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19 October 2021

Dear Supplier

REQUEST FOR TENDER – SUPPLY OF ARIPIPRAZOLE, CELECOXIB, ETORICOXIB AND PREDNISOLONE TO DHB HOSPITALS AND TO COMMUNITY PHARMACIES

Pharmac invites tenders for the supply of aripiprazole, celecoxib, etoricoxib and prednisolone to DHB Hospitals and to community pharmacies in New Zealand.

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

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

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

(c) Schedule 3 describes the process Pharmac intends to follow in relation to this RFT, and provides instructions on how to submit a Tender Bid in relation to community supply and hospital supply;

(d) Schedule 4 sets out the terms that will apply if your Tender Bid in relation to community and hospital supply is awarded Principal Supply Status;

(e) Schedule 5 sets out the additional terms that will apply if your Tender Bid in relation to community supply is awarded Principal Supply Status;

(f) Schedule 6 sets out the additional terms that will apply if your Tender Bid in relation to hospital supply is awarded Principal Supply Status.

If you wish to submit a Tender Bid in relation to community and hospital supply of aripiprazole, celecoxib, etoricoxib or prednisolone you must submit it to Pharmac via the Government Electronic Tenders Service (GETS) no later than **4.00pm** on Tuesday 23 November 2021 (New Zealand time).

Please submit any queries about this RFT via GETS. We look forward to receiving your Tender Bid.

Yours sincerely

Lisa Williams
Director of Operations

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Schedule 1: Definitions and interpretation

1. Definitions

In this RFT:

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

(a) to hold additional stock; and

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

Aggregated Tender Bid means a Tender Bid for more than one Tender Item, which Pharmac is to consider in aggregate, and can include a Tender Bid for more than one Tender Item of the same Chemical Entity or Medical Device(s) but not aggregation within a single Tender Item;

Agreement means:

(a) Schedule Four; and

(b) in relation to a Tender Item with Principal Supply Status for community supply, Schedule Five; and

(c) in relation to a Tender Item with Principal Supply Status for hospital supply, Schedule Six,

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

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

Alternative Pharmaceutical means an alternative brand of a Tender Item that Pharmac, following consultation with PTAC or its Spec, considers to be an acceptable substitute for that Tender Item;

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 Tender Items subsidised in the community and purchased by DHB Hospitals relative to the Total Tender Item Volume in a Relevant Period;

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

Schedule 1

Brand Compensation means the compensation payable to you in accordance with Schedule 4, clause 1.8 (d);

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

Chemical Entity means any pharmaceutical that contains, and is described generically according to, the relevant active ingredient specified in the List of Tender Items in Schedule Two and on GETS in relation to this RFT;

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

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

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

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

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

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

Deadline means 4.00pm on 23 November 2021 (New Zealand time);

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

(a) a delivery point agreed between you and the relevant DHB Hospital, to which delivery point you must supply the Tender Item directly at the Price; and/or

(b) any delivery point designated by the relevant DHB Hospital or Pharmac, such delivery point being within 30km of your national distribution centre;

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

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

Eligible Volume means the Volume Multiplier multiplied by the Brand Differential, being a volume of Tender Items 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 Tender Item with Principal Supply Status, as applicable, the period of three calendar months beginning on the day after the relevant End Date;

First Transition Period means, in respect of a Tender Item 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);

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

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

GTIN means the Global Trade Item Number for a Tender Item;

Lead Time means the number of months (being whole months only) indicated on your Tender Bid that, if your Tender Bid is accepted, you would require following the Successful Tenderer Notification Date in order to source sufficient stock of your brand of the Tender Item to meet the entire market demand for the Tender Item as at the Start Date. For the avoidance of doubt, the Lead Time does not affect, and should incorporate the extra time needed to allow for, your obligations in clause 3.1 of Schedule Five and clause 3.1 of Schedule Six to have stock of the Tender Item available for supply or sale, and supply or sell the Tender Item, at the Price from the 12th day of the month prior to the Start Date;

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

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

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

PCT means a Tender Item for which DHB 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 on GETS in relation to this RFT;

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

Potential Out-of-Stock Event means:

(a) your stock of the Tender Item in New Zealand falls below two-thirds of your most recent three months' total Unit sales of the Tender Item, or, where the Tender Item is designated an ASP, your stock of the Tender Item in New Zealand falls below your most recent four months' total Unit sales of the Tender Item; or

(b) forecast sales demand in respect of the next two-month period is greater than your stock of the Tender Item, or, where the Tender Item is designated an ASP, forecast

sales demand in respect of the next four-month period is greater than your stock of the Tender Item; or

(c) in relation to hospital supply, your stock of the Tender Item in New Zealand falls below the average volume of stock of the Tender Item required to supply the entire New Zealand DHB Hospital market for the Tender Item for any given two-month period, or, where the Tender Item is designated an ASP, your stock of the Tender Item in New Zealand falls below the average volume of stock of the Tender Item required to supply the entire New Zealand DHB Hospital market for the Tender Item for any given four-month period; or

(d) in relation to community supply, your stock of the Tender Item in New Zealand falls below one-sixth of the Unit Volume, or, where the Tender Item is designated an ASP, your stock of the Tender Item in New Zealand falls below one-third of the Unit Volume; or

(e) your stock of the Tender Item in New Zealand is insufficient to enable you to fully fill all orders as they are received (without restricting quantities that may be ordered); or

(f) in relation to New Zealand manufactured products if either:

(i) forecast sales demand in respect of the next two-month period is greater than your stock of the Tender Item; or

(ii) you have insufficient stock to enable you to fully fill all orders as they are received; or

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

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

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

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

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

Principal Supplier means a supplier which has had a Tender Bid accepted for a Tender Item in relation to community and 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 either:

(a) 30 June 2025 or

(b) 30 June 2026 or 30 June 2027, if you and Pharmac agree in writing not less than six (6) months prior to 30 June 2025 to extend the Principal Supply Period for a further twelve (12) month period or twenty-four (24) month period, as applicable.

For the avoidance of doubt, the Principal Supply Period may only be extended for a period of no more than twenty-four (24) months from 30 June 2025;

Principal Supply Status means the status of being the Principal Supplier for community and hospital supply of a Tender Item 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 2022;

(b) 1 July 2022 until 30 June 2023; and

(c) every applicable 12 month period thereafter;

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

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

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

Special Authority (or SA) means a designation in relation to a Tender Item which means that the Tender Item 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 1.4 of Schedule Three;

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

Tender Bid means the Tender Submission Form submitted through GETS for a particular Tender Item, including the Lead Time;

Tender Item means:

(a) in respect of a Chemical Entity, the form and strength of that Chemical Entity (or entities, if applicable); or

(b) in respect of a Medical Device, the presentation and/or form and strength of an item conforming to the individual specifications described for such item in the List of Tender Items set out in clause 2 of Schedule Two,

in each case, for which you:

(c) may submit a Tender Bid, being the form and strength or presentation, as described generically, which any supplier could supply; or

(d) have submitted, and Pharmac has accepted on behalf of the Funder, a Tender Bid, being the form and strength or presentation as supplied by you,

(as applicable according to the context).

Tender Submission Form means the form on which you must submit your bid for each Tender Item, attached to this RFT as Appendix A and available on GETS;

Total Brand Allowance Tender Items means the total volume of Brand Allowance Tender Items subsidised in the community and/or purchased by DHB Hospitals in a Relevant Period, specified in Units of that Tender Item;

Total Tender Item Volume means the total volume of the Tender Item (inclusive of Brand Allowance Tender Items) subsidised in the community and/or purchased by DHB 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 or a syringe);

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 on GETS in relation to this RFT; and

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

2. Interpretation

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

(a) a reference to a clause or a Schedule is a reference to a clause of, or a Schedule to, this RFT;

(b) a reference to a statute or other law includes regulations and other instruments under it and consolidations, amendments, re-enactments or replacements of any of them (whether before or after the date of this Agreement);

(c) the singular includes the plural and vice versa;

(d) the word person includes an individual, a body corporate, an association of persons (whether corporate or not), a trust, a state and an agency of state, in each case, whether or not having a separate legal personality;

(e) a reference to a person includes a reference to the person's executors, administrators, successors, substitutes, (including, but not limited to, persons taking by novation) and permitted assignees;

(f) words importing one gender include the other genders;

(g) headings in this Agreement or on GETS in relation to this RFT are for convenience only and have no legal effect; and

(h) unless the context requires otherwise, references to the **"listing"** of a Tender Item:

  (i) in relation to hospital supply, are to the listing of that Tender Item in Section H of the Pharmaceutical Schedule (and references to "list", "listed", "delist", "delisted", and "delisting" are to be interpreted accordingly);

  (ii) in relation to community supply, are to the listing of that Tender Item in Sections A to G of the Pharmaceutical Schedule (and references to "list", "listed", "delist", "delisted", and "delisting" are to be interpreted accordingly).

Schedule 2: Products to be tendered

1. Information about Tender Items

1.1 List of Tender Items

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

1.2 Patents

(a) Where possible, Pharmac has identified Tender Items that it understands may be the subject of a patent that it believes is due to expire after the Deadline.

(b) 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

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 forecast volumes for the year ending 30 June 2021.

(b) Market value figures, in relation to community supply, are expressed as the Unit Volume in the year ending 30 June 2021, multiplied by the Unit Subsidy as at 1 July 2021.

(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; and

(ii) unless specified by Pharmac, do not include DHB Hospital volumes. For the avoidance of doubt, Pharmac makes no representation as to the size of the DHB Hospital market for any Tender Item, in relation to hospital supply.

(d) You acknowledge and agree that in submitting your Tender Bid you will rely on your own knowledge, skill and independent advice or assessment of the market size for any Tender Item and Pharmac is to have no liability in that regard.

1.4 Special terms

(a) Where there are any special terms relating to a particular Tender Item, those terms are indicated in the List of Tender Items set out at clause 2 below. Special Authority restrictions have been noted for Tender Items where applicable in the List of Tender Items. Further restrictions on the supply 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 is as at 1 July 2021.

(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 2021.

1.6 Alternative Brand Allowance

The Alternative Brand Allowance relating to a particular Tender Item, in relation to hospital and community supply, is indicated as a percentage amount in the column entitled "ABA Limit" in the List of Tender Items set out in clause 2 below.

1.7 Tender Items subject to exclusive supply arrangements

Where a Tender Item is underlined in the List of Tender Items set out in clause 2 below, that item is subject to an exclusive supply contract as at the date of this RFT.

1.8 Community and Hospital Products

You may submit a Tender Bid for Principal Supply Status for community supply and hospital supply for a Tender Item. You may also submit a Tender Bid that is both an Aggregated Tender Bid and a Combined Community/Hospital Tender Bid for a Tender Item in accordance with clause 2.5 of Schedule Three.

1.9 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 Part II of Section H of the Pharmaceutical Schedule subject to clause 11 of Schedule Six.

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

1.10 Capsule and tablet form

Unless otherwise stated, where the List of Tender Items set out in clause 2 below specifies, in respect of a particular Tender Item, 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 Tender Bid may be in either capsule or tablet 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 Tender Bid for the same form and strength as each line item in that Tender Item.

1.11 Pack size preference

In the context of community supply, it is the preference of Pharmac that the Tender Item is in the following pack sizes for the relevant form and strength or presentation of a Tender Item:

Tender Item	Pack Size
Tender Items	
Aripiprazole	
5 mg tab	30 Units
10 mg tab	30 Units
15 mg tab	30 Units
20 mg tab	30 Units
30 mg tab	30 Units
Celecoxib	
100 mg cap/tab	60 Units
200 mg cap/tab	30 Units
Etoricoxib	
30 mg cap/tab	Any
60 mg cap/tab	Any
90 mg cap/tab	Any
120 mg cap/tab	Any
Prednisolone	
1 mg cap/tab	Bottle
2.5 mg cap/tab	Bottle
5 mg cap/tab	Bottle
20 – 25 mg cap/tab	Bottle

Notwithstanding the preference of Pharmac or DHB Hospitals for Tender Items to be in pack sizes as specified above, pack sizes may be specified in the List of Tender Items set out in clause 2 below or you may submit, and Pharmac will consider and may accept, a Tender Bid for any pack size, including larger pack sizes, following its evaluation of Tender Bids under clause 5 of Schedule Three.

1.12 Duration of Principal Supply Period

Without limiting Pharmac's rights in any way, the Principal Supply Period that Pharmac would be willing to consider is a period of approximately thirty-six (36) months ("Initial Period") with the ability to extend this Initial Period by a maximum of twenty-four (24) months from the expiry of the Initial Period. Any such extension would require the written agreement of both the supplier and Pharmac and such written agreement must be obtained no less than 6 months prior to the end of the Initial Period.

1.13 Anticipated timetable

(a) Following receipt of Tender Bids, Pharmac anticipates:

(i) the Evaluation Committee evaluating Tender Bids in November 2021.

(ii) consulting on any Tender Bid (if applicable) in December 2021

(iii) Pharmac's Board of Directors (or its delegate, where applicable) deciding which Tender Bid (if any) to accept for a Tender Item in or after February 2022

provided that the above time frames are only approximate and may be extended, without notice being required from Pharmac, if any stages of the RFT process take longer than anticipated.

(b) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is 1 April 2022.

2. List of Tender Items

2.1 Table One: Products to be Tendered

Tender Item	Unit Subsidy / Price (at 1 July 2021)	ABA Limit	Comments	1 July 2020 – 30 June 2021	
				Units (tablets or capsules)	Cost (ex GST)
Aripiprazole Tab 5 mg	$0.583 per tablet ($17.50 per pack of 30)^	5%	Funding restrictions: None Packaging preference: Blister Rebate: A confidential rebate currently applies	481,833	$281,084
Aripiprazole Tab 10 mg	$0.583 per tablet ($17.50 per pack of 30)^	5%	Funding restrictions: None Packaging preference: Blister Rebate: A confidential rebate currently applies	697,097	$406,689
Aripiprazole Tab 15 mg	$0.583 per tablet ($17.50 per pack of 30)^	5%	Funding restrictions: None Packaging preference: Blister Rebate: A confidential rebate currently applies	233,492	$136,218
Aripiprazole Tab 20 mg	$0.583 per tablet ($17.50 per pack of 30)^	5%	Funding restrictions: None Packaging preference: Blister Rebate: A confidential rebate currently applies	165,753	$96,704
Aripiprazole Tab 30 mg	$0.583 per tablet ($17.50 per pack of 30)^	5%	Funding restrictions: None Packaging preference: Blister Rebate: A confidential rebate currently applies	84,916	$49,543
Celecoxib Cap 100 mg	$0.097 per tablet ($5.80 per 60)^	5%	Funding restrictions: None Packaging preference: Blister	13,027,322	$1,022,645

Schedule 2

Celecoxib Cap 200 mg	$0.110 per tablet ($3.30 per pack of 30)	5%	Funding restrictions: None Packaging preference: Blister	13,896,732	$1,289,984
Etoricoxib 30 mg (Cap/Tab)	N/A Not Subsidised	5%	No funding restrictions proposed Packaging preference: Blister	N/A	N/A
Etoricoxib 60 mg (Cap/Tab)	N/A Not Subsidised	5%	No funding restrictions proposed Packaging preference: Blister	N/A	N/A
Etoricoxib 90 mg (Cap/Tab)	N/A Not Subsidised	5%	No funding restrictions proposed Packaging preference: Blister	N/A	N/A
Etoricoxib 120 mg (Cap/Tab)	N/A Not Subsidised	5%	No funding restrictions proposed Packaging preference: Blister	N/A	N/A
Prednisolone 1 mg (Cap/Tab)	N/A Not Subsidised	5%	No funding restrictions proposed Packaging preference: Bottle	N/A	N/A
Prednisolone 2.5 mg (Cap/Tab)	N/A Not Subsidised	5%	No funding restrictions proposed Packaging preference: Bottle	N/A	N/A
Prednisolone 5 mg (Cap/Tab)	N/A Not Subsidised	5%	No funding restrictions proposed Packaging preference: Bottle	N/A	N/A
Prednisolone 20-25 mg (Cap/Tab)	N/A Not Subsidised	5%	No funding restrictions proposed Packaging preference: Bottle Strengths: 20 – 25 mg means we would accept one strength within the 20 – 25 mg range if tendered.	N/A	N/A

^Note: Unit Subsidies may change before a Tender Bid is accepted.

3. Background information

Pharmac currently lists and fully funds the following Tender Items in the Pharmaceutical Schedule for community and hospital supply:

Chemical and Presentation	Brand	Pack size	Current subsidy and price (ex-man, ex-GST)
Aripiprazole 5 mg tablet	Aripiprazole Sandoz	30	$17.50
Aripiprazole 10 mg tablet	Aripiprazole Sandoz	30	$17.50
Aripiprazole 15 mg tablet	Aripiprazole Sandoz	30	$17.50
Aripiprazole 20 mg tablet	Aripiprazole Sandoz	30	$17.50
Aripiprazole 30 mg tablet	Aripiprazole Sandoz	30	$17.50
Celecoxib 100 mg capsule	Celecoxib Pfizer	60	$5.80
Celecoxib 200 mg capsule	Celecoxib Pfizer	30	$3.30

In order to assist you with understanding the potential market for Prednisolone tablets the indicative volumes and cost information for a similar corticosteroid tablet that is currently funded, Prednisone, are as follows:

Chemical and Presentation	Brand	Pack size	Current subsidy and price (ex-man, ex-GST)	Volume of Units (1 July 2020 – 30 June 2021)
Prednisone 1 mg tablet	Apo-Prednisone	500	$18.58	12,272,702
Prednisone 2.5 mg tablet	Apo-Prednisone	500	$21.04	2,351,659
Prednisone 5 mg tablet	Apo-Prednisone	500	$19.30	13,368,211
Prednisone 20 mg tablet	Apo-Prednisone	500	$50.51	5,377,858

Desired Outcomes

3.1 Approved products and Duration of Agreement

Where you submit a Tender Bid that includes unapproved brands of the pharmaceuticals, you **MUST** indicate in the Tender Submission Form whether you intend to register your brand of

the pharmaceutical with Medsafe. The brand must be approved by Medsafe prior to supply to market.

Where a Tender Bid that includes unapproved brand(s) of the pharmaceuticals is conditionally accepted by Pharmac and the necessary Consents are received within a time period specified by Pharmac, the supplier is eligible to supply for the Initial Period and subject to Schedule 2, clause 1.12 until 30 June 2027.

3.2 Specific to Aripiprazole

Pharmac released the first open procurement process for aripiprazole in April 2017, which led to widening access. Inclusion of aripiprazole in this RFT rather than Pharmac's Annual Invitation to Tender (ITT) offers greater flexibility for the management of any potential brand change and Principal Supply Period.

3.3 Specific to Celecoxib and Etoricoxib

Pharmac released the first open procurement process for cyclooxygenase-2 (COX-2) inhibitor of the 'coxib' class in August 2016 which resulted in open listing for celecoxib. This procurement would consider funding etoricoxib as a new investment alongside celecoxib, should pricing be comparable. This would minimise any potential supply chain disruption as the two have similar uses.

3.4 Specific to Prednisolone

The New Zealand market is an outlier when it comes to the ongoing use of prednisone as the primary oral glucocorticoid. This procurement would consider the funding of prednisolone alongside prednisone to align New Zealand with global markets. Inclusion in this process rather than the ITT would offer greater flexibility in the principal supply period.

Sustainability & Suitability

The currently funded corticosteroid, Prednisone, is currently supplied in large quantities, both in terms of total volume and pack size (500). Pharmac is particularly interested in considering Tender Bids that take into account a reduction in environmental waste. Suppliers may submit separate Tender Bids for environmentally sustainable packaging.

Schedule 3: Tender Process

1. General

1.1 Principal Supply Period

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 DHB Hospital supply.

1.2 Transition Periods

(a) In relation to hospital supply:

(i) there will be two Transition Periods (the First Transition Period and the Final Transition Period) during which the successful tenderer's brand is to be available for supply and purchase by DHB Hospitals. Additionally, where the successful tenderer's brand of the Tender Item is not listed immediately prior to the First Transition Period, the successful tenderer's brand must be available for supply and purchase by DHB Hospitals from the applicable dates specified in clause 3 of Schedule Six;

(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 that will apply 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 Tender Item is not listed immediately prior to the First Transition Period, the successful tenderer's brand must be available for supply from the applicable dates specified in clause 3 of Schedule Five;

(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 that will apply following the end of the Principal Supply Period.

(c) In relation to community and/or hospital supply, Pharmac may, in its sole discretion:

(i) determine a different commencement date for the First Transition Period, 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 or presentation (as applicable) of the Tender Item 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) all other brands of that form and strength or presentation (as applicable) of the Tender Item are to remain listed in accordance with the terms of any existing contract between Pharmac and the particular supplier in respect of the relevant brand(s) until such time as that supplier's brand of that form and strength or presentation (as applicable) of the Tender Item is actually delisted.

(d) In relation to community supply, if the successful tenderer's brand is the only brand of the Tender Item listed on the Pharmaceutical Schedule as at the Market Notification Date, then the First Transition Period and clause 1.1(a) of Schedule Five will not apply.

(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 or presentation (as applicable) of the Tender Item on the first day of the Principal Supply Period operates solely as advance notice of the intended delisting of those items and does not constitute a notice of termination of any existing contract for the supply of those other brands.

1.3 Contract

(a) If Pharmac accepts your 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 1.4 of this Schedule); and

(B) Schedule Four; and

(C) for the community supply element of that Combined Community/Hospital Tender Bid, Schedule Five; and

(D) Schedule Seven (as applicable); and

(E) Schedule Eight (as applicable),

will be deemed to have been entered into between you and Pharmac for Principal Supply Status for community supply for the relevant Tender Item 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 1.4 of this Schedule); and

(B) Schedule Four; and

(C) for the hospital supply element of that Combined Community/Hospital Tender Bid, Schedule Six; and

(D) Schedule Seven (as applicable); and

(E) Schedule Eight (as applicable)

will be deemed to have been entered into between you and Pharmac for Principal Supply Status for hospital supply for the relevant Tender Item and, where applicable, its listing on the Pharmaceutical Schedule.

(b) For the avoidance of doubt, the terms and conditions specified in Schedule Four, Schedule Five, Schedule Six, Schedule Seven and Schedule Eight, 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 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 for community supply and hospital supply, as applicable;

(iv) the price of the Tender Item, but only where Pharmac determines, in its sole discretion, that an increased price for the Tender Item may be necessary for practicality of supply of the Tender Item (for example, because of particular packaging requirements);

(v) 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 RFT.

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

1.5 Termination and amendment of RFT

Pharmac may, having regard to probity principles:

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

(b) terminate this RFT at any time before the acceptance of any Tender Bid by giving five business days' written notice.

2. Information about submitting a Tender Bid

2.1 Choice of forms and strengths

Where a Tender Item includes different forms and strengths or presentations (as applicable), your Tender Bid may, but does not need to, include all of the forms and strengths or presentations (as applicable) of the Tender Item.

2.2 Consents not yet held

(a) You may submit a Tender Bid for a Tender Item where your brand of the Tender Item is yet to obtain all necessary Consents. In those circumstances, you may be required to demonstrate your ability to obtain those consents within a time frame acceptable to Pharmac. For example, you may be required to demonstrate that you have the dossier for that brand of the Tender Item ready to submit to Medsafe within one month of such a request being made by Pharmac.

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

(i) is yet to obtain all necessary Consents, any time period to obtain those Consents shall be exclusive of the Lead Time indicated on your Tender Bid; or

(ii) is supplied under an exemption under the Medicines Act 1981, the Tender Item shall not be classified as holding a Consent for the purposes of this Invitation.

2.3 Individual Tender Bids

You may submit more than one Tender Bid for a Tender Item (for example, you may submit separate bids for different pack sizes a Tender Item). Each Tender Bid or Aggregated Tender Bid **MUST** be a Combined Community/Hospital Tender Bid.

2.4 Aggregated Tender Bids

(a) You may, in addition to submitting a separate Tender Bid for each Tender Item, submit an Aggregated Tender Bid, provided that:

(i) each brand contained in an Aggregated Tender Bid is only a different form and strength of the same Chemical Entity;

(ii) you may not aggregate across different Chemical Entities when submitting an Aggregated Tender Bid;

(iii) you may not aggregate within a single Tender Item (for example, two different brands or pack sizes);

(iv) you may not aggregate with products that are not part of this RFT.

(b) Where a Tender Item includes different forms and strengths or presentations (as applicable) (for example, a two-part injection), and you bid for the whole Tender Item, that is not an Aggregated Tender Bid.

2.5 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 clause 2.4 above.

2.6 No conditions

Subject to the specific circumstances indicated in Schedule 2 where Pharmac is willing to consider a conditional Tender Bid, you cannot make a conditional Tender Bid nor qualify a Tender Bid in any way.

2.7 Separate offers

Pharmac will treat each Tender Bid as a separate offer.

2.8 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.

Pharmac will **NOT** consider any Tender Bids submitted in response to this RFT that include expenditure caps, rebates or other expenditure risk-sharing mechanisms (including volume based tiered pricing).

2.9 No alternative bids

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

3. What to include in your Tender Submission Form

3.1 Compulsory use of Tender Submission Form

(a) You must submit your Tender Bid using GETS and attach a completed Tender Submission Form for each Tender Item.

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

3.2 Information that must be supplied about you

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

(a) your company structure;

(b) your management and technical skills;

(c) your financial resources;

(d) your (or your supplier's) existing supply commitments;

(e) your (or your supplier's) previous supply performance;

(f) your quality assurance processes, where applicable;

(g) information related to how your company complies with the New Zealand Government's Supplier Code of Conduct (see https://www.procurement.govt.nz/assets/procurement-property/documents/supplier-code-of-conduct.pdf); and

(h) information related to how your organisation contributes to environmental sustainability.

3.3 Information that must be supplied about the Tender Item

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

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

(b) a physical sample sample of the Tender Item(s), to be provided within 10 business days of Pharmac's request.

(c) for any Tender Item (not being a Medical Device) that does not require Consent from Medsafe:

  (i) evidence and justification as to why Consent from Medsafe 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 and shelf-life;

(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 community supply; or

  (ii) to, at a DHB Hospital's discretion, Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), in respect of hospital supply;

(e) whether it has 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 for Medical Devices);

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

(i) other markets in which you currently provide the Tender Item.

3.4 Pharmac may request further information

(a) Pharmac may request such further information as it considers necessary from or about you for the purposes of clarifying or evaluating your Tender Bid, including (but not limited to):

(i) information about your credit status;

(ii) information on the price of a Tender Item, but only where Pharmac requires clarification to confirm the exact price being offered, or where Pharmac initiates negotiations with you under clause 1.4 of this Schedule;

(iii) where a Tender Item is a controlled drug, information about the form in which the Tender Item will be supplied, in which case you must supply that information within 10 business days of Pharmac requesting the information;

(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 (such as any labelling or packaging) associated with the Tender Item.

(a) If Pharmac requests further information from or about you it is not obliged to request the same or any other information from or about any other party.

4. How to submit a Tender Bid

4.1 Submission of Tender Bids

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

4.2 Key dates

Your Tender Bid must:

(a) be submitted via GETS by no later than the Deadline; and

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

(i) six months following the Deadline; or

(ii) if Pharmac so requests at any time, such later date as you agree in writing.

5. Evaluation

5.1 Process of evaluation

The Evaluation Committee, taking such regulatory, legal, medical and other advice as it considers appropriate, will evaluate all conforming Tender Bids that have been checked for conformity under clause 6(a) of this Schedule, and any non-conforming Tender Bids that are admitted for consideration under clause 6(b) of this Schedule.

5.2 Matters for evaluation

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

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

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

(a) your ability to ensure continued availability of the Tender Item throughout the Principal Supply Period and each of the Transition Periods, as applicable, taking into account each of the following separate points:

  (i) your organisation structure;

  (ii) your financial resources;

  (iii) your management and technical skills;

  (iv) your, or your supplier's, existing supply commitments;

  (v) your, or your supplier's, previous supply performance;

  (vi) your quality assurance processes, where applicable;

  (vii) the site of manufacture and packaging of the Tender Item, and site of manufacture of the active ingredient;

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

  (ix) other markets in which you currently supply the Tender Item (if applicable);

  (x) your proposed distribution and supply arrangements for the Tender Item; and

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

(b) physical details of the Tender Item, including:

(i) for a pharmaceutical, tablet or capsule shape and size and the pack size;

(ii) for all Tender Items, the type of packaging, conformance to Pharmac labelling preferences, minimum shelf-life and suitability for the end users;

(c) the price of the Tender Item;

(d) the amount and timing of any costs or savings, including non-Tender Item costs or savings accruing to the Funder or Pharmac during the Principal Supply Period;

(e) either:

(i) evidence that you have obtained, and still have, market approval for your brand of the Tender Item, and all necessary Consents; or

(ii) evidence that will enable the Evaluation Committee to form a view on the likelihood and timing of your brand of the Tender Item gaining all necessary Consents;

(f) evidence of how the Tender Item would reduce environmental waste (i.e. sustainability considerations);

(g) any other benefits to the Funder of selecting you as the supplier of the Tender Item.

This information should be provided by completing Appendix A Tender Response form.

6. Conformity

(a) Pharmac may, in its sole discretion, check your Tender Bid for conformity with this RFT. If Pharmac does elect to check your Tender Bid, it is not obliged to check all or any other Tender Bids for conformity, provided that in Pharmac's judgment this would not be unfair to you in comparison to any other party. A Tender Bid will conform if it:

(i) is submitted via GETS by the Deadline;

(ii) is submitted on the Tender Submission Form as stated in Appendix A;

(iii) has no conditions or qualifications attached;

(iv) includes all information required under clauses 3.2 and 3.3 of this Schedule; and

(v) otherwise complies, both as to form and substance, with the requirements of this RFT.

(b) Pharmac may, in its sole discretion, provided that in Pharmac's judgement this would not be unfair to you in comparison to any other party:

(i) exclude any non-conforming Tender Bid from consideration; or

(ii) consider, and accept, any non-conforming Tender Bid.

7. Decision

7.1 Decision on acceptance of Tender Bid

(a) The Evaluation Committee will make a recommendation as to which Tender Bid should be accepted to Pharmac's Board of Directors (or its delegate under Delegated Authority pursuant to Section 73 of the Crown Entities Act 2004, where applicable).

(b) Pharmac's Board of Directors (or its delegate, where applicable) will have the sole discretion to decide whether or not to accept a Tender Bid for any Tender Item.

(c) Pharmac's Board of Directors (or its delegate, where applicable):

(i) will use the Factors in Pharmac's then current OPPs as applicable, in deciding whether or not to accept a Tender Bid for any Tender Item; and

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

7.2 Notification of acceptance

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

(i) 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) conditionally accepted, Pharmac will, within a reasonable period of time of that Tender Bid becoming unconditionally accepted, notify each unsuccessful tenderer in writing of the identity of the successful tenderer.

(b) If for any reason you do not receive written notification from Pharmac in accordance with paragraph (a) above, you will be deemed to have received the required notification on the date that each Tender Item you bid for is notified in the Pharmaceutical Schedule.

7.3 Pharmac's rights reserved

(a) Pharmac reserves the right to accept or reject any Tender Bid and, other than to the extent necessary to debrief an unsuccessful tenderer, is not obliged to give reasons for its decision.

(b) While it is Pharmac's current intention, unless specified otherwise in Schedule Two or on GETS in relation to this RFT, to enter into an agreement to award Principal Supply Status for community and 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 price or any other Tender Bid for a Tender Item.

(c) Acceptance only occurs if, and when, Pharmac's Board of Directors (or its delegate, where applicable) resolves to accept a Tender Bid (following such consultation as

Pharmac considers necessary or appropriate) and this acceptance is notified to the successful tenderer.

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

(e) Pharmac may, at any time, suspend or cancel in whole or in part, this tender process in order to fulfil its public law obligations through consultation, or otherwise. In this situation Pharmac may (without limitation) ask you to adapt and resubmit your Tender Bid in light of consultation, or alternatively we may request that new Tender Bids be submitted (or in the case of a suspension Pharmac may also resume the tender process without further change following the end of the period of suspension).

7.4 Conditional acceptance

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

(i) the contract referred to in clause 1.3 of this Schedule will be conditional upon such Consents being received within a time period specified by Pharmac; and

(ii) Pharmac may terminate the contract if such Consents have not been obtained, or in Pharmac's view are unlikely to be obtained, within the period specified by Pharmac.

(b) Acceptance of a Tender Bid by Pharmac's Board of Directors (or its delegate, where applicable), and the contract referred to in clause 1.3 of this Schedule may be conditional upon you satisfying Pharmac that you will have sufficient stock of the Tender Item available to commence supply as at a date reasonably determined by Pharmac.

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

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

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

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

8. Back-up supply

8.1 Back-up Supply Agreements

(a) Pharmac may at any time negotiate a Back-up Supply Agreement with another supplier for any Tender Item.

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

9. Dealing with information

9.1 Confidentiality

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

(a) pursuant to the Official Information Act 1982; or

(b) in publicly notifying any acceptance of your Tender Bid; or

(c) otherwise pursuant to Pharmac's public law or any other legal obligations.

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

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

(e) the other party has been reasonably informed prior to disclosure, and the disclosure is:

(i) for the purposes of this Agreement; or

(ii) required by law; or

(iii) in a form, and of content, agreed to by us.

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

9.2 Use of information

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

10. Miscellaneous

10.1 Process contract

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

10.2 Costs

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

10.3 No reliance

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

10.4 No further liability

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

10.5 No lobbying

(a) You are not to initiate any communication with Pharmac or its advisors, the Minister of Health (or any Associate Ministers), the Ministry of Health, (including its operating unit Medsafe), or a District Health Board or any of their officers or directors, at any time with a view to influencing the outcome of the tendering process.

(b) Failure to comply with this clause will entitle Pharmac, in its sole discretion, to disqualify you from this tendering process.

10.6 Enquiries

If you have any enquiries about this RFT you should submit them on GETS. Any additional information that Pharmac gives to you as a result of your enquiry will also be given by Pharmac to other potential tenderers, if Pharmac determines that such information is material.

10.7 Jurisdiction and governing law

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

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

1. General

1.1 Operating Policies and Procedures

(a) You acknowledge that:

(i) Pharmac is required to pursue the objectives, carry out the functions, and otherwise comply with the statutory obligations, prescribed for Pharmac in the New Zealand Public Health and Disability Act 2000;

(ii) Pharmac is subject to other statutory and public law obligations, which govern Pharmac's decision-making processes;

(iii) Pharmac has OPPs which provide guidance on the way in which Pharmac carries out its statutory responsibilities in relation to the management of the Pharmaceutical Schedule;

(iv) Pharmac's OPPs may be amended or updated from time to time, following consultation with relevant groups;

(v) the actions which Pharmac may take under its OPPs include (without limitation):

(A) listing new pharmaceuticals;

(B) changing guidelines or restrictions on the purchasing, prescribing and dispensing of listed pharmaceuticals;

(C) changing the subsidy levels and/or market dynamics for pharmaceuticals as a result of Pharmac adopting one of the strategies set out in the OPPs or by any other means;

(D) amending the basis on which pharmaceuticals are classified into therapeutic groups and sub-groups;

(E) delisting pharmaceuticals, or delisting all or part of a therapeutic group or sub-group; and

(vi) any action taken by Pharmac pursuant to its OPPs may impact on the listing of the Tender Item.

(b) Pharmac agrees not to apply, amend or update its OPPs in order to avoid any of Pharmac's obligations under this Agreement.

1.2 Amendments to Pharmaceutical Schedule

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

1.3 Product identification codes

(a) You agree to obtain and notify Pharmac, by submitting a "notification of product changes form", of the Pharmacode, the GTIN and the CTPP for the Tender Item as soon as these are notified to you, and in any event:

(i) for brand changes, no later than the earlier of:

(A) 10 business days following the Market Notification Date; or

(B) the 5th of the month immediately prior to the Start Date.

(ii) for price changes, on the 12th of the month prior to the Start Date.

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

(b) You agree to provide Pharmac with digital photos of the Tender Item (e.g. tablet, vial or patch) and its associated packaging, which will be supplied to the New Zealand market, when the Tender Item is available for distribution in New Zealand. If any changes are made to the Tender Item or its associated packaging whilst the Tender Item is listed on the Pharmaceutical Schedule, you shall provide Pharmac with updated digital photos as soon as practicable following those changes being implemented.

1.4 Stock Reporting

You shall provide Pharmac with reports on stock levels for the Tender Items upon Pharmac's request during the Principal Supply Period.

1.5 Supplier Code of Conduct

You shall comply with the New Zealand Government's Supplier Code of Conduct (see https://www.procurement.govt.nz/assets/procurement-property/documents/supplier-code-of-conduct.pdf).

1.6 Principal Supplier

(a) The Alternative Brand Allowance is specified as a percentage of the Total Tender Item Volume for the Tender Item, that percentage being as set out in Schedule Two.

(b) You acknowledge and agree that Brand Allowance Tender Items 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 Tender Item on the Pharmaceutical Schedule.

1.7 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 Tender Item after consultation with a relevant medical adviser (being either the Ministry of Health, PTAC or its sub-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 sub-committees, based on a significant clinical issue.

(b) Subject to clause 1.8 of this Schedule, you acknowledge and agree that while you have Principal Supply Status:

(i) Brand Allowance Tender Items may be subsidised in the community and/or purchased by DHB Hospitals, subject to the Alternative Brand Allowance; and

(ii) Without derogating from any other rights available to Pharmac, the Funder or DHB Hospitals under this Agreement or otherwise, if you fail to supply the Tender Item 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 Brand Allowance Tender Items may be subsidised in the community and/or purchased by DHB Hospitals without limitation during that period of non-supply and any calculation performed in accordance with clause 1.8 below shall exclude that period of non-supply.

1.8 Principal Supply Status Monitoring

(a) If you reasonably believe that the percentage usage of Brand Allowance Tender Items subsidised in the community and/or purchased by DHB Hospitals exceeds the Alternative Brand Allowance for a particular Tender Item 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 1.8, 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 Tender Item, Pharmac will carry out any calculations for those markets in combination, with a single, combined figure to be used for each of Total Tender Item Volume and Total Brand Allowance Tender Items 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) (Total Brand Allowance Tender Items / Total Tender Item Volume) x 100 = Brand Allowance Indicator; and

(ii) Brand Allowance Indicator – Alternative Brand Allowance = 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) Total Tender Item Volume / 100 = Volume Multiplier;

(ii) Volume Multiplier x Brand Differential = Eligible Volume; and

(iii) (Eligible Volume x Unit Price and Unit Subsidy (as applicable)) / 2 = 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, for

example the relevant DHB(s). Following such notification to you from Pharmac, you may invoice the relevant party or parties for the Brand Compensation.

(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.

2. Crown Direction

(a) You acknowledge that Pharmac must comply with any Crown Direction.

(b) Pharmac may terminate or amend the Agreement, or impose restrictions on the prescribing or dispensing of a Tender Item, at any time during the Principal Supply Period or the Transition Periods, if the termination, amendment or imposition of restrictions is required to give effect to a Crown Direction.

(c) In the event that a Crown Direction is issued to Pharmac that requires an amendment to be made to this Agreement to give effect to that direction:

(i) Pharmac will give you as much notice as practicable of the Crown Direction and of any amendments to this Agreement that are required to give effect to that direction;

(ii) the Agreement will be deemed to be amended so as to give effect to the Crown Direction from the date when such direction is due to take effect; and

(iii) you may terminate this Agreement on not less than six months' written notice to Pharmac where the effect of the amendment required under sub-clause (ii) above is such that it is no longer viable, financially or otherwise, for you to continue supplying the Tender Item or to perform your obligations under this Agreement.

3. Pharmac Audit

(a) Pharmac may, from time to time, review your records and any other information you hold that relates to this Agreement with regard to stock levels, registration information and supply issues, for the purposes of auditing your compliance with this Agreement. In these circumstances, Pharmac, in consultation with you, will determine the terms and manner of any such audit, which as a minimum, must include the following:

(i) the audit will be conducted by an auditor authorised by Pharmac;

(ii) you agree to co-operate fully with Pharmac and provide Pharmac and the auditor with all reasonable assistance to ensure that any audit conducted under this clause is fully and properly completed to Pharmac's satisfaction, including:

(A) allowing the auditor access to your premises, records and other information you hold that relates to this Agreement with regard to stock levels, registration information and supply issues, for the purposes of, and during the course of, conducting the audit;

(B) answering promptly any questions from Pharmac or the auditor concerning any aspect of your compliance with this Agreement.

(iii) Pharmac will give you 10 business days' notice of its intention to conduct an audit under this clause and will ensure that the conduct of any such audit, and access in terms of sub-paragraph (A) above, does not unreasonably disrupt your business operations.

(b) Pharmac will notify you in writing if an audit under this clause reveals any non-compliance with this Agreement. You agree to remedy any non-compliance within 10 business days of receiving such notice from Pharmac or such other period as agreed with Pharmac.

4. Miscellaneous

4.1 Litigation support

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

(a) give rise to proceedings being issued against Pharmac; or

(b) result in Pharmac being made a party to any proceedings issued by a third party,

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

4.2 Dispute resolution

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

(a) the party claiming a dispute has arisen must give written notice to the other party specifying the nature of the dispute;

(b) we will endeavour, in good faith, to resolve the dispute referred to in the notice by using informal dispute resolution techniques;

(c) if we do not agree on a dispute resolution technique within 14 days after the date notice of a dispute was given, the dispute is to be mediated according to the standard mediation agreement of the Resolution Institute(a body corporate incorporated in Australia and registered as an overseas company in New Zealand in accordance with Part 18 of the Companies Act 1993), and the Chair of the Resolution institute (or the Chair's nominee) will select the mediator and determine the mediator's remuneration;

(d) a party seeking urgent interlocutory relief may, by notice to the other party, elect not to comply with the provisions of this clause, but only to the extent of the relief sought, and only for the period required to dispose of the application for interlocutory relief; and

(e) pending resolution of the dispute, this Agreement will remain in full effect without prejudicing our respective rights and remedies.

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

4.3 Advertising

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

(a) statute or regulation, including the Fair Trading Act 1986, Medicines Act 1981 and Medicines Regulations 1984; or

(b) industry standard, including the Advertising Standards Authority Codes of Practice and Medicines New Zealand Code of Practice.

For the purposes of this clause:

(c) "**Advertisement**" means any words, whether written, printed or spoken, any pictorial representation or design, any sounds or visual images, or combination of sounds and

visual images, or any other form of communication used or appearing to be used to promote:

(i) the sale of a Tender Item; or

(ii) the use of a method of treatment involving a Tender Item; and

(d) references to a statute, regulation or industry standard include that statute, regulation or industry standard as amended or replaced from time to time.

4.4 No derogation

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

4.5 No waiver

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

4.6 Agreement prevails

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

4.7 Entire agreement

This Agreement:

(a) is the entire agreement between us regarding the terms on which the Tender Item is, as applicable:

(i) listed in Section B of the Pharmaceutical Schedule and subsidised by the Funder; and

(ii) listed in Section H of the Pharmaceutical Schedule and purchased by DHB Hospitals; and

(b) supersedes and extinguishes, from the Start Date, all prior agreements and understandings between us, and between you and any DHB regarding supply of the Tender Item to DHB Hospitals.

4.8 Amendments

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

4.9 Assignment

You will not permit any part of this Agreement to be transferred, assigned or sub-contracted (either directly or due to a change of ownership or control) without Pharmac's prior written consent (such consent not to be unreasonably withheld). Any such consent may be given

subject to such reasonable conditions as Pharmac sees fit but no such consent will relieve you from any liability or obligation under the terms of the Agreement, and you will continue to be responsible for the acts, defaults and neglects of your transferee, assignee or sub-contractor.

4.10 Further assurances

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

4.11 Contracts privity

(a) For the purposes of the Contract and Commercial Law Act 2017, Part 2, Subpart 1, we both acknowledge that your obligations in this Agreement constitute promises which confer or are intended to confer a benefit on the Funder and related persons and/or DHB Hospitals and related persons (as applicable), and are enforceable at the suit of the Funder, any such DHB Hospitals or any related persons.

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

(c) For the avoidance of doubt, you acknowledge that Pharmac may pursue damages or any other claim (including injunctive or other such relief) under this Agreement on its own account and/or on behalf of the Funder and/or DHB Hospitals (as applicable), in respect of any form of loss or damage incurred by Pharmac and/or the Funder and/or DHB Hospitals.

4.12 Jurisdiction and governing law

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

Schedule 5: Additional contract terms for Principal Supply Status for community supply

1. Effect of Principal Supply Status for community supply

1.1 Subsidy arrangements

(a) Subject to clause 3.1 of this Schedule, the Tender Item will be subsidised, and you must supply it, during the First Transition Period at the Price. If any other brands of the Tender Item 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 or presentation (as applicable) of the Tender Item will be delisted (except to the extent any Brand Allowance Tender Items 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 or presentation of the Tender Item during the Principal Supply Period.

(c) Subject to Pharmac's other rights under this Agreement in relation to the Tender Item, the Tender Item 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 Tender Item, the Tender Item will not be delisted during the Final Transition Period.

1.2 Principal Supplier for the Principal Supply Period

(a) Subject to:

(i) Pharmac's other rights under this Agreement in relation to the Tender Item; and

(ii) clauses 1.6, 1.7 and 1.8 of Schedule Four relating to the Alternative Brand Allowance,

Pharmac will not subsidise another supplier's brand of the Tender Item on the Pharmaceutical Schedule 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 or presentations (as applicable) of the Tender Item, 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 Tender Item during the Final Transition Period as it sees fit, including lowering the subsidy of a Tender Item as a result of the implementation of new tender arrangements.

1.3 Withdrawal of Principal Supply Status

(a) Pharmac may withdraw Principal Supply Status in relation to your community supply of the Tender Item (in which case clauses 1.1 and 1.2 of this Schedule will no longer

apply), by written notice to you at any time during the Principal Supply Period or (in anticipation) during the First Transition Period if:

(i) you have failed to notify Pharmac as required under clause 5.1 of this Schedule;

(ii) you are unable to supply the Tender Item in accordance with this Agreement for a period of 30 days;

(iii) any Consent for the Tender Item is withdrawn; or

(iv) you otherwise fail to supply the Tender Item in accordance with this Agreement.

(b) In the event that Pharmac exercises its rights under clause 1.3(a) above in relation to a Tender Item, it may also withdraw Principal Supply Status in relation to your community supply of all forms and strengths or presentations (as applicable) of that Tender Item (in which case clauses 1.1 and 1.2 of this Schedule will no longer apply), following a recommendation from its clinical advisors, either by the written notice provided under clause 1.3(a) above or by further written notice to you at any time during the Principal Supply Period or (in anticipation) during the First Transition Period.

(c) Any withdrawal of Principal Supply Status for community supply is without prejudice to Pharmac's rights under clauses 5.2 and 5.3 of this Schedule.

1.4 Suspension of Principal Supply Status for community supply

(a) If, at any time during the Principal Supply Period or (in anticipation) during the First Transition Period, you are unable to meet demand for the Tender Item, or you notify Pharmac under clause 5.1 of this Schedule of a Potential Out-of-Stock Event, or you otherwise fail to supply the Tender Item in accordance with this Agreement, Pharmac may suspend Principal Supply Status in relation to your community supply of the Tender Item for the period of such inability.

(b) In the event that Pharmac exercises its rights under clause 1.4(a) above in relation to a Tender Item, it may also suspend Principal Supply Status in relation to your community supply of all forms and strengths or presentations (as applicable) of that Tender Item, following a recommendation from its clinical advisors, by written notice

to you at any time during the Principal Supply Period or (in anticipation) during the First Transition Period.

(c) Any suspension of Principal Supply Status for community supply is without prejudice to Pharmac's rights under clauses 5.2 and 5.3 of this Schedule.

(d) Pharmac may, at any time, in its sole discretion, notify you of the date on which the suspension of Principal Supply Status under this clause 1.4 ceases and on which date:

(i) Principal Supply Status for community supply is to be re-implemented in respect of the Tender Item; or

(ii) Principal Supply Status for community supply is to be withdrawn in accordance with clause 1.3 of this Schedule.

1.5 Subsidy arrangements after the End Date

(a) Subject to paragraphs (b) and (c) below, the Tender Item 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 community supply for that form and strength of the Tender Item (in the case of a Chemical Entity); or

(ii) you will cease to have Principal Supply Status for community supply in respect of that presentation and/or form and strength of the Tender Item (in the case of a Medical Device); and

(iii) the Tender Item will remain listed in Section B of the Pharmaceutical Schedule subject to Pharmac's standard terms of supply for pharmaceuticals used in the community (as recorded in the then current general listing terms Annex of Pharmac's standard community contract template);

(iv) you may increase the price ex-manufacturer (exclusive of GST) at which you supply the Tender Item to wholesalers and other such distributors on giving Pharmac six months' written notice of that price increase. You may provide Pharmac with this written notice at any time after, but not before, the End Date. Pharmac reserves the right to consult on any price increases prior to determining whether to increase the subsidy for the Tender Item to the new price notified under this paragraph (a)(iv). In the event you increase the price at which you supply the Tender Item under this paragraph (a)(iv), you will not subsequently increase the price at which you supply the Tender Item for at least 12 months from the effective date of the price increase;

(v) if Pharmac does not increase the subsidy for the Tender Item to the new price notified under paragraph (a)(iv) above, you may withdraw the Tender Item from supply on not less than six months' prior written notice;

(vi) if Pharmac does increase the subsidy for the Tender Item to the new price notified under paragraph (a)(iv) above, you may withdraw the Tender Item from supply on not less than two years' prior written notice (except where the withdrawal is for reasons that Pharmac considers to be wholly outside of your control, in which case you must first provide to Pharmac such information as it

may require from you in order to satisfy it, in its sole discretion, that you are required to withdraw supply); and

(vii) if at the time of providing notice under paragraph (a)(vi) above, you advise Pharmac that you are required to purchase a significant quantity of extra stock of the Tender Item 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 Tender Item 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 Tender Item (including delisting the Tender Item 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 Tender Item 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 Tender Item is designated an ASP, Pharmac will provide at least four months written notice of another supplier's brand of the Tender Item being listed on the Pharmaceutical Schedule.

2. Consents

2.1 Warranty and indemnity that Consents are held

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

(a) Pharmac is entitled to terminate this Agreement by 14 days' written notice to you; and

(b) whether or not Pharmac terminates this Agreement under paragraph (a) above, you are to indemnify the Funder for any additional costs incurred by it (or by Pharmac on its behalf) as a result of that failure to hold all necessary Consents. This clause confers a benefit on (and is enforceable by) the Funder in accordance with the Contract and Commercial Law Act 2017, Part 2, Subpart 1.

2.2 Changed medicine notification

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

(a) you must immediately notify Pharmac; and

(b) Pharmac may take such action as it considers appropriate in relation to that Tender Item or the CMN Tender Item including (but not limited to):

(i) withdrawing Principal Supply Status for community supply of the Tender Item;

(ii) reviewing the terms of listing of that Tender Item; and

(iii) determining whether, and the extent to which, the Funder may subsidise the CMN Tender Item.

3. Price

3.1 Price change

(a) Subject to clauses 3.1(b)(ii), (iii) and (iv) of this Schedule your brand of the Tender Item must be available for supply and you must supply the Tender Item, at the Price from the 12th day of the month prior to the Start Date, and the Tender Item will be subsidised at the Price from the Start Date.

(b) In the event your brand of the Tender Item 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 Tender Item to the Price on the 12th day of the month prior to the Start Date, and you shall provide price support to wholesalers and other such distributors for a maximum 4 weeks stock on hand (or such other level of stock as agreed between you and Pharmac) of the Tender Item 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 Tender Item must be available for supply and you must supply the Tender Item, at the Price from the 1st day of the month prior to the Start Date, and the Tender Item will be subsidised at the Price from the Start Date which is conditional upon you having at least 2 months Lead Time for the Tender Item; and

(iii) notwithstanding clauses 3.1(b)(i) or (ii) above, if the Price would result in a price increase for your brand of the Tender Item you must supply the Tender Item at the Price from the 22nd day of the month prior to the Start Date, and the Tender Item will be subsidised at the Price from the Start Date; and

(iv) notwithstanding clauses 3.1(b)(i), (ii) or (iii) above, Pharmac may agree a process with you, that results in your brand of the Tender Item being available for supply and you must supply the Tender Item, which includes a rebate (as applicable), at the Price from the 22nd day of the month prior to the Start Date, and you shall provide price support to wholesalers and other such distributors for a maximum 4 weeks stock on hand (or such other level of stock as agreed between you and Pharmac) of the Tender Item held at wholesalers and other

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

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

(c) You shall upon request by Pharmac, provide information on how you intend to manage the price changes stated in clauses 3.1(b)(i) to (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.

3.2 Supply Price

During each of the First Transition Period, the Principal Supply Period and the Final Transition Period, the price at which the Tender Item is supplied by you must not exceed the Price.

3.3 Tender Item 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.

3.4 No reference pricing during Principal Supply Period

The subsidy payable for the Tender Item 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 Tender Item to reduce the subsidy payable for it from the End Date.

3.5 Unsold stock following delisting

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

4. Shelf-life of Tender Item

(a) You will not supply the Tender Item to wholesalers, or other such distributors, or pharmacies if:

(i) the remaining shelf-life of the Tender Item is less than six months; or

(ii) where the total shelf-life of the Tender Item is less than six months, the remaining shelf-life is less than 75% of the Tender Item's total shelf-life,

without prior written agreement from Pharmac.

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

or pharmacy to return the Tender Item to you and to provide that wholesaler, or other such distributor, or pharmacy with a credit for the Tender Item.

5. Out-of-stock arrangements

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

(a) You must notify Pharmac in writing as soon as you have reasonable cause to believe at any time that you will fail to supply the Tender Item in accordance with this Agreement and, in any event, you must notify Pharmac if at any time a Potential Out-of-Stock Event occurs, including during the Principal Supply Period or the First Transition Period, in which case Pharmac may suspend Principal Supply Status in relation to your supply of the Tender Item.

(b) If a Potential Out-of-Stock Event occurs, or your failure to supply the Tender Item in accordance with this Agreement will result in insufficient stock of the Tender Item being available, then at Pharmac's option:

(i) Pharmac may implement an arrangement with another supplier to supply an Alternative Pharmaceutical (including an arrangement for back-up supply); or

(ii) you must use your best endeavours to procure wholesalers and other such distributors to supply, as soon as practicable, an Alternative Pharmaceutical to pharmacies at the Price, and Pharmac will subsidise the Alternative Pharmaceutical at the Price.

5.2 General indemnity

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

(a) your inability to meet demand for supply of the Tender Item;

(b) your withdrawal of the Tender Item from supply;

(c) any failure to have and maintain a Consent as specified in clause 2 of this Schedule;

(d) any failure to notify Pharmac in accordance with clause 5.1 above; or

(e) for any other reason.

This indemnity:

(f) covers all additional costs, including without limitation all costs (if any) incurred in securing and subsidising an Alternative Pharmaceutical, incurred by the Funder (or by Pharmac on its behalf) as a result of your failure that are additional to any costs specified in clause 5.3; and

(g) confers a benefit on (and is enforceable by) the Funder in accordance with the Contract and Commercial Law Act 2017, Part 2, Subpart 1.

5.3 Liquidated damages

(a) If you fail to supply the Tender Item in accordance with this Agreement (other than for reasons that Pharmac reasonably considers, following discussion with you, to be wholly outside your control) and:

(i) you have not notified Pharmac under clause 5.1 of this Schedule, then without prejudice to Pharmac's rights under clause 5.2:

(A) subject to paragraph (e) below, you must pay to Pharmac (for the benefit of Pharmac and the Funder) liquidated damages for the administrative and/or operational costs incurred by Pharmac as a result of your failure to supply in the amount of $50,000 per Tender Item in respect of which you failed to notify Pharmac; and

(B) Pharmac may withdraw Principal Supply Status in relation to your community supply of the Tender Item under clause 1.3 of this Schedule; or

(ii) you have notified Pharmac under clause 5.1 of this Schedule, then without prejudice to Pharmac's rights under clause 5.2:

(A) you are not liable to pay any liquidated damages under this clause 5.3; and

(B) if you fail to supply the Tender Item in accordance with this Agreement for more than 30 days, Pharmac may withdraw Principal Supply Status in relation to your community supply of the Tender Item under clause 1.3 of this Schedule.

(b) If, having notified Pharmac under clause 5.1 of this Schedule, you remain able to, and you continue to, supply the Tender Item, or an Alternative Pharmaceutical in accordance with clause 5.1(b)(ii) of this Schedule, such that there is no interruption to supply of the Tender Item or of the Alternative Pharmaceutical in accordance with this Agreement, you will not be liable for any costs unless Pharmac, in its sole discretion, has considered it necessary to enter into an arrangement with an alternative supplier under which Pharmac has agreed to make a payment to that supplier to ensure continuity of supply, in which case you must indemnify the Funder or Pharmac for that payment. Such indemnity will be limited to an amount of $10,000.

(c) You acknowledge and agree that:

(i) the amounts of liquidated damages in this clause represent a reasonable estimate of the administrative and operational costs incurred by Pharmac (including the use of staff and loss of opportunity as a result of use of staff time, and communication costs), the estimate being based on Pharmac's previous experience; and

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

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

(d) Where a Tender Item in respect of which you are liable to pay liquidated damages pursuant to clause 5.3(a)(i)(A) above also has Principal Supply Status for hospital supply and where you would otherwise be liable to pay the same amount of liquidated damages in respect of any corresponding failure under the terms of such Principal Supply Status, you will only be required to pay liquidated damages of $50,000 in total in respect of both supply failures.

(e) All amounts referred to in this clause are plus GST.

5.4 Failure to supply

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

(a) no stock of the Tender Item is physically held by you or on your behalf in New Zealand;

(b) the only stock of the Tender Item physically held by you or on your behalf in New Zealand is stock to which clause 4(a)(i) or (ii) of this Schedule applies and no agreement has been reached with Pharmac in terms of clause 4(a) of this Schedule;

(c) you fail, directly or indirectly, to ensure that all orders for the Tender Item are filled (without restricting quantities that may be ordered), including in particular where, for reasons attributable (wholly or partly) to you, not all patients for whom the Tender Item is prescribed receive the full amount of the Tender Item they require, or to which they are entitled, under their prescriptions, within the required time frames for dispensing under the then current contract, or notice under section 88 of the New Zealand Public Health and Disability Act 2000, in respect of pharmacy services;

(d) you fail to supply the Tender Item on and from the Start Date.

5.5 Default interest and recovery costs

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

(a) interest will accrue in such sum as remains unpaid at a rate per annum equal to the relevant SME overdraft rate (weighted average rate) of the Reserve Bank of New Zealand plus five percentage points, calculated and compounded on a daily basis, from the due date until such time as the sum due (including interest) is paid in full. This obligation to pay default interest is to arise without the need for a notice or demand from Pharmac for such default interest; and

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

6. Termination and restrictions

6.1 Termination and restrictions for clinical reasons

Pharmac reserves the right, but only after consultation with you and a relevant medical adviser (being either the Ministry of Health, PTAC or its Specialist Advisory Committees), to:

(a) terminate this Agreement at any time during the Principal Supply Period or the First Transition Period if the medical adviser determines for clinical reasons that it is no longer appropriate to have either:

(i) a principal supplier of that form and strength or presentation (as applicable) of the Tender Item; or

(ii) the Tender Item as the sole subsidised brand; and/or

(b) impose at any time during the Principal Supply Period or the Transition Periods restrictions on the prescribing or dispensing of a Tender Item if those restrictions are necessary for clinical reasons.

6.2 Termination following an audit

Pharmac may terminate the Agreement, or withdraw Principal Supply Status for community supply in relation to a Tender Item, at any time during the Principal Supply Period or the Transition Periods, if you fail to remedy any area of non-compliance in accordance with clause 3(b) of Schedule Four.

7. Guarantee

(a) Pharmac may require an entity acceptable to it to provide a guarantee (in a form satisfactory to Pharmac) of your performance obligations under clauses 5.2 and 5.3 of this Schedule including, without limitation, the payment of any sum payable under the indemnity or as liquidated damages pursuant to those clauses for any failure to supply the Tender Item 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 Tender Item for all claims made by Pharmac under the guarantee.

Schedule 6: Additional contract terms for Principal Supply Status for hospital supply

1. Effect of Principal Supply Status for hospital supply

1.1 Pricing arrangements

(a) Subject to Pharmac's other rights under this Agreement and clause 3.1 of this Schedule, on and from the Start Date, during the remainder of the First Transition Period and during the Principal Supply Period, the Tender Item is to be:

(i) listed at the Price set out in Section H of the Pharmaceutical Schedule; and

(ii) sold by you to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), at the Price.

(b) Where the Tender Item is included in an order by a DHB Hospital where the total value (excluding GST) of the order is less than $1,000, you may invoice the DHB Hospital, in accordance with clause 4.1 below, for the cost of freight for that particular order. For the avoidance of doubt, this clause 1.1(b) does not entitle you to invoice a DHB Hospital for any other costs in relation to the particular order.

(c) Subject to Pharmac's other rights under this Agreement in relation to the Tender Item (including under clause 1.3 of this Schedule), and provided that there are no Alternative Pharmaceuticals listed in Section H of the Pharmaceutical Schedule at the start of the Final Transition Period, the Tender Item:

(i) is to continue to be listed, sold and purchased at the Price referred to in clauses 1.1(a)(i) and (ii) above during the Final Transition Period and beyond; and

(ii) is not to be delisted during the Final Transition Period.

1.2 Principal Supplier for Principal Supply Period

(a) Subject to:

(i) Pharmac's other rights under this Agreement in relation to the Tender Item; and

(ii) clauses 1.6, 1.7 and 1.8 of Schedule Four relating to the Alternative Brand Allowance,

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

(b) This clause does not prohibit Pharmac (on behalf of DHB Hospitals) from entering into negotiations or arrangements with, or inviting tenders from, other suppliers to be the supplier of any forms and strengths or presentations (as applicable) of the particular Tender Item with Principal Supply Status for hospital supply, or a relevant Alternative Pharmaceutical having a status equivalent to Principal Supply Status for hospital

supply, if notification of such an arrangement (once finalised) occurs, and such supply commences, after the end of the Principal Supply Period.

1.3 Supply arrangements after the End Date

(a) Subject to paragraphs (b) and (c) below, the Tender Item 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 hospital supply for that form and strength of the Tender Item (in the case of any Chemical Entity); or

(ii) you will cease to have Principal Supply Status for hospital supply in respect of that presentation and/or form and strength of the Tender Item (in the case of a Medical Device); and

(iii) the Tender Item will remain listed in Section H of the Pharmaceutical Schedule subject to Pharmac's standard terms of supply for pharmaceuticals used in DHB Hospitals (as recorded in the then current general listing terms Annex of Pharmac's standard hospital contract template);

(iv) you may increase the price (exclusive of GST) at which you supply the Tender Item to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), on giving Pharmac six months' written notice of that price increase. You may provide Pharmac with this written notice at any time after, but not before, the End Date. In the event you increase the price at which you supply the Tender Item under this paragraph (a)(iv), you will not subsequently increase the price at which you supply the Tender Item for at least 12 months from the effective date of the price increase;

(v) you may withdraw the Tender Item from supply on not less than two years' prior written notice (except where the withdrawal is for reasons that Pharmac considers to be wholly outside of your control, in which case you must first provide to Pharmac such information as it may require from you in order to satisfy it, in its sole discretion, that you are required to withdraw supply); and

(vi) if at the time of providing notice under paragraph (a)(v) above, you advise Pharmac that you are required to purchase a significant quantity of extra stock of the Tender Item 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 Tender Item 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 Tender Item (including delisting the Tender Item 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 Tender Item from supply on not less than six months' prior written notice. You may provide Pharmac with this written notice at any time after, but not before, the date that the particular strategy takes effect in the Pharmaceutical Schedule.

1.4 Withdrawal of Principal Supply Status

(a) Pharmac may withdraw Principal Supply Status in relation to your hospital supply of the Tender Item (in which case clauses 1.1, and 1.2 of this Schedule will no longer apply), by written notice to you at any time during the Principal Supply Period if:

(i) you have failed to notify Pharmac as required under clause 7.1 of this Schedule;

(ii) you fail, for a period of 30 days, to supply the Tender Item in accordance with this Agreement to any of the DHB Hospitals including to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding);

(iii) any Consent for the Tender Item required under clause 2 of this Schedule is withdrawn;

(iv) you have failed to comply with clause 6 of this Schedule on more than one occasion; or

(v) you otherwise fail to supply the Tender Item in accordance with this Agreement.

(b) In the event that Pharmac exercises its rights under clause 1.4(a) above in relation to a Tender Item, it may also withdraw Principal Supply Status in relation to your hospital supply of all forms and strengths or presentations (as applicable) of that Tender Item (in which case clauses 1.1, and 1.2 of this Schedule will no longer apply), following a recommendation to that effect from its clinical advisors, either by the written notice provided under clause 1.4(a) above or by further written notice to you at any time during the Principal Supply Period or (in anticipation) during the First Transition Period.

(c) Any withdrawal of Principal Supply Status for hospital supply is without prejudice to Pharmac's rights under clauses 7.2 and 7.3 of this Schedule.

1.5 Suspension of Principal Supply Status

(a) If, at any time during the Principal Supply Period or (in anticipation) during the First Transition Period, you are unable to meet demand for the Tender Item, or you notify Pharmac under clause 7.1 of this Schedule of a Potential Out-of-Stock Event, or you otherwise fail to supply the Tender Item in accordance with this Agreement, then

Pharmac may suspend Principal Supply Status in relation to your hospital supply of the Tender Item for the period of such inability.

(b) In the event that Pharmac exercises its rights under clause 1.5(a) above in relation to a Tender Item, it may also suspend Principal Supply Status in relation to your hospital supply of all forms and strengths or presentations (as applicable) of that Tender Item, following a recommendation from its clinical advisors, either by the written notice provided under clause 1.5(a) above or by further written notice to you at any time during the Principal Supply Period or (in anticipation) during the First Transition Period.

(c) Any suspension of Principal Supply Status for hospital supply is without prejudice to Pharmac's rights under clauses 7.2 and 7.3 of this Schedule.

(d) Pharmac may, at any time, in its sole discretion, notify you of the date on which the suspension of Principal Supply Status under this clause 1.5 ceases and on which date:

(i) Principal Supply Status for hospital supply is to be re-implemented in respect of the Tender Item; or

(ii) Principal Supply Status for hospital supply is to be withdrawn in accordance with clause 1.4 of this Schedule.

2. Consents

2.1 Warranty and indemnity that Consents are held

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

(a) Pharmac is entitled to terminate this Agreement by 14 days' written notice to you; and

(b) whether or not Pharmac terminates this Agreement under paragraph (a) above, you are to indemnify the Funder for any additional costs incurred by it (or by Pharmac on its behalf) as a result of that failure to hold all necessary Consents. This clause confers a benefit on (and is enforceable by) the Funder in accordance with the Contract and Commercial Law Act 2017, Part 2, Subpart 1.

2.2 Changed medicine notification

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

(a) you must immediately notify Pharmac; and

(b) Pharmac may take such action as it considers appropriate in relation to that Tender Item or the CMN Tender Item including (but not limited to):

(i) withdrawing Principal Supply Status for the Tender Item;

(ii) reviewing the terms of listing of that Tender Item; and

(iii) determining whether, and the extent to which, DHB Hospitals may purchase the CMN Tender Item.

3. Price

3.1 Price change

(a) Subject to clauses 3.1(b)(ii), (iii) and (iv) of this Schedule, you must change the price at which you supply the Tender Item to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), to the Price with effect from the 12th day of the month prior to the Start Date. If your brand of the Tender Item is not listed on the Pharmaceutical Schedule at the beginning of the First Transition Period, it must be available for supply or sale, and you must supply or sell it, at the Price on and from the 12th day of the month prior to the Start Date.

(b) In the event your brand of the Tender Item 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 Tender Item to the Price on the 12th day of the month prior to the Start Date, and you shall provide price support to wholesalers and other such distributors for a maximum 4 weeks stock on hand (or such other level of stock as agreed between you and Pharmac) of the Tender Item 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 Tender Item must be available for supply and you must supply the Tender Item, at the Price from the 1st day of the month prior to the Start Date, and the Tender Item will be subsidised at the Price from the Start Date which is conditional upon you having at least 2 months Lead Time for the Tender Item; and

(iii) notwithstanding clauses 3.1(b)(i) or (ii) above, if the Price would result in a price increase for your brand of the Tender Item you must supply the Tender Item at the Price from the 22nd day of the month prior to the Start Date, and the Tender Item will be subsidised at the Price from the Start Date; and

(iv) notwithstanding clauses 3.1(b)(i), (ii) or (iii) above, Pharmac may agree a process with you, that results in your brand of the Tender Item being available for supply and you must supply the Tender Item, which includes a rebate (as applicable), at the Price from the 22nd day of the month prior to the Start Date, and you shall provide price support to wholesalers and other such distributors for a maximum 4 weeks stock on hand (or such other level of stock as agreed between you and Pharmac) of the Tender Item held at wholesalers and other

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

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

(c) You shall upon request by Pharmac, provide information on how you intend to manage the price changes stated in clauses 3.1(b)(i) to (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.

3.2 Supply price

Subject to clause 3.1 of this Schedule, during each of the First Transition Period, the Principal Supply Period and the Final Transition Period, if applicable in accordance with clause 1.1 of this Schedule, the price at which the Tender Item is supplied by you to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), must not exceed the Price.

3.3 Supply at lower price

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

3.4 Tender Item 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.

3.5 Unsold stock following delisting

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

4. Invoicing and Payment

4.1 Invoice

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

(a) your delivery note reference number;

(b) the particular DHB's purchase order reference number (if applicable);

(c) the net amount payable in respect of the Tender Item supplied to that DHB in accordance with this Agreement;

(d) full details in respect of the Tender Item supplied to that DHB in accordance with this Agreement, including the:

(i) DHB's item codes;

(ii) quantity of the Tender Item supplied;

(iii) price of the Tender Item;

(iv) cost of freight for orders that included the Tender Item (only where applicable under clause 1.1(b) above);

(v) total cost for the total amount of the Tender Item supplied; and

(e) any other information that DHB Hospital requires you to supply.

(f) The provisions of clause 4.1 do not apply to the extent that both parties have agreed to alternative or varied invoicing arrangements in respect of a particular Tender Item.

4.2 Payment

(a) Provided that the Tender Item has been supplied in accordance with this Agreement, and the particular DHB receives an invoice in accordance with clause 4.1 above, payment by the DHB Hospital to you of the amount required to be paid by it is expected to occur:

(i) by electronic funds transfer or such other method of payment as is designated by that DHB Hospital;

(ii) on the 20th day of the month following the month to which the invoice for the Tender Item relates, or, if the 20th day of the month is not a business day, then on the next business day following the 20th of the month.

(b) Where you invoice a DHB Hospital later than the tenth day following the month to which the invoice in respect of the Tender Item relates then, provided that the Tender Item has been supplied in accordance with this Agreement, and the invoice otherwise accords with clause 4.1 above, payment by the DHB Hospital to you of the amount required to be paid by it is expected to occur:

(i) by electronic funds transfer or such other method of payment as is designated by that DHB Hospital;

(ii) on the 20th day of the month following the month in which you invoice the DHB for the Tender Item, or, if the 20th day of the month is not a business day, then on the next business day following the 20th of the month.

4.3 Future payment

(a) A particular DHB Hospital's failure to dispute any invoice prior to payment does not prejudice that DHB Hospital's right subsequently to dispute the correctness of such an invoice, nor its ability to recover any amount of overpayment from you.

(b) A DHB Hospital may withhold, deduct or set off the amount of any overpayment or any amount recoverable by that DHB Hospital from you under this Agreement from any future amount owing to you.

4.4 Contracts privity

This clause 4 confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contract and Commercial Law Act 2017, Part 2, Subpart 1.

5. Emergency and disaster supply

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

(a) source the Tender Item from other suppliers and distributors within New Zealand; and

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

6. Defective and short-dated Tender Items

6.1 Tender Item recall

(a) In the event that you are required by the Ministry of Health or any other authorities to recall the Tender Item or a particular batch of the Tender Item, you will notify Pharmac and the relevant DHB Hospitals immediately you become aware of the need to recall the Tender Item or that batch of the Tender Item.

(b) You will use your best endeavours to provide replacement Tender Items to DHB Hospitals as soon as possible.

(c) If you fail to provide replacement Tender Items or an Alternative Pharmaceutical within what DHBs consider to be a reasonable time frame, then DHB Hospital(s) may purchase an Alternative Pharmaceutical elsewhere. Any reasonable additional costs incurred by DHB Hospital(s) in purchasing such an Alternative Pharmaceutical will be met by you on demand by Pharmac or the DHB Hospital(s) and will be recoverable from you as a debt due to Pharmac and to the DHB Hospital(s), as applicable.

(d) In the event that the Tender Item or a particular batch of the Tender Item is recalled as contemplated by paragraph (a) above, you shall immediately refund to the relevant DHB Hospitals all money paid by them to you for or on account of the Tender Item or that batch of the Tender Item and such money will be recoverable from you as a debt

due to the relevant DHB Hospitals, unless you have provided a replacement Tender Item to the relevant DHB Hospitals' satisfaction.

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

6.2 Shelf-life of Tender Item

(a) You will not supply the Tender Item if:

(i) the remaining shelf-life of the Tender Item is less than six months; or

(ii) where the total shelf-life of the Tender Item is less than six months, the remaining shelf-life is less than 75% of the Tender Item's total shelf-life,

without prior agreement from the relevant DHB Hospital.

(b) If you have an agreement with the relevant DHB Hospital to supply the Tender Item, where the total shelf-life of the Tender Item is less than six months and the remaining shelf-life is less than 75% of the Tender Item's total shelf-life, and that DHB Hospital does not use the Tender Item before its expiry or use-by date, you agree to allow that DHB Hospital to return the Tender Item to you and to provide that DHB Hospital with a credit for the Tender Item.

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

7. Out-of-stock arrangements

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

(a) You must notify Pharmac in writing as soon as you have reasonable cause to believe at any time that you will fail to supply the Tender Item in accordance with this Agreement and, in any event, you must notify Pharmac and the relevant DHB Hospitals if at any time a Potential Out-of-Stock Event occurs, including during the Principal Supply Period or the First Transition Period.

(b) If a Potential Out-of-Stock Event occurs, or your failure to supply the Tender Item in accordance with this Agreement will result in insufficient stock of the Tender Item being available, then at Pharmac's option:

(i) Pharmac may implement an arrangement with another supplier to supply an Alternative Pharmaceutical (including an arrangement for back-up supply); and/or

(ii) you must use your best endeavours to procure, as soon as practicable, an Alternative Pharmaceutical for supply to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), at the Price, and if you are unable to do so you will pay to DHB Hospitals any additional costs incurred by DHB Hospitals as a

result of the purchase price for the Alternative Pharmaceutical being higher than the Price.

7.2 General indemnity

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

(a) your inability to meet demand for supply of the Tender Item;

(b) your withdrawal of the Tender Item from supply;

(c) any failure to have and maintain a Consent as specified in clause 2 of this Schedule;

(d) any failure to notify Pharmac in accordance with clause 7.1 above; or

(e) for any other reason.

This indemnity:

(f) covers all additional costs, including without limitation all costs (if any) incurred in securing and purchasing an Alternative Pharmaceutical, incurred by DHB Hospitals (or by Pharmac on their behalf) as a result of your failure that are additional to any costs specified in clause 7.3; and

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

7.3 Liquidated damages

(a) If you fail to supply the Tender Item in accordance with this Agreement (other than for reasons that Pharmac reasonably considers, following discussion with you, to be wholly outside your control) and:

(i) you have not notified Pharmac and the relevant DHB Hospitals under clause 7.1 of this Schedule, then without prejudice to Pharmac's and the relevant DHB Hospitals' rights under clause 7.2 above, but subject to paragraph (e) below, you must pay to Pharmac (for the benefit of Pharmac and DHB Hospitals) liquidated damages for the administrative and/or operational costs incurred by Pharmac and DHB Hospitals as a result of your failure to supply in the amount of $50,000 per Tender Item in respect of which you failed to notify Pharmac; or

(ii) you have notified Pharmac and the relevant DHB Hospitals under clause 7.1 of this Schedule, then without prejudice to Pharmac's and the relevant DHB Hospitals' rights under clause 7.2 above you are not liable to pay any liquidated damages under this clause 7.3.

(b) If, having notified Pharmac and the relevant DHB Hospitals under clause 7.1 of this Schedule, you remain able to, and you continue to, supply the Tender Item, or an Alternative Pharmaceutical in accordance with clause 7.1(b)(ii) of this Schedule, such that there is no interruption to supply of the Tender Item or of the Alternative Pharmaceutical in accordance with this Agreement, you will not be liable for any costs unless Pharmac, in its sole discretion, has considered it necessary to enter into an arrangement with an alternative supplier under which Pharmac or the relevant DHB Hospitals have agreed to make a payment to that supplier to ensure continuity of supply, in which case you must indemnify the relevant DHB Hospitals and Pharmac

for that payment. Such indemnity will be limited to an amount of $10,000 per Tender Item.

(c) You acknowledge and agree that:

(i) the amounts of liquidated damages in this clause represent a reasonable estimate of the administrative and operational costs incurred by Pharmac and DHB Hospitals (including the use of staff and loss of opportunity as a result of use of staff time, and communication costs), the estimate being based on Pharmac's and DHB Hospitals' previous experience; and

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

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

(d) Where a Tender Item in respect of which you are liable to pay liquidated damages pursuant to clause 7.3(a)(i) above also has Principal Supply Status for community supply and where you would otherwise be liable to pay the same amount of liquidated damages in respect of any corresponding failure under the terms of such Principal Supply Status, you will only be required to pay liquidated damages of $50,000 in total in respect of both supply failures.

(e) All amounts referred to in this clause are plus GST.

7.4 Failure to supply

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

(a) no stock of the Tender Item is physically held by you or on your behalf in New Zealand;

(b) the only stock of the Tender Item physically held by you or on your behalf in New Zealand is stock to which clause 6.2(a)(i) or (ii) of this Schedule applies and no agreement has been reached with the relevant DHB Hospital in terms of clause 6.2(a) of this Schedule;

(c) you fail, directly or indirectly, to ensure that all orders for the Tender Item are filled (without restricting quantities that may be ordered), including in particular where not all patients for whom the Tender Item is prescribed receive the full amount of the Tender Item they require, or to which they are entitled, under their prescriptions, without delay;

(d) you fail to supply the Tender Item on and from the Start Date.

7.5 Default interest and recovery costs

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

(a) interest will accrue in such sum as remains unpaid at a rate per annum equal to the relevant SME overdraft rate (weighted average rate) of the Reserve Bank of New Zealand plus five percentage points, calculated and compounded on a daily basis, from the due date until such time as the sum due (including interest) is paid in full. This obligation to pay default interest is to arise without the need for a notice or demand from Pharmac for such default interest; and

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

8. Termination and restrictions

8.1 Termination and restrictions for clinical reasons

Pharmac reserves the right, but only after consultation with you and a relevant medical adviser (being either the Ministry of Health, PTAC or its Specialist Advisory Committees), to:

(a) terminate this Agreement at any time during the Principal Supply Period or the First Transition Period if the medical adviser determines for clinical reasons that it is no longer appropriate to have either:

(i) in the case of any Tender Item that is a Chemical Entity, any Tender Item, including the Tender Item or any relevant Alternative Pharmaceutical, having Principal Supply Status for hospital supply of that form and strength of the Tender Item with Principal Supply Status;

(ii) in the case of any Tender Item that is a Medical Device, any Tender Item, including the Tender Item or any relevant Alternative Pharmaceutical, having Principal Supply Status for hospital supply of that presentation and/or form and strength of the Tender Item with Principal Supply Status; or

(iii) the Tender Item as the brand having Principal Supply Status; and/or

(b) impose at any time during the Principal Supply Period or the Transition Periods restrictions on the prescribing or dispensing of a Tender Item if those restrictions are necessary for clinical reasons.

8.2 Termination following an audit

Pharmac may terminate the Agreement, or withdraw Principal Supply Status for hospital supply in relation to a Tender Item, at any time during the Principal Supply Period or the Transition Periods, if you fail to remedy any area of non-compliance in accordance with clause 3(b) of Schedule Four.

9. Guarantee

(a) Pharmac may require an entity acceptable to it to provide a guarantee (in a form satisfactory to Pharmac) of your performance obligations under clauses 7.2 and 7.3 of this Schedule including, without limitation, the payment of any sum payable under the indemnity or as liquidated damages pursuant to those clauses for any failure to supply

the Tender Item 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 Tender Item for all claims made by Pharmac under the guarantee.

10. Access by Pharmac to price and volume data

(a) You acknowledge that Pharmac and its agents will require access to price and volume data held by you and DHB Hospitals in respect of the Tender Item covered by this Agreement to assist Pharmac to carry out its statutory function in relation to managing the purchasing of hospital pharmaceuticals on behalf of DHBs.

(b) Notwithstanding any other provisions in this Agreement, including clauses 9.1 and 9.2 of Schedule Three regarding confidential information, you agree that where the circumstances in this clause apply, a DHB Hospital may provide Pharmac and its agents with any price and volume data held by that DHB Hospital in respect of a Tender Item covered by this Agreement and Pharmac and its agents may provide such data on DHBs.

(c) You agree that within 10 business days following any request from Pharmac, you will provide Pharmac with volume data in respect of the Tender Item covered by this Agreement for each month of the period specified in that request. The provision of volume data under this paragraph (c) shall include but not be limited to a breakdown of the stock of the Tender Item held by each DHB Hospital, distributor and third party compounder.

11. PCTs

11.1 Listing in Section B of the Pharmaceutical Schedule

(a) Where the Tender Item is a PCT, you acknowledge and agree that Pharmac may list the Tender Item 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 Tender Item 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 Tender Item for use in the community;

(ii) listing of the Tender Item in Section B will, at Pharmac's option, be additional to or instead of listing in Part II of Section H;

(iii) references to the "listing" of the Tender Item will, where applicable, be to the listing of the Tender Item in Section B of the Pharmaceutical Schedule (and references to "list", "listed", "delist", "delisted", and "delisting" are to be interpreted accordingly); and

(iv) the standard terms of listing of the Tender Item in Section B of the Pharmaceutical Schedule will, except to the extent otherwise advised in writing

by Pharmac, be the terms set out in Schedule Four and this Schedule, and for that purpose all references in Schedule Four and this Schedule to "Section H" will be deemed to be references to "Section B".

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

(d) Where the Tender Item is a PCT, clause 7.1 of this Schedule will be deleted and replaced by the following:

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

(a) You must notify Pharmac in writing as soon as you have reasonable cause to believe that you will fail to supply a Tender Item in accordance with this Agreement and, in any event, you must notify Pharmac and the relevant DHB Hospitals if at any time a Potential Out-of-Stock Event occurs, including during the Principal Supply Period or the First Transition Period.

(b) If you fail to supply a Tender Item in accordance with this Agreement for more than 1 business day to any DHB Hospital, then:

(i) you must use your best endeavours to procure, within what the relevant DHB Hospitals consider to be a reasonable period of time, an Alternative Pharmaceutical for supply to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding) at the Price; and

(ii) if you fail to procure an Alternative Pharmaceutical at the Price in accordance with sub-clause (i) above (other than for reasons that Pharmac reasonably considers, following discussion with you, to be wholly outside your control) then, at Pharmac's option:

(A) you must pay to Pharmac (for the benefit of Pharmac and DHB Hospitals) any additional costs that Pharmac incurs or that the relevant DHB Hospitals incur as a result of the purchase of the Alternative Pharmaceutical; or

(B) Pharmac may implement an arrangement with another supplier to supply an Alternative Pharmaceutical (including an arrangement for back-up supply), and you must pay to Pharmac (for the benefit of Pharmac and DHB Hospitals) any additional costs that Pharmac incurs or that the relevant DHB Hospitals incur as a result of the purchase of the Alternative Pharmaceutical.

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

Schedule 7: Contract Terms for Tender Items with Rebates

Not applicable for this RFT.

Schedule 8: Other special terms and conditions

Not applicable for this RFT.

Appendix A

Tender Submission Form

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

<Tenderer to Insert Date>

Director of Operations
Pharmac

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

Dear Lisa,

Tender bid for the supply of aripiprazole, celecoxib, etoricoxib and/or prednisolone to DHB Hospitals and community pharmacies – commercial in confidence

In response to your request for tenders (**RFT**) dated 19 October 2021, we put forward the following Tender Bid(s) in respect of aripiprazole, celecoxib, etoricoxib and/or prednisolone.

Set out below is further information in support of our Tender Bid.

1. Our Contact Details	
Trading name:	*[insert the name that you do business under]*
Full legal name (if different):	*[if applicable]*
Physical address:	*[if more than one office – put the address of your head office]*

Appendix A

Postal address:	*[e.g. P.O Box address]*
Registered office:	*[if you have a registered office insert the address here]*
Business website:	*[url address]*
Type of entity (legal status):	*[sole trader / partnership / limited liability company / other please specify]*
Registration number:	*[if your organisation has a registration number insert it here e.g. company registration number]*
Country of residence:	*[insert country where you (if you are a sole trader) or your organisation is resident for tax purposes]*
Does your organisation identify as being a Māori business? Pharmac is committed to the Government's progressive procurement approach to increase the diversity of government suppliers and achieve broader economic and social outcomes, with a specific focus on Māori businesses. As part of this approach, Pharmac is committed to gaining a better understanding of how our agency can support the economic and social outcomes for Māori through this procurement. One aspect is understanding what roles Māori businesses have in the pharmaceutical supply chain and how we can support Māori businesses in those roles. Pharmac is therefore gathering information from organisations as to whether they identify as a Māori business. A Māori business for Government procurement purposes is: • One that has at least 50% Māori ownership, or • A Māori Authority as defined by Inland Revenue. • Within these definitions, does your organisation identify as a Māori business? This information will inform	*[Yes / No]* *As part of adopting a progressive procurement policy, Pharmac are committed to understand and support what roles Māori businesses play in our supply chain*

Pharmac's supplier's database and will be reported to NZGPP, subject to any concerns you identify (see below).	
Pharmac is required to report to NZGPP on whether an organisation identifies as a Māori business as part of new progressive procurement reporting requirements. Please indicate either 'Yes' or 'No' as to whether you agree to Pharmac reporting on your organisation's status. If you indicate 'No', please provide reasons for our consideration.	*[Yes / No]*

2. Our Point of Contact	
Contact person:	*[i.e., who communications relating to the attached bid(s) should be made to]*
Position:	
Phone number:	
Mobile number:	
Email address:	

3. Information About Our Organisation	
(a) Information about our Organisation structure:	
(b) Information about our management and technical skills:	
(c) Information about our financial resources:	

(d) Information about our, or our supplier's, existing supply commitments, including other markets supplied:	
(e) Information about our, or our supplier's, previous supply performance, and ability to ensure continuity of supply of the Tender Items (s)	
(f) Information about our quality assurance processes:	
(g) The New Zealand Government is committed to sustainable and inclusive government procurement and the Supplier Code of Conduct outlines the Government's expectations of suppliers in this respect, please outline: • how your Organisation meets or exceeds the expectations set out in the Supplier Code of Conduct	
(h) Please outline: how does your Organisation support social, economic, cultural and environmental outcomes beyond supply of Pharmaceuticals (see New Zealand Government Procurement Broader Outcomes). Please also outline how your organisation: • supports New Zealand businesses, including Māori, Pasifika and regional businesses, as well as social enterprises if relevant • supports improving conditions for New Zealand workers and support workforce diversity	
(i) Please outline how your Organisation would support improving access and responsible use of medicines (e.g. services and resources that would be offered). In particular to groups experiencing health inequities in New Zealand, specifically Māori and Pacific peoples (adults and children)	
(j) Any additional information Pharmac should consider under its Factors for Consideration Framework:	

Appendix A

4.1 Information About Our Proposed Products - Aripiprazole **For clarity in responding this section of the form has been repeated for each chemical.** **You may remove the sections where you are not bidding on a chemical.**	
(a) Evidence for market approval and any other required consents:	
(b) For any Tender Items without market approval, but where the dossier has been submitted to Medsafe, please provide evidence of the submission, and status of regulatory approval application:	
(c) For any Tender Items without market approval and where the dossier has not been submitted to Medsafe, please provide details of the planned submission date and timeframes to achieve registration:	
(d) Insert the details of any other consents required for the Tender Item(s) and any further details that are relevant to assessing the likelihood and timing of your brand gaining all the necessary consents:	
(e) If not available in the Medsafe approval, please provide details of the packaging type (eg blister, bottle) and descriptions (artwork) a description of the tablet(s) (eg size, shape, colour, markings), and shelf-life:	
(f) The name and location of the manufacturer(s) of the finished product(s) (and name and location of the packaging site, if different):	

(g) The name and location of the manufacturer(s) of the active ingredients:	
(h) The name and location of the alternative manufacturers of the finished product(s) and active ingredients (if any):	
(i) Your proposed distribution and supply arrangements for the Tender Item(s), including batch sizes, approximate manufacturing time, and approximate shipping time:	
(j) other markets in which you currently provide the Tender Item	
(k) Key features of our Tender Bid	
(l) Please confirm that you will supply physical sample of the Tender Item(s), to be provided within 10 business days of Pharmac's request.	

4.2 Information About Our Proposed Products - Celecoxib **For clarity in responding this section of the form has been repeated for each chemical.** **You may remove the sections where you are not bidding on a chemical.**	
(a) Evidence for market approval and any other required consents:	
(b) For any Tender Items without market approval, but where the dossier has been submitted to Medsafe,	

please provide evidence of the submission, and status of regulatory approval application:	
(c) For any Tender Items without market approval and where the dossier has not been submitted to Medsafe, please provide details of the planned submission date and timeframes to achieve registration:	
(d) Insert the details of any other consents required for the Tender Item(s) and any further details that are relevant to assessing the likelihood and timing of your brand gaining all the necessary consents:	
(e) If not available in the Medsafe registration, please provide details of the packaging type (eg blister, bottle) and descriptions (artwork) a description of the tablet(s) (eg size, shape, colour, markings), and shelf-life:	
(f) The name and location of the manufacturer(s) of the finished product(s) (and name and location of the packaging site, if different):	
(g) The name and location of the manufacturer(s) of the active ingredients:	
(h) The name and location of the alternative manufacturers of the finished product(s) and active ingredients (if any):	
(i) Your proposed distribution and supply arrangements for the Tender Item(s), including	

batch sizes, approximate manufacturing time, and approximate shipping time:	
(j) other markets in which you currently provide the Tender Item	
(k) Key features of our Tender Bid	
(l) Please confirm that you will supply physical sample of the Tender Item(s), to be provided within 10 business days of Pharmac's request.	

4.3 Information About Our Proposed Products - Etoricoxib **For clarity in responding this section of the form has been repeated for each chemical.** **You may remove the sections where you are not bidding on a chemical.**	
(a) Evidence for market approval and any other required consents:	
(b) For any Tender Items without market approval, but where the dossier has been submitted to Medsafe, please provide evidence of the submission, and status of regulatory approval application:	
(c) For any Tender Items without market approval and where the dossier has not been submitted to Medsafe, please provide details of the planned submission date and timeframes to achieve registration:	
(d) Insert the details of any other consents required for the Tender Item(s) and any further details that	

are relevant to assessing the likelihood and timing of your brand gaining all the necessary consents:	
(e) If not available in the Medsafe registration, please provide details of the packaging type (eg blister, bottle) and descriptions (artwork) a description of the tablet(s) (eg size, shape, colour, markings), and shelf-life:	
(f) The name and location of the manufacturer(s) of the finished product(s) (and name and location of the packaging site, if different):	
(g) The name and location of the manufacturer(s) of the active ingredients:	
(h) The name and location of the alternative manufacturers of the finished product(s) and active ingredients (if any):	
(i) Your proposed distribution and supply arrangements for the Tender Item(s), including batch sizes, approximate manufacturing time, and approximate shipping time:	
(j) other markets in which you currently provide the Tender Item	
(k) Key features of our Tender Bid	
(l) Please confirm that you will supply physical sample of the Tender Item(s), to be provided within 10 business days of Pharmac's request.	

Appendix A

4.4 Information About Our Proposed Products - Prednisolone **For clarity in responding this section of the form has been repeated for each chemical.** **You may remove the sections where you are not bidding on a chemical.**	
(a) Evidence for market approval and any other required consents:	
(b) For any Tender Items without market approval, but where the dossier has been submitted to Medsafe, please provide evidence of the submission, and status of regulatory approval application:	
(c) For any Tender Items without market approval and where the dossier has not been submitted to Medsafe, please provide details of the planned submission date and timeframes to achieve registration:	
(d) Insert the details of any other consents required for the Tender Item(s) and any further details that are relevant to assessing the likelihood and timing of your brand gaining all the necessary consents:	
(e) If not available in the Medsafe registration, please provide details of the packaging type (eg blister, bottle) and descriptions (artwork) a description of the tablet(s) (eg size, shape, colour, markings), and shelf-life:	
(f) The name and location of the manufacturer(s) of the finished product(s) (and name and location of the packaging site, if different):	

(g) The name and location of the manufacturer(s) of the active ingredients:	
(h) The name and location of the alternative manufacturers of the finished product(s) and active ingredients (if any):	
(i) Your proposed distribution and supply arrangements for the Tender Item(s), including batch sizes, approximate manufacturing time, and approximate shipping time:	
(j) other markets in which you currently provide the Tender Item	
(k) Please provide information on how your Organisation would support improving access and responsible use of medicines (eg services and resources that would be offered). In particular to groups experiencing health inequities in New Zealand, specifically Māori and Pacific peoples (adults and children)	
(l) Key features of our Tender Bid	
(m) Please confirm that you will supply physical sample of the Tender Item(s), to be provided within 10 business days of Pharmac's request.	

5. Environmental Sustainability

Appendix A

(a) Does your Organisation have an environmental/sustainability policy?	Yes		No	
(b) Does your Organisation have a sustainability report?	Yes		No	
(c) If yes to either of the two above questions, please attach or link:				
(d) How does your Organisation contribute to environmental sustainability?	*Please describe the measures you take to contribute to environmental sustainability – in general and specifically in relation to this RFT*			
(e) Has your Organisation received any environmental/sustainability award(s)?	Yes		No	
(f) If yes, provide details:				
(g) Has your Organisation received any environmental fine/prosecution(s)?	Yes		No	
(h) If yes, provide details:				
(i) Has your Organisation received any environmental audit(s) or does it comply with a recognised standard?	Yes		No	
(j) If yes, provide details:				

Appendix A

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

_____
<Insert name>
<Insert designation>

Appendix A

Combined Tender Bids

You may submit a Combined Community/Hospital Tender Bid.

Table One: Combined Bids for Community and Hospital supply

Tender Item	Unit (Pack Size) e.g. (30 tablet pack)	Currency	Listing Amount (Price/Pack)	Brand Name	Market Approval (Yes/No)	If No Market Approval: Actual or Expected Date of Dossier Submission To Medsafe	Lead Time (Months)	Lead Time Comment
[Chemical Entity– Form and Strength (other requirement if relevant eg packaging type)]		NZD	$					

Key	
	Product Information
	Combined Bid for Community AND Hospital market Principal Supply Status.

Appendix A

Aggregate 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 the terms stated in Clause 2 of Schedule 3 of the RFT.

Aggregate bids may be submitted within a chemical only. That means a separate pricing entry can be included in the tender submission form where the bid is for all strengths within a chemical, alongside bids for individual strengths

TableTwo Aggregated Tender Bids

Tender Item	Unit (Pack Size) eg (30 tablet pack)	Currency	Listing Amount (Price/Pack)	Brand Name	Market Approval (Yes/No)	If No Market Approval: Actual or Expected Date of Dossier Submission To Medsafe *	Lead Time (Months)	Lead Time Comment
[Chemical Entity– Form and Strength (other requirement if relevant eg packaging type)]		NZD						

Key	
	Product Information
	Combined Bid for Community AND Hospital market Principal Supply Status.