

21 July 2022

Dear Supplier

**INVITATION TO TENDER – SUPPLY OF PHARMACEUTICALS TO TE WHATU ORA HOSPITALS AND/OR TO COMMUNITY PHARMACIES**

Pharmac invites tenders for the supply of certain pharmaceuticals to Te Whatu Ora hospitals and/or to community pharmacies in New Zealand.

This invitation to tender incorporates the following schedules:

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

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

If you wish to submit a Tender Bid in relation to community supply and/or hospital supply, you must submit it via the Electronic Portal to Pharmac no later than **4 pm** (New Zealand time) on **Thursday, 15 December 2022**.

If you have any enquiries about this invitation you should contact the **Tender Analysts** at [tender@pharmac.govt.nz](mailto:tender@pharmac.govt.nz).

We look forward to receiving your tender.

Yours sincerely,

Director of Operations

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## Schedule 1: Definitions and interpretation

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### 1. Definitions

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In this Invitation:

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

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

**Advertisement** means any advertisement as defined in the Medicines Act 1981;

**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 Schedule Four and includes, to the extent applicable, the other Schedules (including Schedule Five) and the information on the Electronic Portal comprising the Invitation;

**Alternative Brand Allowance** means the alternative brand allowance relating to a particular Tender Item, in relation to hospital and/or community supply, as indicated as a percentage amount of the Total Pharmaceutical Volume, in the column entitled “ABA Limit” in the list of products included in Schedule Two;

**Alternative Pharmaceutical** means an alternative Pharmaceutical that Pharmac has expressly agreed in writing constitutes 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 Principal Supply Status in respect of a particular Tender Item, to cover the contingency that Principal 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;

**Brand Allowance Indicator** means the actual percentage of Brand Allowance Pharmaceuticals subsidised in the community and/or purchased by Te Whatu Ora Hospitals relative to the Total Pharmaceutical Volume in a Relevant Period;

**Brand Allowance Pharmaceuticals** means an alternative supplier's brand of the Pharmaceutical. For the avoidance of doubt, a Brand Allowance Pharmaceutical shall not be interpreted to be an Alternative Pharmaceutical for the purposes of the Agreement;

**Brand Compensation** means the compensation payable to you in accordance with clause 3.3 of Schedule 4;

**Brand Differential** means the difference between the Brand Allowance Indicator and the Alternative Brand Allowance;

**Business Day** means a day of the week, excluding Saturday, Sunday, and national public holidays in New Zealand. A Business Day starts at 8.30am and ends at 5pm;

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

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

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

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

- (a) information regarding the Pharmaceutical that does not identify you, or that cannot reasonably be expected to identify you, and you agree that such information is not Confidential Information and that Pharmac may use and publish such information; and
- (b) information released by Pharmac in accordance with clause 9 of Schedule Three of this Invitation, and you agree that such information ceases to be Confidential Information and that Pharmac may release that information again at any time in future without consulting with you or obtaining your prior agreement;

**Consent** means registrations, consents, permits, licences and authorisations, whether statutory or otherwise;

**Crown Direction** means any direction given to Pharmac under statutory authority;

**Data Sheet** means the Pharmaceutical data sheet published by Medsafe on your behalf;

**Deadline** means 4 pm, Thursday 15 December 2022 (New Zealand time);

**Default Interest Rate** means the base rate of ASB Bank Limited plus 5% per annum;

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

**Eligible Volume** means the Volume Multiplier multiplied by the Brand Differential, being a volume of Pharmaceuticals eligible for Brand Compensation in Units of that Tender Item;

**End Date** means the last day of the Principal Supply Period;

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

**Final Transition Period** means, in respect of a Pharmaceutical with Principal Supply Status, 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 Principal Supply Status, the period beginning on the first day of the month following the Market Notification Date and ending on the day prior to five months from the Start Date (or such different or longer period as Pharmac determines under clause 1.2 of Schedule Three);

**Force Majeure Event** means any cause preventing the affected party from performing any or all of its obligations under this Agreement which arises from or is attributable to acts, events, omissions or accidents beyond the reasonable control of the affected party, which:

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- (a) was not reasonably foreseeable;
- (b) could not have been avoided or mitigated through the exercise of good industry practice and due care, skill and diligence; and
- (c) was not caused by the affected party, its affiliates, officers, Personnel or suppliers,

but does not include any lack of finance or financial means or any changes in market conditions;

**Hospital Tender Bid** means a Tender Bid in relation to hospital supply;

**In-Use Shelf-Life** means the length of time that the Pharmaceutical has been demonstrated to stay effective and safe to use after the packaging of the original container is opened and stored under defined conditions;

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

**Lead Time** means the number of months (being whole months only) indicated on your Tender Bid that, if your Tender Bid is accepted, you would require following the Successful Tenderer Notification Date in order to source sufficient stock of your brand of the Tender Item to meet the entire market demand for the Tender Item as at the Start Date. For the avoidance of doubt, the Lead Time does not affect, and should incorporate the extra time needed to allow for, your obligations in clause 2.3 of Schedule Four;

**Market Approval** means regulatory approval for sale and marketing in New Zealand;

**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;

**Medsafe** means the business unit within the Ministry of Health that has responsibilities in relation to the safety of medicines and medical devices used and supplied in New Zealand;

**New Zealand Government's Supplier Code of Conduct** means the New Zealand Government's supplier code of conduct (as updated from time to time);

**Offer Letter** means the letter of offer which must be submitted with the Tender Submission Form, in the form set out in the Electronic Portal;

**OPPs** means Pharmac's Operating Policies and Procedures (as updated from time to time);

**PCT** means a Pharmaceutical for which Te Whatu Ora Hospitals are eligible to claim a subsidy through the Pharmaceutical Schedule. Tender Items that are PCTs are indicated with "PCT" in the list in clause 2 of Schedule Two and the Electronic Portal;

**Personnel** means all individuals engaged by the relevant party, including the parties' employees, contractors, representatives, legal advisors, clinical advisors and other consultants;

**Pharmaceutical** means the relevant Tender Item (which may be a Medical Device) for which you have submitted, and Pharmac has accepted, a Tender Bid;

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**Pharmaceutical Schedule** means the schedule listing all the medicines and medical devices funded for New Zealanders (as updated from time to time);

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

- (a) in relation to community supply, wholesalers and other such distributors, and at which the Pharmaceutical is to be subsidised, being the price specified in your successful Tender Submission Form, unless there has been a subsequent price change in accordance with the terms of the Invitation, in which case the Price will be the price notified to you by Pharmac upon acceptance of your Tender Bid; or
- (b) in relation to hospital supply, Te Whatu Ora Hospitals, wholesalers and other such distributors, being the price specified in your successful Tender Submission Form, unless there has been a subsequent price change in accordance with the terms of the Invitation, in which case the Price will be the price notified to you by Pharmac upon acceptance of your Tender Bid;

**Principal Supplier** means a supplier which has had a Tender Bid accepted for a Tender Item in relation to community and/or hospital supply, being the principal supplier of the relevant Tender Item (subject to the Alternative Brand Allowance provisions);

**Principal Supply Period** means the period beginning on the day after the expiry of the First Transition Period and ending on 30 June 2026;

**Principal Supply Status** means the status of being the Principal Supplier for community and/or hospital supply of a Pharmaceutical for the Principal Supply Period;

**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;

**Relevant Period** means the periods:

- (a) beginning on the day after the expiry of the First Transition Period and ending on 30 June 2024;
- (b) 1 July 2024 until 30 June 2025; and
- (c) 1 July 2023 until 30 June 2026.

**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 Te Whatu Ora Hospitals;

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**Shelf-Life** means the length of time that the Pharmaceutical has been demonstrated to stay effective and safe to use when packaged in the original container and stored under defined conditions;

**Special Authority (or SA)** means a designation in relation to a Pharmaceutical which means that the Pharmaceutical is only eligible for subsidy or additional subsidy on approval of an application for a named person which meets the criteria specified in the Pharmaceutical Schedule;

**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;

**Supply Issue** means an event which may result, or has resulted, in a failure to supply the Pharmaceutical in accordance with this Agreement, including but not limited to:

- (a) your stock of the Pharmaceutical held by you in New Zealand falls below the minimum stock holding recorded in clause 5.1 of Schedule Four;
- (b) you recall (or have reason to believe you may recall), or are (or have reason to believe you may be) required by Medsafe or any other authorities to recall, the Pharmaceutical;
- (c) any Consent or Market Approval, required in accordance with clause 6.2 of Schedule Four is withdrawn, revoked, suspended or withheld;
- (d) you become aware of any issue that may impact on your ability to fulfil any orders for the Pharmaceutical;
- (e) you plan to withdraw the Pharmaceutical from supply; and/or
- (f) you fail to supply (or have reason to believe you may fail to supply) the Pharmaceutical from the Start Date;

**Supply Issues Report** means a report provided by you to Pharmac in accordance with clause 4.2 of Schedule Four of this Agreement;

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**Te Whatu Ora Hospital** means Te Whatu Ora, including its hospital or associated provider unit for which Te Whatu Ora purchases pharmaceuticals;

**Te Whatu Ora** means Health New Zealand, a Crown agent established under section 11 of the Pae Ora (Healthy Futures) Act 2022;

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

**Tender Item** means:

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

**Tender Submission Form** means the electronic form in which you must enter and submit your bid(s) for each Tender Item, as set out in the Electronic Portal;

**Total Brand Allowance Pharmaceutical Volume** means the total volume of Brand Allowance Pharmaceuticals subsidised in the community and/or purchased by Te Whatu Ora Hospitals in a Relevant Period, specified in Units of that Tender Item;

**Total Pharmaceutical Volume** means the total volume of the Pharmaceutical (inclusive of Brand Allowance Pharmaceuticals) subsidised in the community and/or purchased by Te Whatu Ora Hospitals in a Relevant Period, specified in Units of that Tender Item;

**Transition Periods** collectively refers to the First Transition Period and the Final Transition Period;

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

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

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

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



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**Unique Product Identifiers** means for each Pharmaceutical:

- (a) the 'CTPP', which is the Containered Trade Product Pack SNOMED CT code, which is the unique identifier that describes the packaged, branded product and the container it is dispensed in, as used within the New Zealand Medicines Terminology;
- (b) the 'GTIN' (if available), which is the Global Trade Item Number for a Pharmaceutical;
- (c) the 'Pharmacode', which is the unique identifier assigned to a Pharmaceutical and notified to you by the Pharmacy Guild; and
- (d) the 'Supplier Code', which is the unique product identifier assigned by you to the Pharmaceutical, if applicable; and

**Volume Multiplier** means the Total Pharmaceutical Volume divided by one hundred (100) (which shall equate to 1% of the Total Pharmaceutical Volume), specified in Units of that Tender Item.

## 2. Interpretation

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

- (a) references to "Te Whatu Ora" encompass Te Whatu Ora Hospitals;
- (b) references to "Te Whatu Ora Hospitals" may reflect that certain operational matters can in practice occur at a local hospital level notwithstanding that Te Whatu Ora Hospitals are part of, and not separate legal entities from, Te Whatu Ora;
- (c) references to clauses are to clauses in this Invitation;
- (d) the headings to clauses will be ignored in construing this Invitation;
- (e) the plural includes the singular and vice versa;
- (f) any organisations (including government agencies) referenced in this Invitation include their successors;
- (g) a reference to any statute includes that statute, and regulations made under it, as amended from time to time;
- (h) a reference to any statute includes any statute passed in substitution for that statute;
- (i) an obligation not to do anything includes an obligation not to suffer, permit or cause that thing to be done;
- (j) derivatives of any defined word or term have a corresponding meaning;
- (k) all references to dollars are references to New Zealand dollars unless provided otherwise;
- (l) "including" and similar words do not imply any limitation;
- (m) references to "**you**" include any third parties acting on your behalf, including sub-contractors;

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- (n) references to the “**listing**” of a Pharmaceutical are to the listing of that Pharmaceutical on the Pharmaceutical Schedule (and references to “list”, “listed”, “delist”, “delisted”, and “delisting” are to be interpreted accordingly); and
- (o) none of the terms are to be construed against a party by reason of the fact that that term was first proposed or was drafted by that party.

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## Schedule 2: Products to be tendered

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### 1. Information about Tender Items

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#### 1.1 List of Tender Items

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

#### 1.2 Patents

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

#### 1.3 Unit Volume and market value figures

- (a) Except where indicated otherwise, the Unit Volume figures, in relation to community supply, are based on actual volumes for the year ending 30 June 2022.
- (b) Market value figures, in relation to community supply, are expressed as the Unit Volume in the year ending 30 June 2022, multiplied by the Unit Subsidy as at 1 July 2022.
- (c) The figures referred to in paragraphs (a) and (b):
  - (i) are approximate and indicative only. Pharmac makes no representation as to the accuracy of these figures or as to the level of sales or likely sales of any Tender Item. In particular, if these figures change at any time during the period from Pharmac's pre-tender consultation until decisions have been made about the acceptance of Tender Bids for all Tender Items, Pharmac is not obliged to notify you of any such change; and
  - (ii) unless specified by Pharmac do not include Te Whatu Ora Hospital volumes. For the avoidance of doubt, Pharmac makes no representation as to the size of the Te Whatu Ora Hospital market for any Tender Item, in relation to hospital supply.
- (d) You acknowledge and agree that in submitting your Tender Bid you will rely on your own knowledge, skill and independent advice or assessment of the market size for any Tender Item and Pharmac is to have no liability in that regard.

#### 1.4 Special terms

Where there are any special terms relating to a particular Tender Item, those terms are indicated in the column entitled "Comments" in the list and/or Schedule Five. Special Authority restrictions have been noted for Tender Items where applicable in the list. Further restrictions on the supply

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of Tender Items within the Pharmaceutical Schedule may apply. You acknowledge and agree that in submitting your Tender Bid you will rely on your own knowledge and assessment of any restrictions applicable to a Tender Item within the Pharmaceutical Schedule.

### 1.5 Subsidies

- (a) The level at which each Tender Item, in relation to community supply, is specified in the attached list as being subsidised per Unit as at 1 July 2022.
- (b) Subsidies of Tender Items, in relation to community supply, may change before a Tender Bid is accepted.
- (c) Where a “\*” symbol is indicated next to the Unit Subsidy in the attached list, there is no fully funded product available, in relation to community supply, for that Tender Item as at 1 July 2022.

### 1.6 Alternative Brand Allowance

The Alternative Brand Allowance relating to a particular Tender Item, in relation to hospital and/or community supply, is indicated as a percentage amount in the column entitled “ABA Limit” in the attached list and is also shown in the Electronic Portal.

### 1.7 Tender Items subject to sole supply or principal supply arrangements

Where a Tender Item is underlined in the list of products below, that item is subject to a sole supply or principal supply contract as at the date of this Invitation. Accordingly, the subsidy for those items is fixed until 30 June 2023 (unless otherwise indicated) and, for items that are the subject of a sole supply contract or principal supply contract, the listing of a new brand, in relation to community supply, could only occur after that date. This information is not available in the Electronic Portal.

### 1.8 Hospital only products

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

### 1.9 Community only Products

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

### 1.10 Community and Hospital Products

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

### 1.11 PCTs

Where a “PCT” is indicated, you may submit a Tender Bid for Principal Supply Status for hospital supply 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 6.6 of Schedule Four. This information is also shown in the Electronic Portal.

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Where a Tender Item is indicated as being a “PCT” product, and is in a form intended to be compounded, it is the preference of Pharmac that products have post-compounding stability data greater than 48 hours.

### 1.12 Capsule and tablet form

Unless otherwise stated, where a Tender Item specifies either:

- (a) a capsule; or
- (b) a tablet,

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

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

### 1.13 Pack size preference

Where a Tender Item is specified as being available for a Tender Bid for Principal Supply Status for community supply, it is the preference of Pharmac that the pack size for such a Tender Item is:

- (a) 30 or 90 day pack where the Tender Item is in a tablet or capsule form; or
- (b) specified in the comments column in the attached list.

Notwithstanding the preference of Pharmac for Tender Items to be in pack sizes as specified 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. For the avoidance of doubt, in the event of any conflict between the pack size preference in the comments column in the attached list and the pack size preference in this clause 1.13, the pack size preference in the comments column in the attached list will prevail.

### 1.14 Pack size for use in Te Whatu Ora Hospitals

Where a Tender Item is specified as being available for a Tender Bid for Principal Supply Status for hospital supply, it is the preference of Pharmac that the pack size for such a Tender Item is:

- (a) 500 ml or less, where the Tender Item is in liquid form;
- (b) 30 or 90 day pack where the Tender Item is in a tablet or capsule form; and
- (c) 10 or less injections, where the Tender Item is in injection form.

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

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pack (or other equivalent grouping) size preference for Medical Devices and you may submit, and Pharmac will consider and may accept, a Tender Bid for any pack size (or other equivalent grouping) following its evaluation of Tender Bids under clause 5 of Schedule Three.

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## SCHEDULE TWO: PRODUCTS TO BE TENDERED

Chemical Name Line Item	Units	Cost	Unit Subsidy	ABA Limit	Comments
<b>Acitretin</b>					
Cap 10 mg	520,425	\$154,915	\$0.2977	C H 5%	Preference for a blister pack.
Cap 25 mg	104,703	\$72,175	\$0.6893	C H 5%	Preference for a blister pack.
<b>Alfentanil</b>					
Inj 0.5 mg per ml, 2 ml ampoule				H 5%	
<b>Allopurinol</b>					
Tab 100 mg	28,298,623	\$649,170	\$0.0229	C H 5%	Preference for a scored tablet.
Tab 300 mg	21,118,812	\$1,206,729	\$0.0571	C H 5%	Preference for a scored tablet.
<b>Ambrisentan</b>					
Tab 10 mg	11,650	\$601,917	\$51.6667	C H 5%	Longer transition period may apply to this product.
Tab 5 mg	4,056	\$209,560	\$51.6667	C H 5%	Longer transition period may apply to this product.
<b>Amitriptyline</b>					
Tab 10 mg	25,181,446	\$627,018	\$0.0249	C H 5%	Preference for a scored and/or dispersible tablet.
Tab 25 mg	8,159,364	\$123,206	\$0.0151	C H 5%	
Tab 50 mg	3,073,595	\$77,147	\$0.0251	C H 5%	
<b>Amlodipine</b>					
Tab 2.5 mg	14,097,368	\$169,168	\$0.0120	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
Tab 5 mg	25,695,696	\$274,173	\$0.0107	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
Tab 10 mg	13,591,221	\$179,676	\$0.0132	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
<b>Amorolfine</b>					
Nail soln 5%	148,135	\$442,331	\$2.9860	C H 5%	
<b>Amoxicillin</b>					
Grans for oral liq 125 mg per 5 ml	5,626,189	\$78,767	\$0.0140	C H 5%	Preference for products which include a measuring device.
Grans for oral liq 250 mg per 5 ml	32,477,430	\$561,860	\$0.0173	C H 5%	Preference for products which include a measuring device.
<b>Amoxicillin clavulanate</b>					
Tab amoxicillin 500 mg with potassium clavulanate 125 mg	10,325,281	\$918,950	\$0.0890	@ C H 5%	
<b>Anastrozole</b>					
Tab 1 mg	668,016	\$101,318	\$0.1517	C H 5%	
<b>Aspirin</b>					
Tab 100 mg EC	88,360,404	\$963,932	\$0.0109	C H 5%	
Tab dispersible or soluble 300 mg	781,454	\$35,165	\$0.0450	C H 5%	
<b>Atracurium Besylate</b>					
Inj 10 mg per ml, 2.5 ml				H 5%	
Inj 10 mg per ml, 5 ml				H 5%	
<b>Atropine sulphate</b>					
Eye drops 1%	116,010	\$134,262	\$1.1573	C H 5%	
<b>Azithromycin</b>					
Tab 250 mg	60,420	\$16,495	\$0.2730	C H 5%	
<b>Bendroflumethiazide [Bendrofluazide]</b>					
Tab 2.5 mg	17,533,816	\$701,353	\$0.0400	C H 5%	
Tab 5 mg	2,645,959	\$182,836	\$0.0691	C H 5%	
<b>Benzatropine Mesylate</b>					
Inj 1 mg per ml, 2 ml ampoule	1,002	\$19,038	\$19.0000	C H 5%	
<b>Benzympenicillin sodium [Penicillin G]</b>					
Inj 600 mg	5,526	\$6,128	\$1.1090	C H 5%	

sole supply

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

**SCHEDULE TWO: PRODUCTS TO BE TENDERED**

Chemical Name Line Item	Units	Cost	Unit Subsidy	ABA Limit	Comments
<b>Betahistine dihydrochloride</b>					
<u>Tab 16 mg</u>	4,130,294	\$190,820	\$0.0462	C H 5%	
<b>Betamethasone Dipropionate</b>					
<u>Crn 0.05% (pack size greater than 30 g)</u>	386,770	\$278,474	\$0.7200	C H 5%	
<u>Oint 0.05% (pack size greater than 30 g)</u>	421,840	\$303,725	\$0.7200	C H 5%	
<b>Bicalutamide</b>					
<u>Tab 50 mg</u>	695,680	\$104,602	\$0.1504	C H 5%	
<b>Bisoprolol Fumarate</b>					
Tab 2.5 mg	13,286,711	\$271,580	\$0.0204	C H 5%	Preference for a scored tablet, and for a pack size of 30 or 90 tablets in a bottle pack.
Tab 5 mg	7,057,743	\$199,946	\$0.0283	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
Tab 10 mg	2,412,029	\$97,012	\$0.0402	C H 5%	Preference for a pack ize of 30 or 90 tablets in a bottle pack.
<b>Bleomycin Sulphate</b>					
Inj 15,000 iu vial				PCT H 5%	
<b>Bupivacaine hydrochloride</b>					
Inj 2.5 mg per ml, 20 ml ampoule				H 5%	
Inj 2.5 mg per ml, 100 ml bag				H 5%	
Inj 5 mg per ml, 4 ml				H 5%	
<b>Bupropion hydrochloride</b>					
<u>Tab modified-release 150 mg</u>	3,184,267	\$1,167,575	\$0.3667	C H 5%	
<b>Calcium carbonate</b>					
<u>Tab</u>	8,008,658	\$214,312	\$0.0268	C H 5%	Preference for tab 1.25 g - 1.5 g.
<b>Capsaicin</b>					
<u>Crn 0.025%</u>	2,535,075	\$549,266	\$0.2167	C H 5%	
<b>Capsaicin (current access)</b>					
<u>Crn 0.075%</u>	505,329	\$134,215	\$0.2656	C H 5%	Current restrictions may apply. Pharmac would only award a tender for either current or widened access. Widened access would be a listing on the Schedule without restrictions.
<b>Capsaicin (widened access)</b>					
Crn 0.075%				C H 5%	Pharmac would only award a tender for either current or widened access. Widened access would be a listing on the Schedule without restrictions.
<b>Cefazolin sodium</b>					
Inj 2 g				C H 5%	Not currently listed on the Pharmaceutical Schedule.
<u>Inj 500 mg</u>	340	\$231	\$0.6780	C H 5%	
<u>Inj 1 g</u>	20,197	\$14,098	\$0.6980	C H 5%	
<b>Cefotaxime</b>					
Inj 1 g				H 5%	
<b>Ceftazidime</b>					
Inj 1 g				H 5%	
<b>Cefuroxime sodium</b>					
Inj 750 mg				H 5%	
Inj 1.5 g				H 5%	
<b>Ciprofloxacin</b>					
<u>Tab 250 mg</u>	138,119	\$11,938	\$0.0864	C H 5%	Preference for a scored, dispersible tablet.
<u>Tab 500 mg</u>	769,202	\$93,404	\$0.1214	C H 5%	Preference for a scored, dispersible tablet.
<u>Tab 750 mg</u>	32,175	\$6,837	\$0.2125	C H 5%	Preference for a scored, dispersible tablet.
<b>Cisplatin</b>					
Inj 1 mg per ml, 50 ml				PCT H 5%	

sole supply

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



## SCHEDULE TWO: PRODUCTS TO BE TENDERED

Chemical Name Line Item	Units	Cost	Unit Subsidy	ABA Limit	Comments
<b>Clarithromycin</b> Inj 500 mg				H 5%	
<b>Clonidine</b> <u>TDDS 2.5 mg, 100 mcg per day</u>	66,540	\$172,006	\$2.5850	C H 5%	
<u>TDDS 5 mg, 200 mcg per day</u>	29,123	\$95,960	\$3.2950	C H 5%	
<u>TDDS 7.5 mg, 300 mcg per day</u>	18,479	\$78,212	\$4.2325	C H 5%	
<b>Colecalciferol</b> <u>Cap/Tab 1.25 mg</u>	3,571,101	\$877,884	\$0.2458	C H 5%	
<b>Colistin Sulphomethate</b> Inj 150 mg	5,874	\$381,810	\$65.0000	C H 5%	
<b>Cyproterone acetate with ethinyloestradiol</b> Tab 2 mg with ethinyloestradiol 35 mcg				C H 5%	Not currently listed in the Pharmaceutical Schedule. Pharmac would consider bids for products not containing inert tablets. Pharmac reserves the right to award a single tender for the entire cyproterone with ethinyloestradiol market.
<u>Tab 2 mg with ethinyloestradiol 35 mcg and 7 inert tablets</u>	9,479,568	\$280,974	\$0.0296	C H 5%	Pharmac reserves the right to award a single tender for the entire cyproterone with ethinyloestradiol market.
<b>Darunavir</b> Tab 400 mg	81,856	\$180,083	\$2.2000	C H 5%	Preference for a dispersible tablet.
Tab 600 mg	26,184	\$85,818	\$3.2775	C H 5%	Preference for a dispersible tablet.
<b>Desmopressin</b> <u>Nasal spray 10 mcg per dose</u>	88,284	\$411,256	\$4.6583	C H 5%	
<b>Dexmedetomidine hydrochloride</b> Inj 100 mcg per ml, 2 ml vial				H 5%	
<b>Diazepam</b> <u>Tab 2 mg</u>	2,924,149	\$357,156	\$0.1221	C H 5%	Preference for a scored tablet.
<u>Tab 5 mg</u>	4,394,023	\$646,800	\$0.1472	C H 5%	
<b>Docusate Sodium</b> <u>Tab 50 mg</u>	884,724	\$20,437	\$0.0231	C H 5%	
<u>Tab 120 mg</u>	1,536,799	\$48,102	\$0.0313	C H 5%	
<b>Donepezil hydrochloride</b> <u>Tab 5 mg</u>	1,347,891	\$64,995	\$0.0482	C H 5%	
<u>Tab 10 mg</u>	1,184,480	\$87,391	\$0.0738	C H 5%	
<b>Emulsifying ointment</b> Oint BP (pack size of 200 g or less)				H 5%	
Oint BP (pack size greater than 200 g)	32,574,394	\$221,506	\$0.0068	C H 5%	
<b>Ephedrine</b> Inj 30 mg per ml, 1ml				H 5%	
<b>Escitalopram</b> <u>Tab 10 mg</u>	15,105,621	\$577,186	\$0.0382	C H 5%	Preference for a scored tablet.
<u>Tab 20 mg</u>	5,208,199	\$357,126	\$0.0686	C H 5%	
<b>Ezetimibe</b> <u>Tab 10 mg</u>	8,228,171	\$534,831	\$0.0650	C H 5%	
<b>Febuxostat</b> <u>Tab 120 mg</u>	169,333	\$120,955	\$0.7143	C H 5%	
<u>Tab 80 mg</u>	676,395	\$483,142	\$0.7143	C H 5%	
<b>Fibre supplement</b> <u>Powder/granules</u>	73,638,250	\$1,796,773	\$0.0244	C H 5%	Units and unit subsidy shown as per the 500 g presentation currently listed and expressed as 'per g'. Preference for a product containing psyllium husk.

**SCHEDULE TWO: PRODUCTS TO BE TENDERED**

<b>Chemical Name</b>				<b>Unit Subsidy</b>	<b>ABA Limit</b>	<b>Comments</b>
<b>Line Item</b>	<b>Units</b>	<b>Cost</b>				
<b>Finasteride</b>						
<u>Tab 5 mg</u>	5,811,630	\$279,539	\$0.0481		C H 5%	Preference for a blister pack.
<b>Flecainide Acetate</b>						
Cap long-acting 100 mg	1,109,011	\$486,856	\$0.4390		C H 5%	Longer transition timeframes may apply.
Cap long-acting 200 mg	1,112,332	\$754,655	\$0.6784		C H 5%	Longer transition timeframes may apply.
Inj 10 mg per ml, 15 ml	51	\$1,020	\$20.0000		C H 5%	
Tab 50 mg	419,485	\$139,479	\$0.3325		C H 5%	Longer transition timeframes may apply.
<b>Flucloxacillin sodium</b>						
<u>Inj 1 g</u>	6,161	\$7,024	\$1.1400		C H 5%	
<b>Fluconazole</b>						
<u>Cap 50 mg</u>	181,884	\$17,863	\$0.0982		C H 5%	
<u>Cap 150 mg</u>	134,034	\$87,122	\$0.6500		C H 5%	
<u>Cap 200 mg</u>	80,333	\$36,982	\$0.4604		C H 5%	
<b>Fosfomycin (current access)</b>						
Powder					H 5%	
<b>Fosfomycin (widened access)</b>						
Powder					C H 5%	Not currently listed in Section B. Special Authority criteria may apply. No proposed changes to Section H restrictions.
<b>Ganciclovir</b>						
Inj 500 mg vial					H 5%	
<b>Gemcitabine hydrochloride</b>						
<u>Inj 1 g</u>					PCT H 5%	
<b>Gliclazide</b>						
<u>Tab 80 mg</u>	21,095,238	\$640,451	\$0.0304		C H 5%	
<b>Glucagon Hydrochloride</b>						
<u>Inj 1 mg syringe kit</u>	21,406	\$684,992	\$32.0000		C H 5%	Preference for a graduated and/or prefilled syringe.
<b>Glucose [Dextrose]</b>						
<u>Inj 50%, 10 ml - 20 ml</u>	12,511	\$76,692	\$6.1300		C H 5%	Inj 50%, 10 ml is currently listed on the Pharmaceutical Schedule. Units and subsidy are shown per 10 ml ampoule.
<u>Inj 50%, 90 ml - 100 ml</u>	476	\$7,140	\$15.0000		C H 5%	Inj 50%, 90 ml is currently listed on the Pharmaceutical Schedule. Units and subsidy are shown per 90 ml ampoule.
Solution 15 g					H 5%	
<b>Glyceryl trinitrate</b>						
Inj 1 mg per ml, 10 ml					H 5%	
<b>Goserelin</b>						
Implant 10.8 mg, syringe	26,907	\$3,292,610	\$122.3700		C H 5%	Refer to Schedule 5 for additional Special Terms.
Implant 3.6 mg, syringe	11,410	\$749,435	\$65.6800		C H 5%	Refer to Schedule 5 for additional Special Terms.
<b>Granisetron</b>						
Inj 1 mg per ml					H 5%	
<b>Hydrocortisone with wool fat and mineral oil</b>						
<u>Lotn 1% with wool fat hydrous 3% and mineral oil</u>	10,570,725	\$446,930	\$0.0423		C H 5%	Preference for a pack size of 300 g or less.
<b>Hydroxyurea</b>						
Cap 500 mg	1,353,460	\$322,394	\$0.2382		PCT C H 5%	
<b>Hyoscine N-butylbromide</b>						
<u>Inj 20 mg, 1 ml</u>	179,634	\$228,135	\$1.2700		C H 5%	
<u>Tab 10 mg</u>	5,761,864	\$365,878	\$0.0635		C H 5%	

**SCHEDULE TWO: PRODUCTS TO BE TENDERED**

<b>Chemical Name</b>			<b>Unit</b>			
<b>Line Item</b>	<b>Units</b>	<b>Cost</b>	<b>Subsidy</b>	<b>ABA Limit</b>	<b>Comments</b>	
<b>Imatinib mesilate</b>						
Cap 400 mg	102,421	\$289,476	\$2.8263	C H 5%	Pharmac reserves the right to award a tender for all indications. Additional implementation support may be required to support a brand change. Usage figures are for non-GIST market only.	
Cap 100 mg	155,738	\$151,144	\$0.9705	C H 5%	Pharmac reserves the right to award a tender for all indications. Additional implementation support may be required to support a brand change. Usage figures are for non-GIST market only.	
<b>Indapamide</b>						
Tab 2.5 mg	2,035,333	\$236,323	\$0.1161	C H 5%		
<b>Iodine supplement</b>						
Tab 150 mcg elemental	11,892,079	\$605,188	\$0.0509	C H 5%		
<b>Isosorbide mononitrate</b>						
Tab 20 mg	580,607	\$113,509	\$0.1955	C H 5%		
Tab long-acting 40 mg	636,991	\$174,109	\$0.2733	C H 5%		
Tab long-acting 60 mg	6,410,771	\$658,899	\$0.1028	C H 5%		
<b>Ketoconazole</b>						
Shampoo 2%	6,451,100	\$208,371	\$0.0323	C H 5%		
<b>Lamivudine</b>						
Tab 100 mg	78,239	\$19,420	\$0.2482	C H 5%		
Tab 150 mg	148,170	\$208,672	\$1.4083	C H 5%		
<b>Latanoprost with timolol</b>						
Eye drops 0.005% with timolol 0.5%	46,630	\$23,222	\$0.4980	C H 5%		
<b>Leflunomide</b>						
Tab 10 mg	616,953	\$123,391	\$0.2000	C H 5%	Preference for a scored tablet.	
Tab 20 mg	798,875	\$159,775	\$0.2000	C H 5%		
<b>Levodopa with Carbidopa</b>						
Tab 100 mg with carbidopa 25 mg	9,913,017	\$2,092,638	\$0.2111	C H 5%	Longer transition periods may apply to this product.	
Tab 250 mg with carbidopa 25 mg	347,736	\$133,496	\$0.3839	C H 5%	Longer transition periods may apply to this product.	
Tab long-acting 200 mg with carbidopa 50 mg	1,836,240	\$801,519	\$0.4365	C H 5%	Longer transition periods may apply to this product. Pharmacokinetic data required.	
<b>Levonorgestrel</b>						
Subdermal implant	12,179	\$1,302,179	\$106.9200	C H 5%	Longer transition periods may apply to this product. Training should be provided to clinicians if awarded. Refer to Schedule 5 for additional Special Terms.	
<b>Losartan</b>						
Tab 12.5 mg	5,909,927	\$109,747	\$0.0186	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.	
Tab 25 mg	9,210,090	\$201,701	\$0.0219	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.	
Tab 50 mg	12,457,774	\$333,744	\$0.0268	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.	
Tab 100 mg	7,638,854	\$318,311	\$0.0417	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.	
<b>Macrogol 3350 with potassium chloride, sodium bicarbonate and sodium chloride</b>						
Powder for oral soln 13.125 g with potassium chloride 46.6 mg, sodium bicarbonate 178.5 mg and sodium chloride 350.7 mg	10,381,124	\$2,318,416	\$0.2233	C H 5%		
<b>Macrogol 3350 with sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate and ascorbic acid</b>						
Powder for oral soln				H 5%	Not currently listed in the Pharmaceutical Schedule.	

sole supply

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

**SCHEDULE TWO: PRODUCTS TO BE TENDERED**

<b>Chemical Name</b>				<b>Unit Subsidy</b>	<b>ABA Limit</b>	<b>Comments</b>
<b>Line Item</b>	<b>Units</b>	<b>Cost</b>				
<b>Magnesium sulphate</b>						
<u>Inj 2 mmol per ml, 5ml</u>	21,967	\$56,082	\$2.5530		C H 5%	
<b>Mebeverine hydrochloride</b>						
<u>Tab 135 mg</u>	2,754,493	\$281,564	\$0.1022		C H 5%	
<b>Melphalan</b>						
<u>Inj 50 mg vial</u>					PCT H 1%	
<b>Meropenem</b>						
<u>Inj 500 mg</u>					H 5%	
<u>Inj 1 g</u>					H 5%	
<b>Metaraminol tartrate</b>						
<u>Inj 0.5 mg per ml, 10 ml</u>					H 5%	
<u>Inj 0.5 mg per ml, 20 ml</u>					H 5%	
<u>Inj 0.5 mg per ml, 5 ml</u>						
<u>Inj 1 mg per ml, 1 ml</u>					H 5%	
<u>Inj 1 mg per ml, 10 ml</u>					H 5%	
<u>Inj 10 mg per ml, 1 ml</u>					H 5%	
<b>Methotrexate</b>						
<u>Inj 100 mg per ml, 50 ml</u>		\$65,805	\$79.9900		PCT C H 5%	Preference for products where stability data >48 hours post-compounding.
<b>Methylprednisolone aceponate</b>						
<u>Crm 0.1%</u>	549,540	\$163,395	\$0.2973		C H 5%	
<u>Oint 0.1%</u>	362,580	\$107,806	\$0.2973		C H 5%	
<b>Metoclopramide hydrochloride</b>						
<u>Tab 10 mg</u>	5,736,378	\$74,573	\$0.0130		C H 5%	
<b>Metronidazole</b>						
<u>Inj 5 mg per ml, 100 ml</u>					H 5%	Preference for a bag presentation with space to add another antibiotic.
<u>Tab 200 mg</u>	362,003	\$48,002	\$0.1326		C H 5%	Preference for a scored, dispersible tablet.
<u>Tab 400 mg</u>	2,112,363	\$526,084	\$0.2491		C H 5%	
<b>Metrapone</b>						
<u>Cap 250 mg</u>	29,585	\$330,169	\$11.1600		C 5%	
<b>Miconazole nitrate</b>						
<u>Crm 2% (15 g - 20 g pack)</u>	2,796,060	\$150,987	\$0.0540		C H 5%	
<u>Vaginal crm 2% with applicator</u>	452,760	\$77,988	\$0.1723		C H 5%	Single use applicators preferred.
<b>Morphine</b>						
<u>Inj 1 mg per ml, 10 ml syringe</u>					H 5%	Morphine sulphate inj 1 mg per ml, 10 ml syringe is currently listed in Section H of the Pharmaceutical Schedule.
<u>Inj 1 mg per ml, 100 ml bag</u>					H 5%	Morphine sulphate inj 1 mg per ml, 100 ml bag is currently listed in Section H of the Pharmaceutical Schedule.
<u>Inj 1 mg per ml, 50 ml syringe</u>					H 5%	Morphine sulphate inj 1 mg per ml, 50 ml syringe is currently listed in Section H of the Pharmaceutical Schedule.
<u>Tab immediate-release 10 mg</u>	3,759,493	\$1,052,658	\$0.2800		C H 5%	Preference for blister packs. Units and subsidy shown are for morphine sulphate tab immediate-release 10 mg.
<u>Tab immediate-release 20 mg</u>	632,388	\$349,078	\$0.5520		C H 5%	Preference for blister packs. Units and subsidy shown are for morphine sulphate tab immediate-release 20 mg.
<b>Moxifloxacin</b>						
<u>Tab 400 mg</u>	17,981	\$151,040	\$8.4000		C H 5%	
<b>Naltrexone hydrochloride</b>						
<u>Tab 50 mg</u>	264,115	\$1,173,812	\$4.4443		C H 5%	
<b>Nystatin</b>						
<u>Oral liq 100,000 u per ml</u>	1,728,984	\$126,786	\$0.0733		C H 5%	

sole supply

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

## SCHEDULE TWO: PRODUCTS TO BE TENDERED

Chemical Name Line Item	Units	Cost	Unit Subsidy	ABA Limit	Comments
<b>Nystatin</b>					
<u>Vaginal crm 100,000 u per 5 g with applicator(s)</u>	144,750	\$7,720	\$0.0533	C H 5%	Units and unit subsidy expressed as 'per g'.
<b>Oestriol</b>					
<u>Crn 1 mg per g with applicator(s)</u>	3,622,485	\$1,598,711	\$0.4413	C H 5%	Applicator(s) should be multiple use and a measured dose.
<u>Pessaries 500 mcg</u>	417,780	\$191,063	\$0.4573	C H 5%	
<u>Tab 2 mg</u>	166,032	\$38,735	\$0.2333	C H 5%	Preference for tablets to be scored.
<b>Olanzapine</b>					
<u>Orodispersible tab 5 mg</u>	392,548	\$25,374	\$0.0646	C H 5%	
<u>Orodispersible tab 10 mg</u>	537,702	\$45,705	\$0.0850	C H 5%	
<u>Tab 2.5 mg</u>	2,129,083	\$102,643	\$0.0482	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
<u>Tab 5 mg</u>	2,691,178	\$151,863	\$0.0564	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
<u>Tab 10 mg</u>	2,961,970	\$212,640	\$0.0718	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
<b>Omeprazole</b>					
<u>Cap 10 mg</u>	7,963,375	\$171,690	\$0.0216	C H 5%	Preference for a pack size of 30 or 90 capsules in a bottle pack.
<u>Cap 20 mg</u>	110,835,038	\$2,290,960	\$0.0207	C H 5%	Preference for a pack size of 30 or 90 capsules in a bottle pack.
<u>Cap 40 mg</u>	31,917,260	\$1,103,060	\$0.0346	C H 5%	Preference for a pack size of 30 or 90 capsules in a bottle pack.
<b>Ondansetron</b>					
<u>Tab disp 4 mg</u>	2,986,569	\$226,979	\$0.0760	C H 5%	
<u>Tab disp 8 mg</u>	1,234,570	\$139,506	\$0.1130	C H 5%	
<b>Paclitaxel</b>					
Inj 100 mg				PCT H 5%	Preference for products where stability data >48 hours post-compounding.
Inj 300 mg				PCT H 5%	Preference for products where stability data >48 hours post-compounding.
<b>Paracetamol</b>					
Suppos 125 mg	108,084	\$38,802	\$0.3590	C H 5%	
Inj 10 mg per ml, 100 ml				H 5%	
Suppos 250 mg	60,840	\$25,431	\$0.4180	C H 5%	
Suppos 500 mg	121,489	\$30,129	\$0.2480	C H 5%	
<b>Paraffin</b>					
White soft (pack size 2000 g or more)	2,071,299	\$16,562	\$0.0080	C 5%	Only funded in combination.
White soft (pack size 500 g or less)	128,146	\$1,421	\$0.0111	C H 5%	
<b>Permethrin</b>					
<u>Lotion 5%</u>	1,209,090	\$160,809	\$0.1330	C H 5%	
<b>Pimecrolimus</b>					
<u>Crn 1%</u>	52,530	\$99,807	\$1.9000	C H 5%	
<b>Pine tar with triethanolamine lauryl sulphate and fluorescein</b>					
<u>Soln 2.3% with triethanolamine lauryl sulphate and fluorescein sodium</u>	21,626,777	\$192,046	\$0.0089	C H 5%	
<b>Poloxamer</b>					
<u>Oral drops 10%</u>	275,430	\$36,541	\$0.1327	C H 5%	
<b>Povidone Iodine</b>					
Oint 10%	941,901	\$107,188	\$0.1138	C H 5%	
<b>Pravastatin</b>					
Tab 20 mg	3,822,866	\$288,091	\$0.0754	C H 5%	
Tab 40 mg	2,073,130	\$267,289	\$0.1289	C H 5%	

## SCHEDULE TWO: PRODUCTS TO BE TENDERED

Chemical Name Line Item	Units	Cost	Unit Subsidy	ABA Limit	Comments
<b>Prednisolone</b>					
Rectal Foam 10 - 20%	1,204	\$6,373	\$5.2929	C H 5%	Pharmac reserves the right to award a tender to one steroidal rectal product for the whole market.
<b>Prochlorperazine</b>					
<u>Tab 5 mg</u>	3,449,692	\$110,390	\$0.0320	C H 5%	
<b>Pyridoxine hydrochloride</b>					
<u>Tab 25 mg</u>	1,157,966	\$34,739	\$0.0300	C H 5%	
<b>Quetiapine</b>					
<u>Tab 100 mg</u>	4,138,527	\$232,668	\$0.0562	C H 5%	Preference for a pack size of 30 or 90 tablets in a blister pack.
<u>Tab 200 mg</u>	1,192,165	\$117,893	\$0.0989	C H 5%	Preference for a pack size of 30 or 90 tablets in a blister pack.
<u>Tab 25 mg</u>	28,110,192	\$671,552	\$0.0239	C H 5%	Preference for a scored tablet, and for a pack size of 30 or 90 tablets in a bottle pack.
<u>Tab 300 mg</u>	486,185	\$69,471	\$0.1429	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
<b>Remifentanil hydrochloride</b>					
Inj 1 mg				H 5%	
Inj 2 mg				H 5%	
<b>Rifampicin</b>					
<u>Cap 150 mg</u>	67,362	\$39,434	\$0.5854	C H 5%	
<u>Cap 300 mg</u>	177,112	\$216,183	\$1.2206	C H 5%	
Inj 600 mg				H 5%	
<u>Oral liq 100 mg per 5 ml</u>	74,501	\$15,645	\$0.2100	C H 5%	
<b>Rifaximin</b>					
<u>Tab 200 mg - 550 mg</u>	177,640	\$1,982,588	\$11.1607	C H 5%	Tab 550 mg is currently listed on the Pharmaceutical Schedule. Units shown are for tab 550 mg.
<b>Risperidone</b>					
<u>Oral liquid 1 mg per ml</u>	436,001	\$129,348	\$0.2967	C H 5%	
<u>Tab 0.5 mg</u>	3,374,198	\$104,600	\$0.0310	C H 5%	Preference for a pack size of 60 or 180 tablets in a bottle pack.
<u>Tab 1 mg</u>	2,167,617	\$74,414	\$0.0343	C H 5%	Preference for a pack size of 60 or 180 tablets in a bottle pack.
<u>Tab 2 mg</u>	1,007,412	\$38,453	\$0.0382	C H 5%	Preference for a pack size of 60 or 180 tablets in a bottle pack.
<u>Tab 3 mg</u>	426,586	\$17,776	\$0.0417	C H 5%	Preference for a pack size of 60 or 180 tablets in a bottle pack.
<u>Tab 4 mg</u>	187,866	\$10,708	\$0.0570	C H 5%	Preference for a pack size of 60 or 180 tablets in a bottle pack.
<b>Rizatriptan</b>					
<u>Tab orodispersible 10 mg</u>	2,235,118	\$271,947	\$0.1217	C H 5%	
<b>Ropivacaine hydrochloride</b>					
Inj 2 mg per ml, 10 ml ampoule				H 5%	
Inj 2 mg per ml, 20 ml				H 5%	
Inj 2 mg per ml, 100 ml				H 5%	
Inj 2 mg per ml, 200 ml				H 5%	
Inj 7.5 mg per ml, 10 ml				H 5%	
Inj 7.5 mg per ml, 20 ml				H 5%	
Inj 10 mg per ml, 10 ml				H 5%	
Inj 10 mg per ml, 20 ml				H 5%	
<b>Rosuvastatin</b>					
<u>Tab 5 mg</u>	210,363	\$11,921	\$0.0567	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
<u>Tab 10 mg</u>	371,573	\$29,974	\$0.0807	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.

sole supply

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

## SCHEDULE TWO: PRODUCTS TO BE TENDERED

Chemical Name Line Item	Units	Cost	Unit Subsidy	ABA Limit	Comments
<b>Rosuvastatin</b>					
<u>Tab 20 mg</u>	420,277	\$54,916	\$0.1307	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
<u>Tab 40 mg</u>	337,648	\$59,426	\$0.1760	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
<b>Roxithromycin</b>					
Tab 150 mg	1,312,868	\$217,411	\$0.1656 @	C H 5%	Additional Stock Pharmaceutical
Tab 300 mg	635,051	\$207,408	\$0.3266 @	C H 5%	Additional Stock Pharmaceutical
<b>Simvastatin</b>					
<u>Tab 10 mg</u>	3,075,595	\$42,043	\$0.0137	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
<u>Tab 20 mg</u>	13,253,968	\$299,010	\$0.0226	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
<u>Tab 40 mg</u>	11,383,998	\$452,855	\$0.0398	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
<u>Tab 80 mg</u>	772,532	\$61,115	\$0.0791	C H 5%	Preference for a pack size of 30 or 90 tablets in a bottle pack.
<b>Sodium Citro-Tartrate</b>					
<u>Grans effervescent 4 g sachets</u>	2,335,205	\$185,158	\$0.0793	C H 5%	
<b>Suxamethonium chloride</b>					
Inj 50 mg per ml, 2 ml				H 5%	
<b>Tacrolimus</b>					
<u>Oint 0.1%</u>	62,190	\$68,409	\$1.1000	C H 5%	
<b>Tamoxifen citrate</b>					
<u>Tab 10 mg</u>	44,665	\$11,166	\$0.2500	C H 5%	
<u>Tab 20 mg</u>	1,766,310	\$195,760	\$0.1108	C H 5%	
<b>Temazepam</b>					
<u>Tab 10 mg</u>	2,621,249	\$139,450	\$0.0532	C H 5%	Preference for a scored tablet.
<b>Terbinafine</b>					
<u>Tab 250 mg</u>	2,026,389	\$196,600	\$0.0970	C H 5%	
<b>Teriflunomide</b>					
<u>Tab 14 mg</u>	14,196	\$334,569	\$23.5679	C H 5%	
<b>Timolol</b>					
Eye drops 0.5%, gel forming	55,038	\$83,217	\$1.5120	C H 5%	For products containing BAK, Pharmac reserves its right to list a BAK or preservative free product for a restricted market. Units and unit subsidy shown are per ml
<b>Timolol maleate</b>					
<u>Eye drops 0.25%</u>	212,790	\$77,030	\$0.3620	C H 5%	For products containing BAK, Pharmac reserves the right to list a BAK or preservative free product for a restricted market. Please note that this line item is for non gel-forming drops.
<u>Eye drops 0.5%</u>	145,920	\$59,535	\$0.4080	C H 5%	For products containing BAK, Pharmac reserves the right to list a BAK or preservative free product for a restricted market. Please note that this line item is for non gel-forming drops.
<b>Tobramycin</b>					
<u>Solution for inhalation 60 mg per ml, 5 ml</u>	15,015	\$105,909	\$7.0536	C H 5%	
<b>Tramadol hydrochloride</b>					
<u>Cap 50 mg</u>	31,652,770	\$886,278	\$0.0280	C H 5%	
Inj 50 mg per ml, 1 ml ampoule				H 5%	
Inj 50 mg per ml, 2 ml ampoule				H 5%	
<u>Tab sustained-release 100 mg</u>	5,186,631	\$394,184	\$0.0760	C H 5%	
<u>Tab sustained-release 150 mg</u>	480,172	\$50,418	\$0.1050	C H 5%	
<u>Tab sustained-release 200 mg</u>	355,869	\$48,932	\$0.1375	C H 5%	

sole supply

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

**SCHEDULE TWO: PRODUCTS TO BE TENDERED**

<b>Chemical Name</b> Line Item	<b>Units</b>	<b>Cost</b>	<b>Unit Subsidy</b>	<b>ABA Limit</b>	<b>Comments</b>
<b>Triamcinolone acetonide</b>					
<u>0.1% in Dental Paste USP</u>	127,930	\$136,373	\$1.0660	C H 5%	
<u>Inj 10 mg per ml, 1 ml</u>	4,352	\$18,104	\$4.1600	C H 5%	Pharmac reserves the right to list a preservative free product in addition to this product for the ophthalmic market.
Inj 10 mg per ml, 1 ml preservative-free				C H 5%	Not currently listed in the Pharmaceutical Schedule. Restrictions may apply.
<u>Inj 40 mg per ml, 1 ml</u>	71,614	\$731,895	\$10.2200	C H 5%	Pharmac reserves the right to list a preservative free product in addition to this product for the ophthalmic market.
Inj 40 mg per ml, 1 ml preservative-free				C H 5%	Not currently listed in the Pharmaceutical Schedule. Restrictions may apply.
<u>Crm 0.02%</u>	3,294,400	\$207,547	\$0.0630	C H 5%	
<u>Oint 0.02%</u>	1,887,600	\$119,863	\$0.0635	C H 5%	
<b>Ursodeoxycholic acid</b>					
<u>Cap 250 mg - 300 mg</u>	1,096,709	\$361,366	\$0.3295	C H 5%	Cap 250 mg is currently listed on the Pharmaceutical Schedule. Units shown are for cap 250 mg.
<b>Vancomycin hydrochloride</b>					
<u>Inj 500 mg</u>	7,653	\$17,985	\$2.3500	C H 5%	



## Schedule 3: Tender Process

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### 1. General

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#### 1.1 Principal Supply Period

- (a) Hospital Tender Bids are to be submitted on the basis that if your Hospital Tender Bid is accepted, you will have Principal Supply Status for hospital supply for the particular Tender Item for the Principal Supply Period.
- (b) Community Tender Bids are to be submitted on the basis that if your Community Tender Bid is accepted, you will have Principal Supply Status for community supply for the particular Tender Item for the Principal 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 Principal Supply Status for the particular Tender Item for community and hospital supply for the Principal 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 Te Whatu Ora 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 Te Whatu Ora Hospitals from the applicable dates specified in clause 2.3 of Schedule Four;
  - (ii) the First Transition Period is intended to allow for an orderly transition to the arrangements that will apply during the Principal Supply Period;
  - (iii) the Final Transition Period is intended to allow for an orderly transition to any new arrangements following the end of the Principal Supply Period.
- (b) Subject to paragraph (d) below, in relation to community 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 subsidised. Additionally, where the successful tenderer's brand of the Pharmaceutical is not listed immediately prior to the First Transition Period, the successful tenderer's brand must be available for supply from the applicable dates specified in clause 2.3 of Schedule Four;
  - (ii) the First Transition Period is intended to allow for an orderly transition to the arrangements that will apply during the Principal Supply Period;
  - (iii) the Final Transition Period is intended to allow for an orderly transition to any new arrangements following the end of the Principal Supply Period.
- (c) In relation to community and/or hospital supply, Pharmac may, in its sole discretion:

### Schedule 3

- (i) determine a different commencement date for the First Transition Period, 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, by determining a different end date, and may do so before or after the commencement date of the First Transition Period. For the avoidance of doubt, in the event that Pharmac extends the First Transition Period under this clause 1.2(c)(ii):
  - (A) the delisting (subject to Alternative Brand Allowance arrangements) of other brands of that form and strength of the Chemical Entity is to be deferred until the actual commencement date of the Principal Supply Period, notwithstanding any date previously notified to suppliers by Pharmac as being the intended date of delisting;
  - (B) 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 2.1(a) of Schedule Four will not apply.
- (e) For the avoidance of doubt, any notification by Pharmac of the delisting (subject to Alternative Brand Allowance arrangements) of all other brands of that form and strength of the Chemical Entity on the first day of the Principal 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 (as applicable),will be deemed to have been entered into between you and Pharmac for Principal Supply Status for community supply 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

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(iii) Schedule Five (as applicable),

will be deemed to have been entered into between you and Pharmac for Principal Supply Status for hospital supply 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) Schedule Five (as applicable),

will be deemed to have been entered into between you and Pharmac for Principal Supply Status for community supply 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) Schedule Five (as applicable),

will be deemed to have been entered into between you and Pharmac for Principal Supply Status for hospital supply 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 and Schedule Five, 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 Principal Supply Period.

#### 1.4 Extension of Principal Supply Status for hospital supply

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

(A) Principal Supply Status for community supply; or

(B) a listing in Section B of the Pharmaceutical Schedule, which does not have Principal Supply Status; or

### Schedule 3

- (ii) if Pharmac has accepted your Hospital Tender Bid for the particular Tender Item, to supply the Tender Item for use in the community 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:
  - (A) Principal Supply Status for community supply; or
  - (B) a listing in Section B of the Pharmaceutical Schedule, which does not have Principal Supply Status.
- (b) The Community Tender Bid referred to in paragraph (a)(i) above and the contract for community supply 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:
    - (A) Schedules Four and Five in the context of Principal Supply Status; or
    - (B) Pharmac's standard terms of supply for pharmaceuticals used in the community (as recorded in the then Standard Terms Annex of Pharmac's Agreement for the listing of Pharmaceutical(s) on the New Zealand Pharmaceutical Schedule) in the context of a listing, which does not have Principal Supply Status; and
  - (iv) for such quantities of the Pharmaceutical as are required for use in the community.

#### 1.5 Extension of Principal Supply Status for community supply

- (a) You acknowledge and agree that if your Community Tender Bid is for a Tender Item that is specified in the product list in clause 2 of Schedule Two as being a Tender Item for which you may submit a Tender Bid for Principal Supply Status for hospital supply, 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:
    - (A) Principal Supply Status for hospital supply; or
    - (B) a listing in Section H of the Pharmaceutical Schedule, which does not have Principal Supply Status; or
  - (ii) if Pharmac has accepted your Community Tender Bid for the particular Tender Item, to supply the Tender Item for use in Te Whatu Ora Hospitals 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:
    - (A) Principal Supply Status for hospital supply; or

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- (B) a listing in Section H of the Pharmaceutical Schedule, which does not have Principal Supply Status.
- (b) The Hospital Tender Bid referred to in paragraph (a)(i) above and the contract for hospital supply 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:
    - (A) Schedules Four and Five in the context of Principal Supply Status; or
    - (B) Pharmac's standard terms of supply for pharmaceuticals used in Te Whatu Ora Hospitals (as recorded in the then Standard Terms Annex of Pharmac's Agreement for the listing of Pharmaceutical(s) on the New Zealand Pharmaceutical Schedule) in the context of a listing, which does not have Principal Supply Status; and
  - (iv) for such quantities of the Pharmaceutical as are required for use in Te Whatu Ora Hospitals.

#### 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 Principal Supply Period;
  - (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) the Lead Time and/or the Start Date; or
  - (vi) any other matter that Pharmac considers necessary or appropriate.
- (b) If Pharmac initiates negotiations or discussions with you under paragraph (a), and as a result there is a change to any of the terms and conditions relating to the supply of a Tender Item, Pharmac is not obliged to inform the other tenderers of that change, nor give those tenderers an opportunity to amend their bid for that Tender Item, unless the change is one which would result in the terms and conditions being materially different in scope from those set out in this Invitation.

## Schedule 3

- (c) The initiation and pursuit of any negotiations or discussions under this clause shall not constitute a counter-offer and your original Tender Bid will remain open for acceptance in accordance with clause 4.2(b) of this Schedule in the absence of agreement on any variation to that Tender Bid.

### 1.7 Termination and amendment of Invitation

Pharmac may:

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

## 2. Information about submitting a Tender Bid

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### 2.1 Types of Tender Bids

- (a) Where a Tender Item includes different forms and strengths of a Chemical Entity or entities, your Tender Bid may, but does not need to, include all of the forms and strengths of the Chemical Entity or entities contained in that Tender Item.
- (b) Where you submit a Tender Bid for a Tender Item, you must submit separate Tender Bids for that Tender Item for each unique product you are proposing to supply. For example different pack sizes or brands must be submitted as separate Tender Bids.

### 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 Market Approval and all necessary Consents. In those circumstances, you may be required to demonstrate your ability to obtain Market Approval and those Consents within a time frame acceptable to Pharmac. For example, you may be required to demonstrate that you have the dossier for that brand of the Tender Item ready to submit to Medsafe within one month of such a request being made by Pharmac.

For the avoidance of doubt, where your brand of the Tender Item:

- (a) is yet to obtain Market Approval and all necessary Consents, any time period to obtain Market Approval and those Consents shall be exclusive of the Lead Time indicated on your Tender Bid;
- (b) is supplied under an exemption under the Medicines Act 1981, the Tender Item shall not be classified as holding Market Approval or a Consent for the purposes of this Invitation.

### 2.3 Individual Tender Bids

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

## Schedule 3

### 2.4 Aggregated Tender Bids

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

### 2.5 Combined Community/Hospital Tender Bids

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

### 2.6 Aggregated Combined Community/Hospital Tender Bids

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

### 2.7 No conditions

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

### 2.8 Separate offers

Pharmac will treat each Tender Bid as a separate offer.

### 2.9 Tender Bid prices

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

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

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

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

### Schedule 3

- (b) An electronic version of the Offer Letter is available on the Electronic Portal.

#### 3.2 Information that must be supplied about you

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

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

#### 3.3 Information that must be supplied about the Tender Item

You must supply all the information requested in the Tender Submission Form and as otherwise requested by Pharmac, including the following information about the Tender Item:

- (a) in the case of a pharmaceutical that is not a Medical Device, the chemical, form, strength, brand name, pack size and type of packaging;
- (b) for any Pharmaceutical that does not require Market Approval and any other Consent:
  - (i) evidence and justification as to why Market Approval and any other Consent is not required for the Tender Item(s);
  - (ii) confirmation that the Tender Item(s) that you are submitting a Tender Bid in respect of meet the relevant standards and/or regulatory requirements for its intended use and what those standards and/or regulatory requirements are; and
  - (iii) details of the Tender Item(s), including excipients, Shelf-Life and In-Use Shelf-Life;
- (c) for any Medical Device:
  - (i) the brand name, pack size (or other equivalent grouping) and type of packaging;
  - (ii) details of the Tender Item(s) and any associated services available in relation to the Tender item(s), including training, education and product support;
  - (iii) confirmation that the Tender Item(s) that you are submitting a Tender Bid in respect of meet the relevant standards and regulatory requirements for its intended use;
  - (iv) information on current usage of and expenditure on the Tender Item(s) by Te Whatu Ora;
  - (v) confirmation that you have a business continuity plan with a brief summary of the plan;



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- (vi) demonstration of experience and knowledge within the healthcare sector, and specifically Te Whatu Ora Hospitals;
  - (vii) the WAND registration number of the Tender Item(s); and
  - (viii) the name of the sponsor of the Tender Item for the purpose of the Medicines (Database of Medical Devices) Regulations 2003;
- (d) a single price in New Zealand dollars (exclusive of GST) at which you will supply the Tender Item:
- (i) to wholesalers and other distributors, in respect of a Community Tender Bid; or
  - (ii) to Te Whatu Ora Hospitals, wholesalers and other distributors, in respect of a Hospital Tender Bid;
- (e) whether it has Market Approval and all necessary Consents (and if not, what the status of registration is);
- (f) the Lead Time for supply of the Tender Item;
- (g) 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 (not required in respect of Medical Devices); and
  - (iii) alternative manufacturers of the finished product and active ingredients (if any) (not required in respect of Medical Devices);
- (h) 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, you may supply, for any Pharmaceutical or Medical Device, information about other markets you currently provide the Pharmaceutical or Medical Device in.

#### 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;
  - (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;

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- (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;
  - (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; and
  - (v) digital artwork associated with the Tender Item.
- (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**

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### **4.1 Submission of Tender Bids**

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

### **4.2 Key dates**

Your Tender Bid must:

- (a) be submitted via the Electronic Portal by no later than the Deadline; and
- (b) be irrevocable and remain open for acceptance by Pharmac until, as applicable:
  - (i) Friday, 4 August 2023;
  - (ii) the date specified for a Tender Item in Schedule Two or on the Electronic Portal (if any); or
  - (iii) if Pharmac so requests at any time, such later date as you agree in writing.

## **5. Evaluation**

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### **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),

### Schedule 3

as published on Pharmac's website ([www.pharmac.govt.nz](http://www.pharmac.govt.nz)), to the extent applicable. More information on the Factors can be found at [www.pharmac.health.nz/factors-for-consideration](http://www.pharmac.health.nz/factors-for-consideration).

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

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

- (a) your ability to ensure continued availability of the Tender Item throughout the Principal Supply 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) alternative manufacturers of the finished product and active ingredients (if any);
  - (viii) other markets in which you currently supply the Pharmaceutical;
  - (ix) your proposed distribution and supply arrangements for the Tender Item; and
  - (x) the Lead Time for supply of the Tender Item;
- (b) the pack size (or other relevant grouping for a Medical Device) of the Tender Item and the type of packaging;
- (c) the Shelf-Life and In-Use Shelf-Life of the Tender Item.
- (d) the price of the Tender Item;
- (e) the amount and timing of savings, including non-pharmaceutical savings accruing to Pharmac during the Principal Supply Period;
- (f) either:
  - (i) evidence that you have obtained, and still have, Market Approval and all necessary Consents; or

### Schedule 3

- (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 Market Approval and all necessary Consents;
- (g) the name and location of the manufacturer of the finished product and active ingredients of the Tender Item; and
- (h) any other benefits of selecting you as the supplier of the Tender Item.

## 6. Conformity

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

## 7. Decision

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### 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.

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

### 7.4 Conditional acceptance

- (a) Where the successful tenderer's brand of a Tender Item is yet to receive Market Approval and all necessary Consents:
  - (i) The contract referred to in clause 1.3 of this Schedule will be conditional upon such Market Approval and Consents being received within a time period specified by Pharmac; and

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

## 8. Back-up supply

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### Back-up Supply Agreements

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

## 9. Dealing with information

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### 9.1 Confidentiality

- (a) Subject to clause 9.2 below, all Confidential Information is confidential to you, Pharmac, Te Whatu Ora and those parties' respective Personnel (as applicable).
- (b) You acknowledge that Pharmac may be required to disclose Confidential Information in accordance with:
  - (i) the Official Information Act 1982; and
  - (ii) any other legal and administrative obligations,and you consent to such disclosure.
- (c) Pharmac may consult with you, and will act in good faith, before deciding at its sole discretion whether to disclose Confidential Information for the purposes stated in paragraph (b) above.
- (d) Confidential Information must not be disclosed by you, Pharmac, Te Whatu Ora or those parties' respective Personnel unless:
  - (i) the information is publicly available or enters the public domain through no fault of the applicable parties; or
  - (ii) the disclosure is:
    - (A) required or permitted for the purposes of this Invitation;
    - (B) required or permitted by law; or

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(C) agreed to between the applicable parties.

### 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

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### 10.1 Process contract

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

### 10.2 Costs

Pharmac is not liable in any way whatsoever for any direct or indirect costs incurred, or loss (including loss of profit) or damage sustained, by you in respect, or arising out, of this tendering process or the obtaining or granting of Principal Supply Status for community and/or hospital supply, as applicable, for your supply of the Tender Item including, without limitation, costs of obtaining Market Approval and 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 the Electronic Portal).

### 10.4 No further liability

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

### 10.5 No lobbying

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

### 10.6 Enquiries

If you have any enquiries about this Invitation you should contact the Tender Analysts (tender@pharmac.govt.nz) at Pharmac. Any additional information that Pharmac gives to you as a result of your enquiry will also be given by Pharmac to other potential tenderers, if Pharmac determines that such information is material.

10.7 **Jurisdiction and governing law**

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

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## Schedule 4: Contract terms for Principal Supply Status for both community and hospital supply

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### 1. Pharmac's Role

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#### 1.1 Rights and Responsibilities

- (a) You acknowledge that:
- (i) Pharmac is required to pursue its statutory objectives, carry out its statutory functions and otherwise comply with its statutory obligations;
  - (ii) Pharmac is subject to a range of legal and administrative 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 role and functions;
  - (iv) the actions which Pharmac may take under its OPPs include (without limitation):
    - (A) listing new pharmaceuticals;
    - (B) changing the terms on which a pharmaceutical is listed; and
    - (C) delisting pharmaceuticals or delisting part or all of a therapeutic group or sub-group; and
  - (v) 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.
- (c) Pharmac may terminate or amend this Agreement at its sole discretion in the following circumstances:
- (i) Pharmac is issued a Crown Direction;
  - (ii) in accordance with any advice from Medsafe or clinical advice, based on patient safety or any other clinical reasons;
  - (iii) a Supply Issue results in a failure to supply the Pharmaceutical;
  - (iv) any Consent or Market Approval is not held by you or is withdrawn for the Pharmaceutical;
  - (v) a Changed Medicine Notification is approved by Medsafe for the Pharmaceutical; or
  - (vi) the Pharmaceutical is delisted for any reason.
- (d) In the event that:

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- (i) this Agreement is terminated (or notice of termination is given) or amended due to any of the circumstances set out in clause 1.1(c)(i) to (v), Pharmac reserves the right to delist, or suspend or amend the listing of, the Pharmaceutical; or
- (ii) the Pharmaceutical is delisted, or has its listing suspended, for any reason then, unless this Agreement is terminated under clause 1.1(c)(vi), this Agreement shall continue in full force and effect until expiry or termination in accordance with its terms and such delisting or suspension shall not constitute or be construed as a repudiation or breach of the terms of this Agreement by Pharmac. You agree that you do not have, and you expressly waive, any rights, at law, including in equity or under statute, and particularly under Part 2, subpart 3 of the Contract and Commercial Law Act 2017 (Contractual remedies), to terminate this Agreement as a result of the delisting, or suspension of the listing, of the Pharmaceutical.

### 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 Supplier Code of Conduct

You must comply with the New Zealand Government's Supplier Code of Conduct as amended or substituted from time to time.

## 2. Price and Payment

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### 2.1 Subsidy arrangements for community supply

- (a) Subject to clause 2.3 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) All other brands of that form and strength of the Chemical Entity will be delisted (except to the extent any brands remain listed under Alternative Brand Allowance arrangements) on the first day of the Principal Supply Period, with the result that you will have Principal Supply Status in the community for that form and strength of the Chemical Entity during the Principal Supply Period.
- (c) Subject to Pharmac's other rights under this Agreement in relation to the Pharmaceutical, the Pharmaceutical will continue to be fully subsidised, and you must continue to supply it, at the Price throughout the Principal Supply Period.
- (d) 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.

### 2.2 Pricing arrangements for hospital supply

- (a) Subject to Pharmac's other rights under this Agreement and clause 2.3 of this Schedule, on and from the Start Date, during the remainder of the First Transition Period and during the Principal Supply Period, the Pharmaceutical is to be:
  - (i) listed at the Price set out in the Pharmaceutical Schedule;
  - (ii) sold by you to Te Whatu Ora Hospitals at the Price.
- (b) Where the Pharmaceutical is included in an order by a Te Whatu Ora Hospital for pharmaceuticals where the total value (excluding GST) of the order is less than \$1,000, you may invoice the Te Whatu Ora Hospital, in accordance with clause 2.8 below, for the cost of freight for that particular order. For the avoidance of doubt, this clause does not entitle you to invoice a Te Whatu Ora 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 3.6 of this Schedule Four), and provided that there are no Alternative Pharmaceuticals listed in 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 2.2(a)(i) and (ii) above during the Final Transition Period and beyond; and
  - (ii) is not to be delisted during the Final Transition Period.

### 2.3 Price change

- (a) Subject to clause 2.3(c)(ii), clause 2.3(c)(iii) and clause 2.3(c)(iv) of this Schedule your brand of the Pharmaceutical must be available for supply, and you must supply the

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Pharmaceutical, at the Price from the 12<sup>th</sup> day of the month prior to the Start Date, and the Pharmaceutical will be subsidised at the Price from the Start Date.

- (b) Subject to clause 2.3(c)(ii), clause 2.3(c)(iii) and clause 2.3(c)(iv) of this Schedule, you must change the price at which you supply the Pharmaceutical to Te Whatu Ora Hospitals to the Price with effect from the 12<sup>th</sup> 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 12<sup>th</sup> day of the month prior to the Start Date.
- (c) 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 12<sup>th</sup> 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 1<sup>st</sup> day of the month prior to the Start Date, and the Pharmaceutical will be subsidised or purchased 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 2.3(c)(i) or (c)(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 22<sup>nd</sup> day of the month prior to the Start Date, and the Pharmaceutical will be subsidised or purchased at the Price from the Start Date; and
  - (iv) notwithstanding clauses 2.3(c)(i), (c)(ii) or (c)(iii) above, Pharmac may agree a process with you, that results in your brand of the Pharmaceutical, which includes a rebate, being available for supply, and you must supply the Pharmaceutical, at the Price from the 22<sup>nd</sup> 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 2.3(c)(i) or (c)(ii) above apply to the Pharmaceutical, clause (c)(i) above shall apply.

- (d) You shall upon request by Pharmac, provide information on how you intend to manage the price changes stated in clauses 2.3(c)(i) to (c)(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 Three.

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### 2.4 Supply Price

During each of the First Transition Period, the Principal Supply Period and the Final Transition Period, the price at which the Pharmaceutical is supplied by you to wholesalers, other such distributors and/or to a Te Whatu Ora Hospital, must not exceed the Price.

### 2.5 Pharmaceutical Price

You warrant that the Price is inclusive of all costs, for example but not limited to any costs relating to manufacturing, supply chain and price fluctuations, which may occur during the First Transition Period, the Principal Supply Period and the Final Transition Period.

### 2.6 No reference pricing during Principal 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 Principal 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.

### 2.7 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.

### 2.8 Invoices to hospitals

Where a Te Whatu Ora Hospital is to be invoiced for the Pharmaceutical, you are to invoice the particular Te Whatu Ora Hospital at the end of each month, but no later than the 10<sup>th</sup> 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 Te Whatu Ora Hospital's purchase order reference number (if applicable);
- (c) the net amount payable in respect of the Pharmaceutical supplied to that Te Whatu Ora Hospital in accordance with this Agreement;
- (d) full details in respect of the Pharmaceutical supplied to that Te Whatu Ora Hospital in accordance with this Agreement, including the:
  - (i) Te Whatu Ora Hospital 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 2.2(b) above);

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- (v) total cost for the total amount of the Pharmaceutical supplied; and
- (e) any other information that Te Whatu Ora Hospital requires you to supply.
- (f) The provisions of clause 2.8 do not apply to the extent that both parties have agreed to alternative or varied invoicing arrangements in respect of a particular Pharmaceutical.

### 2.9 Payment by hospitals

- (a) Provided that the Pharmaceutical has been supplied in accordance with this Agreement, and the particular Te Whatu Ora Hospital receives an invoice in accordance with clause 2.8 above, payment by the Te Whatu Ora 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 Te Whatu Ora Hospital;
  - (ii) on the 20<sup>th</sup> day of the month following the month to which the invoice for the Pharmaceutical relates, or, if the 20<sup>th</sup> day of the month is not a business day, then on the next business day following the 20<sup>th</sup> of the month.
- (b) Where you invoice a Te Whatu Ora Hospital later than the 10<sup>th</sup> 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 2.8 above, payment by the Te Whatu Ora 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 Te Whatu Ora Hospital;
  - (ii) on the 20<sup>th</sup> day of the month following the month in which you invoice the Te Whatu Ora Hospital for the Pharmaceutical, or, if the 20<sup>th</sup> day of the month is not a business day, then on the next business day following the 20<sup>th</sup> of the month.

### 2.10 Future payment by hospitals

- (a) A particular Te Whatu Ora 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 Te Whatu Ora Hospital may withhold, deduct or set off the amount of any overpayment or any amount recoverable by that Te Whatu Ora Hospital from you under this Agreement from any future amount owing to you.

### 3. Principal Supply Status

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#### 3.1 Principal Supplier

- (a) Subject to:
- (i) Pharmac's other rights under this Agreement in relation to the Pharmaceutical; and
  - (ii) this clause 3 of Schedule Four relating to the Alternative Brand Allowance,
- Pharmac will not subsidise another supplier's brand of the Pharmaceutical on the Pharmaceutical Schedule and/or Te Whatu Ora Hospitals will not purchase another supplier's brand of the Pharmaceutical, at any time during the Principal 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 principal supplier of any forms and strengths of the Chemical Entity, if such supply commences after the end of the Principal 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.
- (d) You shall have Principal Supply Status during the Principal Supply Period, which shall be subject to the Alternative Brand Allowance, where other supplier brands of the Pharmaceutical may be subsidised in the community and/or purchased by Te Whatu Ora Hospitals.
- (e) The Alternative Brand Allowance referred to in paragraph (a) above is specified as a percentage of the Total Pharmaceutical Volume for the Pharmaceutical, that percentage being as set out in Schedule Two.
- (f) You acknowledge and agree that any other supplier brands of the Pharmaceutical may be concurrently listed on the Pharmaceutical Schedule at any time during the First Transition Period, the Principal Supply Period and the Final Transition Period and your rights under this Agreement do not extend to an exclusive listing of the Pharmaceutical on the Pharmaceutical Schedule.

#### 3.2 Exceptions to Principal Supply Status

- (a) Pharmac may, from time to time during the Principal Supply Period or the First Transition Period, amend the Alternative Brand Allowance for the Pharmaceutical after consultation with a relevant medical adviser (being either the Ministry of Health, PTAC or its Specialist Advisory Committees), provided that Pharmac may only increase the Alternative Brand Allowance without your prior agreement if it has a direction to that effect from Medsafe or its successor, or a recommendation that it do so from PTAC or its Specialist Advisory Committees, based on a significant clinical issue.
- (b) Subject to clause 3.3 of this Schedule, you acknowledge and agree that while you have Principal Supply Status:

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- (i) other supplier brands of the Pharmaceutical may be subsidised in the community and/or purchased by Te Whatu Ora Hospitals, subject to the Alternative Brand Allowance; and
- (ii) without derogating from any other rights available to Pharmac or Te Whatu Ora 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) at any time during the Principal Supply Period, then the Alternative Brand Allowance shall not apply and other supplier brands of the Pharmaceutical may be subsidised in the community and/or purchased by Te Whatu Ora Hospitals without limitation during that period of non-supply and any calculation performed in accordance with clause 3.3 below shall exclude that period of non-supply.

### 3.3 Principal Supply Status Monitoring

- (a) If you reasonably believe that the percentage usage of other supplier brands of the Pharmaceutical subsidised in the community and/or purchased by Te Whatu Ora Hospitals exceeds the Alternative Brand Allowance for a particular Pharmaceutical during the Principal Supply Period, you may at any date after a three (3) month period following the end of any Relevant Period, request that Pharmac carry out calculations for that Relevant Period in accordance with the procedure set out in this clause 3.3, and Pharmac may, acting reasonably, agree to carry out such calculations, provided that if Pharmac refuses to carry out such calculations, it will provide you with the reasons for refusing to do so. For the avoidance of doubt, where you have Principal Supply Status for both community and hospital supply of a Pharmaceutical, Pharmac will carry out any calculations for those markets in combination, with a single, combined figure to be used for each of Total Pharmaceutical Volume and Total Brand Allowance Pharmaceutical Volume when carrying out the calculations below.
- (b) Within 30 business days of Pharmac accepting your request to carry out calculations in accordance with paragraph (a) above, Pharmac shall carry out the following calculations for the Relevant Period in question:
  - (i)  $(\text{Total Brand Allowance Pharmaceutical Volume} / \text{Total Pharmaceutical Volume}) \times 100 = \text{Brand Allowance Indicator}$ ;
  - (ii)  $\text{Brand Allowance Indicator} - \text{Alternative Brand Allowance} = \text{Brand Differential}$
- (c) In the event the Brand Differential is a number greater than zero i.e. a positive amount, Pharmac shall carry out the following calculations for the Relevant Period in question:
  - (i)  $\text{Total Pharmaceutical Volume} / 100 = \text{Volume Multiplier}$ ;
  - (ii)  $\text{Volume Multiplier} \times \text{Brand Differential} = \text{Eligible Volume}$ ;
  - (iii)  $(\text{Eligible Volume} \times \text{Unit Price and/or Unit Subsidy}) / 2 = \text{Brand Compensation}$
- (d) Pharmac will notify you in writing of any Brand Compensation payable or not in accordance with paragraphs (b) and (c) above and will provide you with the details of the relevant party or parties to be invoiced for any Brand Compensation payable. Following such notification to you from Pharmac, you may invoice the relevant party or parties for the Brand Compensation.



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- (e) You acknowledge and agree that the data extracted from the records used by Pharmac are the best data and those records are the best records, for the purposes of carrying out the calculations.
- (f) You may, within 10 business days following notification of the outcome of the calculations in accordance with paragraph (d) above (the “**Calculation**”), notify Pharmac in writing that you dispute the particular Calculation and that you require an audit of that Calculation to be carried out. If you do give a notice to Pharmac under this clause within that 10-business day period, then the following provisions are to apply:
  - (i) The audit is to be carried out by an independent person jointly approved by us or, if there is no agreement on a mutually acceptable person within 5 business days of the date of your notice under this clause, then by an independent person nominated for that purpose by the President for the time being of the Institute of Chartered Accountants of New Zealand.
  - (ii) The independent person is to audit the particular Calculation, which is disputed by you, based on all relevant electronic data which is extracted by Pharmac from the records maintained by it. For the avoidance of doubt, the independent person will have no right to inspect, review or have access to the written prescriptions on which the data extracted by Pharmac from those electronic records are based, nor any right to request copies of those written prescriptions.
  - (iii) In carrying out the audit, the independent person is to be considered as acting as an expert and not as an arbitrator.
  - (iv) The independent person will be required to complete the audit, and to provide us with a written determination in that regard, within 5 business days of receiving all the information required by the independent person to make a determination and, in any case, no later than 10 business days from the date of his or her acceptance of appointment or nomination under this clause, unless we agree otherwise. The independent person’s determination of the particular Calculation is to be final and binding on both of us.
  - (v) The costs incurred by the independent person in completing the audit are to be met by you, irrespective of the outcome of the audit.

### **3.4 Withdrawal of Principal Supply Status**

- (a) Pharmac may withdraw Principal Supply Status in relation to the Pharmaceutical (in which case clauses 3.1 and 3.3 of this Schedule Four will no longer apply), by written notice to you at any time during the Principal Supply Period or (in anticipation) during the First Transition Period in the event of a Supply Issue.
- (b) Any withdrawal of Principal Supply Status is without prejudice to Pharmac’s rights under clauses 5.5 and 5.6 of this Schedule Four.

### **3.5 Suspension of Principal Supply Status**

- (a) Pharmac may suspend Principal Supply Status in relation to the Pharmaceutical, by written notice to you at any time during the Principal Supply Period or (in anticipation) during the First Transition Period in the event of a Supply Issue.
- (b) Any suspension of Principal Supply Status is without prejudice to Pharmac’s rights under clauses 5.5 and 5.6 of this Schedule Four.

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- (c) Pharmac may, at any time, in its sole discretion, notify you of the date on which the suspension of Principal Supply Status under this clause 3.5 ceases and on which date:
  - (i) Principal Supply Status is to be re-implemented in respect of the Pharmaceutical; or
  - (ii) Principal Supply Status is to be withdrawn in accordance with clause 3.4 of this Schedule Four.

### 3.6 Subsidy and 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 Principal Supply Status for that form and strength of the Chemical Entity or you will cease to have Principal Supply Status for hospital supply in respect of an item conforming to the individual specifications described for the item in the product list in clause 2 of Schedule Two which the Pharmaceutical was listed as conforming with (in the case of any Pharmaceutical that is a Medical Device);
  - (ii) the Pharmaceutical will remain listed in the Pharmaceutical Schedule subject to the current standard terms Annex of Pharmac's Agreement for the listing of Pharmaceutical(s) on the New Zealand Pharmaceutical Schedule contract template;
  - (iii) you may increase the price ex-manufacturer (exclusive of GST) at which you sell or supply, or make available for supply or sale, by you, to:
    - (A) in relation to community supply, wholesalers and other such distributors; or
    - (B) in relation to hospital supply, Te Whatu Ora Hospitals, 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, subject to sub-paragraphs (A) to (C) as follows:
    - (A) Pharmac reserves the right to consult on any subsidy increases prior to determining whether to increase the subsidy for the Pharmaceutical to the new price notified under this paragraph (a)(iii);
    - (B) Where you increase the price at which you supply the Pharmaceutical under this paragraph (a)(iii), you will not subsequently increase the price at which you supply the Pharmaceutical for at least 12 months from the effective date of the price increase;
    - (C) Where you did not obtain Market Approval and all necessary Consents for the Pharmaceutical within 12 months following the Deadline, you may not provide six months' written notice of any price increase until a date on or after 12 months following the End Date.

#### Schedule 4

- (iv) if Pharmac does not increase the subsidy or price 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 or price 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 due to a Force Majeure Event); 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 two months' written notice of another supplier's brand of the Pharmaceutical being listed on the Pharmaceutical Schedule and a seven-month initial transition period.

## 4. Reporting

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### 4.1 Information

- (a) You agree to provide any information related to the Pharmaceutical and its listing that Pharmac reasonably requests, in such manner and timeframe as Pharmac reasonably requests.
- (b) In particular, and without limiting the generality of clause 4.1(a) above, you:
- (i) acknowledge that Pharmac requires the provision of Unique Product Identifiers in order to implement the listing of each Pharmaceutical and you agree to obtain and notify Pharmac of the Unique Product Identifiers of each Pharmaceutical as follows:
- (A) for brand changes, no later than the earlier of:
- the 12<sup>th</sup> of the month following the Market Notification Date; or
  - the 5<sup>th</sup> of the month immediately prior to the Start Date;
- (B) for price changes, on the 12<sup>th</sup> of the month prior to the Start Date.

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

- (ii) agree to provide Pharmac with digital photos of the Pharmaceutical (e.g. tablet, vial or patch) and its associated packaging, which will be supplied to the New Zealand market, when the Pharmaceutical is available for distribution in New Zealand. If any changes are made to the Pharmaceutical or its associated packaging whilst the Pharmaceutical is listed on the Pharmaceutical Schedule, you shall provide Pharmac with updated digital photos as soon as practicable following those changes being implemented;
- (iii) agree that in the event that you supply an Alternative Pharmaceutical in accordance with this Agreement, or in the event of a Changed Medicine Notification for a Pharmaceutical, you must notify Pharmac of any changed Unique Product Identifiers (or advise if there is no change) as soon as practicable;
- (iv) acknowledge that in the event the listing of the Pharmaceutical includes Special Authority criteria or any other access criteria, you must, for the duration that the Pharmaceutical is listed:
- (A) notify Pharmac in the event the Data Sheet is amended in a manner which, when considered in the context of any current Special Authority criteria or other current access criteria, could impact on patient safety; and
- (B) provide Pharmac with a summary of the amendment to the Data Sheet as set out in clause 4.1(b)(iv)(A) above;

Following the notification in clause 4.1(b)(iv)(A) Pharmac reserves the right at its sole discretion to amend the Special Authority criteria or any other access criteria for the Pharmaceutical based on patient safety;

## Schedule 4

- (v) acknowledge that Pharmac may require stock reports and batch details held by you for the Pharmaceutical and you agree to provide all such stock reports and batch details to Pharmac upon request;
- (vi) acknowledge that Pharmac may require price and volume data held by you relating to sales of the Pharmaceutical and you agree to provide all such price and volume data to Pharmac upon request; and
- (vii) agree that Te Whatu Ora may provide Pharmac and its agents with any price and volume data held by Te Whatu Ora in respect of the Pharmaceutical, and Pharmac may share any price and volume data held by Pharmac with Te Whatu Ora.

### 4.2 Supply Issues Reporting

- (a) You must send a Supply Issues Report to Pharmac in accordance with clause 5.3(a)(ii) of this Agreement or otherwise at Pharmac's request.
- (b) The Supply Issues Report must be provided to Pharmac in any form notified by Pharmac to you. Unless notified otherwise, the Supply Issues Report must include the following information:
  - (i) average usage of the Pharmaceutical in New Zealand;
  - (ii) quantity of Pharmaceutical stock:
    - (A) held by you (or on your behalf) in New Zealand;
    - (B) held by you (or on your behalf) in other international markets, and available for supply in New Zealand; and
    - (C) held by wholesalers in New Zealand;
  - (iii) reason for the Supply Issue;
  - (iv) when the Supply Issue occurred;
  - (v) expected delivery dates of the Pharmaceutical to New Zealand;
  - (vi) expected date of authorised release into the New Zealand market (including the date on which the Pharmaceutical is expected to be available for supply) and any applicable supporting evidence, for example export and import licences or other official authorisations and customs formalities necessary for the exportation and importation of the Pharmaceutical;
  - (vii) the estimated duration of the Supply Issue; and
  - (viii) any steps that you have taken or will take to mitigate the risk that you may fail to supply a Pharmaceutical.
- (c) You acknowledge that Pharmac may wish to engage with you in respect of any steps that you advise Pharmac of under clause 4.2(b)(viii) above or any other steps that may be required to mitigate the risk that you may fail to supply the Pharmaceutical,

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and you agree that you will engage and cooperate with Pharmac in relation to all such actual and proposed mitigation activities.

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## 5. Supply Obligations and Managing Supply Issues

### 5.1 Stock Holdings

The minimum stock holding of the Pharmaceutical that must be held by you (or on your behalf) in New Zealand and available for supply is set out in each of the rows in the table below. For the avoidance of doubt:

- (a) each minimum stock holding specified in the table in respect of an ASP or non-ASP Pharmaceutical is independent and separate from the other minimum stock holdings specified in the table, such that a failure to meet any of these minimum stock holding requirements for (as applicable) an ASP or non-ASP Pharmaceutical will be a Supply Issue; and
- (b) the minimum stock holdings set out in the table 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.

Stock Holding Type	Community and/or Hospital Supply	Minimum Stock Holding
General (non-ASP) stock holding requirement	Community or hospital supply	Two-thirds of your most recent three months' total Unit sales of the Tender Item
ASP	Community or hospital supply	Your most recent four months' total Unit sales of the Tender Item
General (non-ASP) stock holding requirement	Community or hospital supply	Forecast sales demand in respect of the next two-month period is greater than your stock of the Pharmaceutical
ASP	Community or hospital supply	Forecast sales demand in respect of the next four-month period is greater than your stock of the Pharmaceutical
General (non-ASP) stock holding requirement	Hospital	The average volume of stock of the Pharmaceutical required to supply the entire Te Whatu Ora Hospital market for the Pharmaceutical for any given two-month period
ASP	Hospital	The average volume of stock of the Pharmaceutical required to supply the entire Te Whatu Ora Hospital market for the Pharmaceutical for any given four-month period

## Schedule 4

General (non-ASP) stock holding requirement	Community	One-sixth of the Unit Volume
ASP	Community	One-third of the Unit Volume
General stock holding requirement (ASP and non-ASP)	Community or hospital supply	Insufficient to enable you to fully fill all orders as they are received (without restricting quantities that may be ordered)
New Zealand manufactured products (ASP and non-ASP)	Community or hospital supply	Forecast sales demand in respect of the next two-month period is greater than your stock of the Pharmaceutical; or you have insufficient stock to enable you to fully fill all orders as they are received; or 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

### 5.2 Continuity of Supply

- (a) You must supply, and continue to supply, the Pharmaceutical on the terms set out in this Agreement.
- (b) You warrant that you have entered into all contractual and other arrangements to the extent necessary, including licence and supply agreements with third parties, to ensure that you will meet all of your obligations under clause 5.2(a) above and this Agreement generally.

### 5.3 Notification

- (a) You must:
  - (i) notify Pharmac as soon as you become aware of a Supply Issue; and
  - (ii) send a Supply Issues Report to Pharmac within 2 Business Days of becoming aware of a Supply Issue.
- (b) In the event that you consider (acting reasonably) that any circumstances or events may result in a Supply Issue you must notify Pharmac in writing as soon as practicable, including (but not limited to) any of the following circumstances:
  - (i) you plan any changes to your supply chain, for example but not limited to a change in manufacturing site, in respect of the Pharmaceutical;
  - (ii) you plan any changes to your ordering or delivery systems;
  - (iii) you plan to re-structure your organisation; or



## Schedule 4

- (iv) you plan to change the presentation of the Pharmaceutical, including the brand name, pack size, packaging and strength.
- (c) After giving Pharmac notice in accordance with clauses 5.3(a)(i) and/or 5.3(b), you must comply with all reasonable requests by Pharmac in respect of steps that may be required to mitigate the risk that you may fail to supply the Pharmaceutical.

### 5.4 Managing Supply Issues

- (a) In addition to your obligations set out in clause 5.3 you must comply with the obligations set out in this clause 5.4.
- (b) In the event of:
  - (i) a decision or notification by Medsafe or any other authorities to recall the Pharmaceutical; or
  - (ii) the withdrawal of any Consent or Market Approval for the Pharmaceutical,you must use your best endeavours to engage and co-operate with Medsafe and any other relevant authorities and must, at all times, meet all your regulatory obligations.
- (c) In the event a Supply Issue actually results in a failure to supply, or you have reason to believe may cause you to fail to supply, the Pharmaceutical in accordance with the terms of this Agreement, then:
  - (i) subject to the prior written consent of Pharmac, you must use your best endeavours to procure, within what Pharmac considers to be a reasonable period of time, an Alternative Pharmaceutical for supply to:
    - (A) wholesalers and other such distributors; and
    - (B) any Te Whatu Ora Hospital,at the Price; and
  - (ii) if you fail to procure an Alternative Pharmaceutical at the Price and within the timeframe in accordance with clause 5.4(c)(i) above then 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 any additional costs, fees and/or expenses incurred by Te Whatu Ora or Pharmac as a result of the purchase of the Alternative Pharmaceutical over and above the costs that would have been incurred by Pharmac had you supplied the Pharmaceutical.
- (d) In the event Pharmac receives information that indicates that you may fail to supply a Pharmaceutical in accordance with this Agreement (whether you notify Pharmac under this Agreement or otherwise), you agree that Pharmac may inform other interested parties who may be impacted, including providing other suppliers with sufficient information to allow those suppliers to adequately prepare for a potential change in demand.

### 5.5 Indemnity

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You agree to indemnify Pharmac and Te Whatu Ora (as applicable) for any damages, liability, loss, cost (operational or otherwise) or expense awarded against, incurred or suffered by Pharmac and/or Te Whatu Ora as a result of or arising from a Supply Issue (other than a Supply Issue resulting directly from a Force Majeure Event). This indemnity shall be deemed to indemnify Pharmac and Te Whatu Ora for all additional costs, including all costs incurred by Pharmac and/or Te Whatu Ora as a result of the purchase of the Alternative Pharmaceutical that are additional to any costs specified in clause 5.6.

### 5.6 Liquidated Damages

- (a) Subject to clause 5.6(c) and clause 5.6(d), for each and every Supply Issue which actually results in a failure to supply the Pharmaceutical (other than a Supply Issue resulting directly from a Force Majeure Event) you must pay to Pharmac liquidated damages (plus GST (if any)) of \$50,000 to cover Pharmac's administrative and/or operational costs.
- (b) You acknowledge that Pharmac's right to claim the full liquidated damages amount specified in clause 5.6(a) in these circumstances reflects Pharmac's legitimate interests in securing delivery of the Pharmaceutical by the relevant date and in accordance with the terms of this Agreement and is proportionate to those interests during the period, and in the circumstances, in which the liquidated damages are payable under this clause 5.6.
- (c) Liquidated damages are payable where you have not:
  - (i) notified Pharmac under and in accordance with clause 5.3; and/or
  - (ii) complied with all reasonable requests by Pharmac in respect of steps that may be required to mitigate the risk that you may fail to supply the Pharmaceutical.
- (d) Pharmac may, in its sole discretion, require you to pay less than the amount specified as liquidated damages in clause 5.6(a) if Pharmac is satisfied that the actual costs in the circumstances are less than this amount.

### 5.7 Interest

If payment of any amount required to be paid by you under clauses 5.5 or 5.6 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 on such sum as remains unpaid at a rate per annum equal to the Default Interest Rate, 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 does not limit any other right or remedy of Pharmac; and
- (b) Pharmac may take any action, including legal action, without first needing to implement the dispute resolution procedure contained in clause 6.4, to recover that unpaid amount and you agree to pay to Pharmac actual enforcement costs incurred in relation to that action.

## 6. General Obligations

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### 6.1 Shelf-life of Pharmaceutical

You will not supply the Pharmaceutical:

- (a) if the remaining shelf-life of that Pharmaceutical is less than 6 months; or
- (b) where the total shelf-life of that Pharmaceutical is less than 6 months, the remaining shelf-life is less than 75% of that Pharmaceutical's total shelf-life,

without prior written agreement from Pharmac or the applicable Te Whatu Ora Hospital.

### 6.2 Consents

- (a) Prior to the Start Date you must obtain:
  - (i) Market Approval for the Pharmaceutical;
  - (ii) any Consent required for the supply of the Pharmaceutical; and
  - (iii) any other Consent Pharmac requires you to have or hold.
- (b) You must maintain Market Approval and any other Consent specified in clauses 6.2(a)(ii) and 6.2(a)(iii) for the Pharmaceutical for the duration the Pharmaceutical is listed.

### 6.3 Health and Safety

Where delivery of the Pharmaceutical (or provision of any related services described in this Agreement) occurs within the facilities of a Te Whatu Ora Hospital, you and your Personnel will comply with all relevant health and safety requirements, including:

- (a) the Health and Safety at Work Act 2015 and all regulations made under that Act; and
- (b) any policies and procedures communicated to you by the Te Whatu Ora Hospital.

### 6.4 Dispute Resolution

If there is a dispute between you and Pharmac arising out of, or in connection with, this Agreement, neither of the parties 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) You and Pharmac will endeavour, in good faith, to resolve the dispute referred to in the notice by using informal dispute resolution techniques.
- (c) If you and Pharmac have not resolved the dispute within 14 days after the date notice of a dispute was given, the parties may agree that the dispute is to be:

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- (i) mediated according to the standard mediation agreement of the Resolution Institute (a body corporate incorporated in Australia and registered as an overseas company in New Zealand), and the Chair of the Resolution Institute (or the Chair's nominee) will select the mediator and determine the mediator's remuneration, if you and Pharmac are unable to agree on such matters; or
  - (ii) submitted to arbitration in accordance with the Arbitration Act 1996, with such arbitration being conducted by a single arbitrator to be agreed on by the parties or, failing agreement, the Chair of the Resolution Institute (or the Chair's nominee) will select the arbitrator.
- (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.
- (e) Pending resolution of the dispute, this Agreement will remain in full effect without prejudicing the parties' respective rights and remedies (including Pharmac's rights under its OPPs).

### 6.5 Litigation Support

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

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

you will give Pharmac all assistance it reasonably requires for the purpose of the handling of any negotiations and/or litigation related to those proceedings or any claim.

### 6.6 Listing in Section B of the Pharmaceutical Schedule of a PCT

- (a) Where the Pharmaceutical is a PCT and supplied in a Te Whatu Ora Hospital, 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; and
  - (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

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references to “list”, “listed”, “delist”, “delisted”, and “delisting” are to be interpreted accordingly).

### 6.7 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 5.5 and 5.6 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 Principal Supply 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.

## 7. General Terms

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### 7.1 No Derogation

The express provision of a remedy for, or consequence of, breach of any term of this Agreement does not derogate from, or limit, any other legal right or remedy available to Pharmac under this Agreement or otherwise in respect of such breach.

### 7.2 No Waiver

A failure or delay by either you or Pharmac 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.

### 7.3 Remedies Cumulative

Except as is expressly stated otherwise in this Agreement:

- (a) the rights, powers and remedies provided in this Agreement are cumulative and are not exclusive of any rights, powers or remedies provided by law or under this Agreement; and
- (b) the exercise of any of the rights, powers and remedies provided in this Agreement will not prejudice the exercise of any other right, power or remedy under this Agreement or existing at law.

### 7.4 Entire Agreement

This Agreement:

- (a) is the entire agreement between you and Pharmac regarding the terms on which the Pharmaceutical is listed; and
- (b) supersedes and extinguishes all prior agreements and understandings between you and Pharmac, and between you and Te Whatu Ora, and any prior agreements and understandings originally entered into between you and district health boards (as applicable), regarding the Pharmaceutical and the subject matter contained herein.

### 7.5 Advertising

You must ensure that any Advertisement aimed at consumers of the Pharmaceutical does not breach any applicable statute, regulation or industry standard, including the Advertising Standards Authority Codes of Practice and the Medicines New Zealand Code of Practice.

### 7.6 Contracts Privity

- (a) You and Pharmac acknowledge that your obligations in this Agreement constitute promises and obligations which confer or are intended to confer a benefit on Te Whatu Ora and related persons, and are enforceable by Te Whatu Ora and any such persons pursuant to Part 2, subpart 1 of the Contract and Commercial Law Act 2017 (Contractual Privity).

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- (b) Except as expressly provided in clause 7.6(a) above, the parties do not intend to create rights in, or grant remedies to, any third party as a beneficiary to this Agreement, and all of the provisions of this Agreement shall be for the sole and exclusive benefit of the parties.
- (c) 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 Te Whatu Ora.

### **7.7 No Reliance**

You acknowledge that you have entered into this Agreement in reliance on your own knowledge, skill and independent advice, and not in reliance on any representations made, or any information made available to you, by Pharmac.

### **7.8 Amendments**

Amendments to this Agreement must be in writing.

### **7.9 Assignment**

You will not permit this Agreement, or any part of this Agreement, to be transferred or assigned (either directly or due to a change of 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.

### **7.10 Further Assurances**

You and Pharmac agree to execute any further documents and do any further acts as may be reasonably necessary from time to time to give effect to the terms and intentions of this Agreement.

### **7.11 Specific Performance**

You acknowledge that in the event of any breach or threatened breach of this Agreement by you, damages may not be an adequate remedy and Pharmac may seek specific performance of the terms of this Agreement or injunctive relief or any other similar remedy, in addition to any other rights, powers or remedies provided under this Agreement or by law (including equity).

### **7.12 Agreement Prevails**

Where any of your terms of supply, for example on invoices or any purchase orders, conflict or are inconsistent with any of the terms of this Agreement, the terms of this Agreement will prevail.

## Schedule 5: Additional Special Terms

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### 1. Goserelin implants

Included in this Invitation are the following Tender Items:

- Goserelin – Implant 3.6 mg, syringe
- Goserelin – Implant 10.8 mg, syringe

You must provide the following information when submitting Tender Bids for any of the above Tender Items (“Goserelin Implants”):

- Product specifications such as needle length, gauge, bevel design, whether there are active or passive safety features for example retractable needles;
- If applicable, details on support and resources (including any supplementary products) currently supplied to end users of your brand of Goserelin Implants, and the availability of this if there are regional differences.

You must provide the following Resources at no cost for the Goserelin Implants Tender Items for the provision of education, training and support to end users in respect of the use of your brand of Goserelin Implants.

For the purposes of this clause “Resources” shall include but not be limited to the:

- provision of training materials (such as DVDs, pamphlets, leaflets, brochures) to end users;
- provision of an information sheet explaining the differences between the current brand of Goserelin Implants and your brand of Goserelin Implants; and
- any additional information that Pharmac should consider when evaluating your Tender Bid.

### 2. Levonorgestrel subdermal implants

Included in this Invitation are the following Tender Items:

- Levonorgestrel – Subdermal implant

You must provide the following information when submitting Tender Bids for any of the above Tender Items (“Levonorgestrel subdermal implants”):

- Product specifications such as needle length, gauge, bevel design, whether there are active or passive safety features for example retractable needles;
- If applicable, details on support and resources (including any supplementary products) currently supplied to end users of your brand of Levonorgestrel subdermal implants, and the availability of this if there are regional differences.

You must provide the following Resources at no cost for the Levonorgestrel subdermal implants Tender Items for the provision of education, training and support to end users in respect of the use of your brand of Levonorgestrel subdermal implants.

For the purposes of this clause “Resources” shall include but not be limited to the:

- provision of training materials (such as DVDs, pamphlets, leaflets, brochures) to end users;



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- provision of an information sheet explaining the differences between the current brand of Levonorgestrel subdermal implants and your brand of Levonorgestrel subdermal implants; and
- any additional information that Pharmac should consider when evaluating your Tender Bid.

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