 Items:

- evidence of meeting International Compliance Standards (copies of certificates must be supplied). Please insert relevant CE/TGA numbers as per format in Attachment 1 Spreadsheet Compression Hosiery Product Details;
- (b) as all Tender Items (as applicable) must be WAND registered, WAND registration numbers must be provided, <u>do not</u> provide copies of WAND documents (please insert WAND as per format in Attachment 1 spreadsheet Compression Hosiery Product Details);
- (c) latex status (indicate if Tender Items contain latex or are latex free, as per format in Attachment 1);
- (d) warranty periods (if applicable) please insert as per format in Attachment 1;
- (e) total volumes and sale revenues for Compression Hosiery Products to:

(i) DHB Hospitals; and

- (ii) New Zealand private market (public sales);
- (f) confirmation that the Tender Item(s) that you are submitting in respect of Compression Hosiery Products meet the relevant standards and/or regulatory requirements for its intended use and what those standards and/or regulatory requirements are (please insert as per format in Attachment 1 Compression Hosiery Product Details);
- (g) for any Pharmaceutical that does not require Consent from Medsafe, evidence and justification as to why Consent from Medsafe is not required for the Tender Item(s);
- (h) the Lead Time for supply of the Tender Item;

- (i) 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) alternative manufacturers of the finished product; and
- (j) your proposed distribution and supply arrangements for the Tender Item.

3.4 Information that may be supplied about the Tender Item

In your Tender Submission Form, for any Tender Item, you may supply information about the markets in which you currently provide the Tender Item.

3.5 **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; and
 - (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 1.2 of this Schedule.
- (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 (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 in applying the Factors by the Evaluation Committee will include, in particular:

- (a) your ability to ensure continued availability of the Tender Item, 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, previous supply performance;
 - (iv) your quality assurance processes, where applicable;
 - (v) your clinician education and training resources;
 - (vi) your patient education resources;
 - (vii) other markets in which you currently supply the Tender Items (if applicable);
 - (viii) your proposed distribution and supply arrangements for the Tender Item; and
 - (ix) the Lead Time for supply of the Tender Item;
- (b) the price of the Tender Item; and
- (c) 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, provided that in PHARMAC's judgment this would not be unfair to you in comparison to any other party. A Tender Bid will conform if it:
 - (i) is submitted via GETS by the Deadline;
 - (ii) is submitted on the Tender Submission Form attached;
 - (iii) Attachment 1 Compression Hosiery Product Details is fully completed
 - (iv) has no conditions or qualifications attached;
 - (v) includes all information required under clauses 3.2 and 3.3 of this Schedule; and
 - (vi) otherwise complies, both as to form and substance, with the requirements of this RFT.
- (b) PHARMAC may, in its sole discretion, provided that in PHARMAC's judgment this would not be unfair to you in comparison to any other party:
 - (i) exclude any non-conforming Tender Bid from consideration; or
 - (ii) consider, and accept, any non-conforming Tender Bid.

7. Decision

7.1 Decision on acceptance of Tender Bid

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

7.2 Notification of acceptance

(a) Once PHARMAC's Board of Directors (or its delegate, where applicable) has decided under clause 7.1 above which Tender Bid (if any) to accept for a Tender Item, PHARMAC will, within a reasonable period of time, notify the successful tenderer in writing that it has been successful and in addition:

- (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 Bid becoming unconditionally accepted, notify each unsuccessful tenderer in writing of the identity of the successful tenderer.
- (b) If for any reason you do not receive written notification from PHARMAC in accordance with paragraph (a) above, you will be deemed to have received the required notification on the date that each Tender Item you bid for is notified in the Pharmaceutical Schedule.

7.3 **PHARMAC's rights reserved**

- (a) PHARMAC reserves the right to accept or reject any Tender Bid and, other than to the extent necessary to debrief an unsuccessful tenderer, is not obliged to give reasons for its decision.
- (b) 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) 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.
- (b) Notwithstanding any other provision in this RFT, the contract referred to in clause 1.1 of this Schedule will be conditional upon:
 - 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).
- (c) 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 (b) above, PHARMAC may initiate negotiations with any other supplier(s).

8. Dealing with information

8.1 **Confidentiality**

Subject to clause 8.2 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.

8.2 **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.

9. Miscellaneous

9.1 **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.

9.2 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.

9.3 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.

9.4 **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.

9.5 **No lobbying**

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

9.6 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.

9.7 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 Hospital Supply

1. General

1.1 **Operating Policies and Procedures**

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

1.2 Amendments to Pharmaceutical Schedule

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

1.3 **Product identification codes**

You agree to obtain and notify PHARMAC by submitting a notification of product changes form of the GTIN (if the product already has one) or supplier product code for the Pharmaceutical and in any event no later than the earlier of:

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

1.4 Stock Reporting

You shall provide PHARMAC with reports on stock levels for the Pharmaceuticals upon PHARMAC's request.

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 supply of the Pharmaceuticals, if the termination, amendment or imposition of restrictions is required to give effect to a Crown Direction.
- (c) In the event that a Crown Direction is issued to PHARMAC that requires an amendment to be made to this Agreement to give effect to that direction:
 - PHARMAC will give you as much notice as practicable of the Crown Direction and of any amendments to this Agreement that are required to give effect to that direction;
 - (ii) the Agreement will be deemed to be amended so as to give effect to the Crown Direction from the date when such direction is due to take effect; and
 - (iii) you may terminate this Agreement on not less than six months' written notice to PHARMAC where the effect of the amendment required under sub-paragraph (ii) above is such that it is no longer viable, financially or otherwise, for you to continue supplying the Pharmaceutical or to perform your obligations under this Agreement.

3. Audit

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

- (iii) PHARMAC will give you 10 business days' notice of its intention to conduct an audit under this clause and will ensure that the conduct of any such audit, and access in terms of sub-paragraph (A) above, does not unreasonably disrupt your business operations.
- (b) PHARMAC will notify you in writing if an audit under this clause reveals any noncompliance with this Agreement. You agree to remedy any non-compliance within 10 business days of receiving such notice from PHARMAC or such other period as agreed with PHARMAC.

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 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 DHB 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 Contract and Commercial Law Act 2017, Part 2, Subpart 1, 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 Hospital Supply

1. Consents

1.1 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 Contract and Commercial Law Act 2017, Part 2, Subpart 1.

1.2 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) reviewing the terms of listing of that Pharmaceutical; and
 - (ii) determining whether, and the extent to which, DHB Hospitals may purchase the CMN Pharmaceutical.

2. Price

2.1 **Price change**

- (a) Subject to clause 2.1(b)(ii), clause 2.1(b)(iii) and clause 2.1(b)(iv) 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, 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 prior to the Start Date, 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 prior to the Start Date:
 - (i) you must ensure that wholesalers and other such distributors change the price at which they supply the Pharmaceutical to the Price on the 12th day of the month prior to the Start Date, and you shall provide price support to wholesalers and other such distributors for a maximum 4 weeks stock on hand (or such other level of stock as agreed between you and PHARMAC) of the Pharmaceutical held at

wholesalers and other such distributors, provided that such wholesalers and other such distributors can provide you with stock on hand reports upon request; or

- (ii) your brand of the Pharmaceutical must be available for supply and you must supply the Pharmaceutical, at the Price from the 1st day of the month prior to the Start Date, and the Pharmaceutical will be subsidised at the Price from the Start Date which is conditional upon you having at least 2 months Lead Time for the Pharmaceutical; and
- (iii) notwithstanding clauses 2.1(b)(i) or (b)(ii) above, if the Price would result in a price increase for your brand of the Pharmaceutical you must supply the Pharmaceutical at the Price from the 22nd day of the month prior to the Start Date, and the Pharmaceutical will be subsidised at the Price from the Start Date; and
- (iv) notwithstanding clauses 2.1(b)(i), (b)(ii) or (b)(iii) above, PHARMAC may agree a process with you, that results in your brand of the Pharmaceutical, that has a rebate, being available for supply and you must supply the Pharmaceutical, at the Price from the 22nd day of the month prior to the Start Date, and you shall provide price support to wholesalers and other such distributors for a maximum 4 weeks stock on hand (or such other level of stock as agreed between you and PHARMAC) of the Pharmaceutical held at wholesalers and other such distributors, provided that such wholesalers and other such distributors can provide you with stock on hand reports upon request.

For the avoidance of doubt if you do not notify PHARMAC in your Tender Bid in the electronic portal which of the options stated in clauses 2.1(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 2.1(b)(i) to b(iv) 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.

2.2 Supply price

Subject to clause 2.1 of this Schedule, the price at which the Pharmaceutical is supplied by you to, at a DHB Hospital's discretion, any Designated Delivery Points must not exceed the Price.

2.3 **Supply at lower price**

Notwithstanding clauses 2.1 and 2.2 above but subject to clause 2.4 below, you may supply the Pharmaceutical to, at a DHB Hospital's discretion, any Designated Delivery Points 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.

2.4 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).

2.5 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.

3. Invoicing and Payment

3.1 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 Hospital's purchase order reference number (if applicable);
- (c) the net amount payable in respect of the Pharmaceutical supplied to that DHB Hospital in accordance with this Agreement;
- (d) full details in respect of the Pharmaceutical supplied to that DHB Hospital 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;
 - (v) total cost for the total amount of the Pharmaceutical supplied; and
- (e) any other information that DHB Hospital requires you to supply.
- (f) The provisions of this clause 3.1 do not apply to the extent that both parties have agreed to alternative or varied invoicing arrangements in respect of a particular Pharmaceutical.

3.2 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 3.1 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 3.1 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.

3.3 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.

3.4 **Contracts Privity**

This clause 3 confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contract and Commercial Law Act 2017, Part 2, Subpart 1.

4. Emergency and disaster supply

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

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

5. Defective and short-dated Pharmaceuticals

5.1 **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 Contract and Commercial Law Act 2017, Part 2, Subpart 1.

5.2 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 Contract and Commercial Law Act 2017, Part 2, Subpart 1.

6. **Out-of-stock arrangements**

6.1 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.
- (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, 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.

6.2 **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 1 of this Schedule;
- (d) any failure to notify PHARMAC in accordance with clause 6.1 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 6.3; and
- (g) confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contract and Commercial Law Act 2017, Part 2, Subpart 1.

6.3 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 6.1 of this Schedule, then without prejudice to PHARMAC's and the relevant DHB Hospitals' rights under clause 6.2 above, but subject to paragraph (d) 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 6.1 of this Schedule, then without prejudice to PHARMAC's and the relevant DHB Hospitals' rights under clause 6.2 above you are not liable to pay any liquidated damages under this clause 6.3.
- (b) If, having notified PHARMAC and the relevant DHB Hospitals under clause 6.1 of this Schedule, you remain able to, and you continue to, supply the Pharmaceutical, or an Alternative Pharmaceutical in accordance with clause 6.1(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:
 - 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) All amounts referred to in this clause are plus GST.

6.4 **Failure to supply**

References in this clause 6 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 5.2(a)(i) or (ii) of this Schedule applies and no agreement has been reached with the relevant DHB Hospital in terms of clause 5.2(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.

6.5 **Default interest and recovery costs**

If payment of any amount required to be paid by you under this clause 6 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.

7. Termination and restrictions

7.1 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 terminate this Agreement if the medical adviser determines for clinical reasons that it is no longer appropriate to have the Pharmaceutical listed on the Pharmaceutical Schedule.

7.2 Termination following an audit

PHARMAC may terminate the Agreement if you fail to remedy any area of non-compliance in accordance with clause 3(b) of Schedule Four.

8. 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 6.2 and 6.3 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.
- (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.

9. 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 8.1 and 8.2 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.

Schedule 6: Special terms and conditions

Not Applicable

Tender Submission Form

An electronic version of this form is available on GETS. You should expand the boxes as necessary.

<Tenderer to Insert Date>

Director of Operations PHARMAC

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

Dear Sir/Madam

Tender Bid for the supply of Knee Length Compression Hosiery and Donning Aids to DHB Hospitals - commercial in confidence

In response to your request for tenders (**RFT**) dated 16 August 2018, we put forward the following Tender Bid in respect of Compression Hosiery Products.

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	
Physical Address	
Phone	
Facsimile	
Email address	

(b) Information about our company structure:

(c)

Information about our management and technical skills:

Appendix A

(d) Information about our clinician education and training resources:

(e) Information about our patient education resources:

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

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

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

(i) Tender Items must be WAND registered (as applicable): please insert relevant WAND numbers as per format in Attachment 1 spreadsheet Compression Hosiery Product Details:

(j) Evidence that your Tender Items meet International Compliance Standards (copies of CE/TGA certificates must be supplied) please insert relevant CE/TGA numbers as per format in Attachment 1 spreadsheet Compression Hosiery Product Details):

Appendix A

(k) Please specify lead time for all off-the-shelf and made-to-measure Compression Hosiery Products:

(I)

Key features of our Tender Bid:

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

(n) Any additional information that PHARMAC should consider when evaluating your Tender Bid:

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

<Insert name> <Insert designation Appendix A