

18 September 2024

Dear Supplier

REQUEST FOR TENDER – SUPPLY OF BEVACIZUMAB TO HEALTH NZ HOSPITALS

Pharmac invites tenders for the supply of bevacizumab to Health NZ hospitals in New Zealand.

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

- (a) Schedule 1 sets out the definitions used in this RFT
- (b) Schedule 2 specifies the pharmaceuticals and scenarios for which you may submit a Tender Bid in relation to hospital supply and provides background information regarding this RFT
- (c) Schedule 3 describes the process Pharmac intends to follow in relation to this RFT, and provides instructions on how to submit a Tender Bid in relation to hospital supply
- (d) Schedule 4 sets out terms that will apply if your Tender Bid in relation to hospital supply is awarded Principal Supply Status
- (e) Schedule 5 sets out any rebate terms that will apply if your Tender Bid in relation to hospital supply is awarded Principal Supply Status
- (f) Appendix A contains the RFT response form in which you are to provide details of your tender.

If you wish to submit a Tender Bid in relation to hospital supply, you must submit it to Pharmac via the Government Electronic Tenders Service (GETS) no later than **12:00 pm on 23 October 2024 New Zealand time**.

If you have any questions about this RFT, please post these on GETS prior to 12:00 pm on 15 October 2024.

We will also be holding an online supplier briefing at 2:00 pm NZT Monday 23 September 2024. If you are interested in attending this, please register your interest by emailing procurement@pharmac.govt.nz

We look forward to receiving your Tender Bid.

Yours sincerely



Geraldine MacGibbon
Director, Pharmaceuticals

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Schedule 1: Definitions and interpretation

1. Definitions

In this RFT:

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

Agreement means Schedule Four and includes, to the extent applicable, the other Schedules (including Schedule Five and Schedule Six) and the information on GETS comprising the RFT;

Alternative Brand Allowance means the alternative brand allowance relating to a particular Tender Item and the relevant scenario, in relation to hospital and/or community supply, as indicated as a percentage amount of the Total Pharmaceutical Volume, entitled "ABA Limit" in clause 2.2 in Schedule Two;

Alternative Pharmaceutical means an alternative Pharmaceutical that Pharmac has expressly agreed in writing constitutes an acceptable substitute for that Pharmaceutical;

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

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

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

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

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

Business Day means a day of the week, excluding Saturday, Sunday, and national public holidays in New Zealand. A Business Day starts at 8:30 am and ends at 5:00 pm;

Changed Medicine Notification means a notification provided by you, in accordance with the Medicines Act 1981, to the Director-General of Health, of a planned material change to the Pharmaceutical, and the reasons for the change;

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 clause 2 of Schedule Two and on GETS in relation to this RFT. For the avoidance of doubt, the term Chemical Entity does not include any Medical Device;

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, but excludes:

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

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

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

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

Deadline means 12:00 PM on 23 October 2024 (New Zealand time);

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

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

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

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

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

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

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

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

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

GETS means the Government Electronic Tenders Service;

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

Health NZ Hospital means Health NZ, including its hospital or associated provider unit for which Health NZ purchases pharmaceuticals;

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

Intellectual Property means all industrial and intellectual property rights whether conferred by statute, common law, or in equity, including (but not limited to) copyright, trademarks, designs and patents;

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

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

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

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

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

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

Offer Letter means the letter of offer which must be submitted with the Tender Submission Form;

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

PCT means a Pharmaceutical for which Health NZ Hospitals are eligible to claim a subsidy through the Pharmaceutical Schedule.;

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

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

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

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

- (a) in relation to community supply, wholesalers and other such distributors, and at which the Pharmaceutical is to be subsidised, being the price specified in your successful Tender Submission Form, unless there has been a subsequent price change in accordance with the terms of the 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, Health NZ Hospitals, wholesalers and other such distributors, being the price specified in your successful Tender Submission Form,

unless there has been a subsequent price change in accordance with the terms of the 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/or hospital supply, being the principal supplier of the relevant Tender Item (subject to the Alternative Brand Allowance provisions);

Principal Supply Period means the period beginning on the day after the expiry of the First Transition Period and ending on 31 August 2028;

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

PTAC means the Pharmacology and Therapeutics Advisory Committee;

Quarter means the periods:

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

Relevant Period means the periods:

- (a) beginning on the day after the expiry of the First Transition Period and ending on 30 June 2025;
- (b) 1 July 2025 until 30 June 2026; and
- (c) 1 July 2026 until 30 June 2027; and
- (d) 1 July 2027 until 31 August 2028.

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 Health NZ Hospitals;

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

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

Start Date means:

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

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

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

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

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

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

Tender Item means in the case of a Chemical Entity, a Chemical Entity that conforms with the form and strength of that Chemical Entity (or entities, if applicable) described for such item in the List of Tender Items in clause 2 of Schedule Two;

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

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

Total Pharmaceutical Volume means the total volume of the Pharmaceutical (inclusive of Brand Allowance Pharmaceuticals) subsidised in the community and/or purchased by Health NZ 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, vial, 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 hospital supply, the approximate number of Units of the Tender Item to be subsidised by Pharmac, and claimed for by Health NZ Hospitals, in one year, as specified in Schedule Two and on GETS in relation to this RFT;

Unique Product Identifiers means for each Pharmaceutical:

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

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

2. Interpretation

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

- (a) references to "Health NZ" encompass Health NZ Hospitals;

- (b) references to “Health NZ Hospitals” may reflect that certain operational matters can in practice occur at a local hospital level notwithstanding that Health NZ Hospitals are part of, and not separate legal entities from, Health NZ;
- (c) references to clauses are to clauses in this RFT;
- (d) the headings to clauses will be ignored in construing this RFT;
- (e) the plural includes the singular and vice versa;
- (f) any organisations (including government agencies) referenced in this RFT include their successors;
- (g) a reference to any statute includes that statute, and regulations made under it, as amended from time to time;
- (h) a reference to any statute includes any statute passed in substitution for that statute;
- (i) an obligation not to do anything includes an obligation not to suffer, permit or cause that thing to be done;
- (j) derivatives of any defined word or term have a corresponding meaning;
- (k) all references to dollars are references to New Zealand dollars unless provided otherwise;
- (l) “including” and similar words do not imply any limitation;
- (m) references to “**you**” include any third parties acting on your behalf, including sub-contractors;
- (n) references to the “**listing**” of a Pharmaceutical are to the listing of that Pharmaceutical on the Pharmaceutical Schedule (and references to “list”, “listed”, “delist”, “delisted”, and “delisting” are to be interpreted accordingly); and
- (o) none of the terms are to be construed against a party by reason of the fact that that term was first proposed or was drafted by that party.

Schedule 2

Schedule 2: Pharmaceuticals 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) At the time of the release of this RFT, Pharmac is not aware of the existence of any patents regarding the Tender Items in this RFT.
- (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, including infringement of process patents.

1.3 Unit Volume figures

- (a) Except where indicated otherwise, the Unit Volume figures, in relation to hospital supply, are based on forecast volumes for the year ending 30 June 2025.
- (b) The figures referred to in paragraph (a):
 - (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) in particular, if these figures change at any time during the period from Pharmac's pre-tender consultation until decisions have been made about acceptance of Tender Bids for all Tender Items, Pharmac is not obliged to notify you of any such change.
- (c) You acknowledge and agree that in submitting your Tender Bid you will rely on your own knowledge, skill and independent advice or assessment of the market size for any Tender Item and Pharmac is to have no liability in that regard.

1.4 Special terms

Where there are any special terms relating to a particular Tender Item, those terms are indicated in the List of Tender Items set out at 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) There is no current subsidy for this Tender Item. Any brand can be purchased at any price by Health NZ hospitals for the currently funded use. This may change as a result of this RFT.

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1.6 Alternative Brand Allowance

The Alternative Brand Allowance relating to a particular Tender Item and scenario, in relation to hospital supply and/or community supply, is indicated as a percentage amount entitled “ABA Limit” in clause 2.2 below.

1.7 PCTs

Where a “PCT” is indicated, you may submit a Tender Bid for Principal Supply Status for hospital supply for that Tender Item on the basis that, if Pharmac accepts your Tender Bid, the Tender Item would be listed in Section B and/or Part II of Section H of the Pharmaceutical Schedule subject to clause 6.6 of Schedule Four.

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

1.8 Vial and ampoule form

Unless otherwise stated, where a Tender Item specifies either:

- (a) an ampoule; or
- (b) a vial,

form of the Chemical Entity, your brand of the relevant Chemical Entity for which you submit a bid may be in either ampoule or vial 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 ampoule and vial form of that Chemical Entity as separate line items, you must submit a bid for the same form and strength for each line item in that Tender Item.

1.11 Anticipated timetable

- (a) Following the receipt of Tender Bids, Pharmac anticipates the following indicative timetable:
 - (i) the Evaluation Committee evaluating Tender Bids in early November 2024
 - (ii) Pharmac consulting on any Tender Bid in December 2024;
 - (iii) Pharmac’s Board of Directors (or its delegate, where applicable) deciding which Tender Bid (if any) to accept for bevacizumab in or after January or February 2025; and;
 - (iv) the Start Date of the Pharmaceutical would commence at the earliest possible time (allowing for Lead Time) after a decision has been made.
- (b) Under this indicative timetable, Pharmac is aiming to make any changes to the Pharmaceutical Schedule by 1 April 2025.
- (c) The timeframes set out in paragraphs (a) and (b) are only approximate and may be extended without notice by Pharmac, if any stages of the RFT process take longer than anticipated.

Schedule 2

2. List of Tender Items

2.1 Products to be Tendered

Pharmac will only consider tender bids in response to this RFT that are for the following presentations of bevacizumab.

Presentation	Market
Inj 25 mg per ml, 4 ml vial	Section H (+ PCT)
Inj 25 mg per ml, 16 ml vial	Section H (+ PCT)

Tender Bids for bevacizumab will not be awarded by presentation. Each Tender Bid is for all presentations proposed. See *Presentations* above for which presentations must be included in any Tender Bid.

2.2 Funding Scenarios

- (a) Pharmac would consider the following two funding scenarios as potential outcomes of the RFT. Tender Bids must include a bid for Scenario A and may include a bid for Scenario B.
- (i) **Scenario A:** Funding of bevacizumab for the existing market (as per the indication restrictions in Section H of the Schedule), and for the ovarian cancer (advanced) and hepatocellular carcinoma (unresectable, 1st line) markets, with a total 10% ABA Limit for all funded markets combined.
 - (ii) **Scenario B:** Funding of bevacizumab for the existing market (as per the indication restrictions in Section H of the Schedule), and for the ovarian cancer (advanced), hepatocellular carcinoma (unresectable, 1st line), cervical cancer (advanced), and glioblastoma (recurrent or relapsed) markets, with a total 5% ABA Limit for all funded markets combined.

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- (b) The table below outlines the permitted Tender Bid options for the scenarios set out in paragraph (a). Both scenarios are for Hospital supply and PCT. You may submit more than one Tender Bid for each scenario in the Tender Submission Form. No more than one scenario and one Tender Bid will be awarded Principal Supply Status through this RFT process. Please note the mandatory requirements in the table below.

Scenario	Existing market	Ovarian cancer (advanced)	Hepatocellular carcinoma (unresectable, 1 st line)	Cervical cancer (advanced)	Glioblastoma (recurrent or relapsed)	ABA%
A	✓	✓	✓			10%
B	✓	✓	✓	✓	✓	5%

- (c) Pharmac may have regard to the following matters (without limitation) in deciding which (if any) scenario to progress: evaluation of bids (as described in this RFT), the relative ranking of widened access funding proposals on Pharmac’s Options for Investment list, and available budget. Pharmac reserves the right to award a tender for either, or neither, of Scenario A or Scenario B, in its sole discretion.

2.3 Eligibility Criteria

Funding restrictions (also known as eligibility criteria) would apply to funded indications through this RFT. Funding restrictions currently apply to the existing market also ([Current Funding Restrictions](#)).

The eligibility criteria below are based on those recommended to Pharmac by the Cancer Treatments Advisory Committee (CTAC) and/or the Pharmacology and Therapeutics Advisory Committee (PTAC). The criteria are intended to be indicative and may change following consideration of consultation feedback or further advice from CTAC and/or PTAC. Pharmac reserves the right to change the criteria as part of this RFT process.

- (a) Ovarian cancer (advanced)

Initial application – (advanced or metastatic ovarian cancer) only from a relevant specialist or relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following

1. Either:
 - 1.1. The patient has FIGO Stage IV epithelial ovarian, fallopian tube, or primary peritoneal cancer; or

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1.2. Both:

1.2.1. The patient has previously untreated advanced (FIGO Stage IIIB or IIIC) epithelial ovarian, fallopian tube, or primary peritoneal cancer; and

1.2.2. Either:

1.2.2.1. Debulking surgery is inappropriate; or

1.2.2.2. The cancer is sub-optimally debulked (maximum diameter of any gross residual disease greater than 1cm); and

2. Maximum cumulative dose of 135 mg/kg (12 month's treatment); and
3. 18 weeks concurrent treatment with chemotherapy is planned.

Renewal application - (advanced or metastatic ovarian cancer) only from a relevant specialist or relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months where there is no evidence of disease progression.

(b) Hepatocellular carcinoma (unresectable, 1st line)

Initial application – (hepatocellular carcinoma) only from relevant specialist, or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1. Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma; and
2. Patient has preserved liver function (Child-Pugh Classification score of 5-6); and
3. Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma; and
4. Patient has ECOG performance score of 0-2; and
5. To be given in combination with atezolizumab.

(c) Cervical cancer (advanced)

Initial application – (cervical cancer, metastatic, recurrent, persistent) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1. Patient has persistent, metastatic or recurrent carcinoma of the cervix; and
2. The cancer is not amenable to curative surgery or radiation; and
3. The patient has an ECOG performance score of 0-2; and
4. The patient has not received prior funded bevacizumab; and
5. Treatment must be undertaken with concomitant platinum based chemotherapy and paclitaxel.

Note: concomitant platinum based chemotherapy and paclitaxel includes six cycles.

Renewal application – (cervical cancer, metastatic, recurrent, persistent) only from any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where there is no evidence of disease progression.

(d) Glioblastoma (recurrent or relapsed)

Initial application – (relapsed or recurrent high-grade gliomas) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

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All of the following:

1. Either:
 - 1.1. Patient has relapsed glioblastoma multiforme; or
 - 1.2. Patient has relapsed anaplastic astrocytoma; and
2. Patient has been assessed for maximal safe resection and radiotherapy; and
3. Patient has been previously treated with temozolomide; and
4. Patient has not received prior funded treatment with bevacizumab.

Renewal application – (relapsed recurrent high-grade gliomas) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where the patient has clinically stable disease.

2.4 Estimated Market Size

- (a) The following table sets out the estimated subsidised market size of the Chemical Entity, based on the eligibility criteria outlined in clause 2.3 of Schedule 2 above.

The information set out in the table below is approximate and indicative only. Pharmac makes no representation as to the accuracy of this information or as to the level of sales or likely sales of the Chemical Entity and, while Pharmac has taken all reasonable care in preparing the information set out below, it accepts no liability for any errors or omissions in the information. Pharmac is not obliged to notify you in the event of any changes to our estimates of the market size. 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.

- (b) Please note that units are expressed as mg, rather than number of vials.

Scenario A			Year 1	Year 2	Year 3	Year 4	Year 5
Existing market AND ovarian cancer AND hepatocellular carcinoma	Existing market	Patient numbers*	n/a	n/a	n/a	n/a	n/a
		Units (mg)	54,100	54,100	54,100	54,100	54,100

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	Ovarian cancer	Patient numbers	55	89	90	92	93
		Units (mg)	380,270	615,346	622,260	636,088	643,002
	Hepatocellular carcinoma	Patient numbers	73	60	62	63	64
		Units (mg)	895,112	1,007,698	1,067,388	1,097,852	1,118,253

*Patient numbers for existing market not available.

Scenario B			Year 1	Year 2	Year 3	Year 4	Year 5
Existing market AND ovarian cancer AND hepatocellular carcinoma AND cervical cancer AND glioblastoma	Existing market*	Patient numbers	n/a	n/a	n/a	n/a	n/a
		Units (mg)	54,100	54,100	54,100	54,100	54,100
	Ovarian cancer	Patient numbers	55	89	90	92	93
		Units (mg)	380,270	615,346	622,260	636,088	643,002

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	Hepatocellular carcinoma	Patient numbers	73	60	62	63	64
		Units (mg)	895,112	1,007,698	1,067,388	1,097,852	1,118,253
	Cervical cancer	Patient numbers	34	33	32	32	31
		Units (mg)	343,664	431,901	442,676	445,028	435,667
	Glioblastoma	Patient numbers	101	102	103	104	106
		Units (mg)	1,214,207	1,226,228	1,238,250	1,250,272	1,274,316

*Patient numbers for existing market not available.

Schedule 2

3. Background Information

3.1 Background

- (a) Pharmac currently lists bevacizumab on Part II of Section H of the Pharmaceutical Schedule under 'Any Brand' as there is no contract for Price or Subsidy. Please refer to Rule 9.6 of the [Rules of the Schedule](#).
- (b) Bevacizumab is listed under the Monoclonal Antibodies subheading of the Oncology Agents and Immunosuppressants therapeutic group. Bevacizumab is currently funded subject to indication restrictions in Section H. See [Hospital Indication Restriction](#) for bevacizumab.

	Subsidy/Price (NZ\$)	Per	Brand or Generic Manufacturer
BEVACIZUMAB			
Inj 25 mg per ml, 4 ml vial	-	-	'Any brand'
Inj 25 mg per ml, 16 ml vial	-	-	'Any brand'

3.2 Bevacizumab

- (a) Bevacizumab is a biologic medicine. It is a recombinant humanised monoclonal antibody that selectively binds to and neutralises the biologic activity of human vascular endothelial growth factor. Bevacizumab is Medsafe approved for a number of cancer indications but is also used in New Zealand in other settings, as per the Hospital Indication Restrictions in Section H of the Pharmaceutical Schedule.
- (b) There are four additional indications for bevacizumab included within this RFT, for which Pharmac has received and assessed funding applications:
- [P-001366 Ovarian cancer, advanced](#).
 - [P-001618 Hepatocellular carcinoma, unresectable, 1st line \(with atezolizumab\)P-000311 Cervical cancer, advanced](#)
 - [P-000265/ P-000740](#) Glioblastoma, relapsed or recurrent

Full records of the clinical advice Pharmac has received for these proposals are available through the relevant links above to the Application Tracker. Pharmac reserves the right to, at its sole direction and at any time (including within the Principal Supply Period), further widen access to bevacizumab (beyond any such access, or widened access proposals, currently contemplated in this RFT).

3.3 Desired Outcome

Approved products

- (a) Pharmac is seeking to list a brand of bevacizumab (Inj 25 mg per ml, 4 ml vial and inj 25 mg per ml, 16 ml vial) in Part II of Section H and Section B (as per Clause 6.6 in Schedule 4) of the Pharmaceutical Schedule that is approved by Medsafe. Where you submit a Tender Bid that includes unapproved brands of the Chemical Entity, you **MUST** indicate in the Tender Submission Form whether you intend to register your brand of the Chemical Entity with Medsafe. In order to submit a conforming bid, you must provide evidence that demonstrates your ability to obtain Market Approval and Consents for that Tender Item by 12 May 2025, including demonstrating that you have the dossier for the Tender Item

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ready to submit to Medsafe within one month of such a request being made by Pharmac. The brand must be approved by Medsafe prior to supply to market.

- (b) Pharmac seeks to fund bevacizumab in one of the scenarios described in section 2.2 above. Pharmac would prefer products with Lead Times that would support an April 2025 listing date or earlier and reserves the right to negotiate Lead Times with you.
- (c) Where a Tender Bid that includes unapproved brand(s) of the Chemical Entity is conditionally accepted by Pharmac and the necessary Consents are received within a time period specified by Pharmac, the Principal Supply Status (PSS) period would be until 31 August 2028.

3.4 Principal Supply Status

- (a) Through this RFT, Pharmac intends to award the successful supplier(s) PSS for bevacizumab in Part II of Section H of the Pharmaceutical Schedule.
- (b) The awarding of PSS means that the successful supplier's brand would be the principal funded brand of bevacizumab used by Health New Zealand hospitals.
- (c) The successful supplier would be guaranteed at least:
 - (i) 90% of the funded bevacizumab market if Scenario A is progressed.
 - (ii) 95% of the funded bevacizumab market if Scenario B is progressed.
- (d) Brands of bevacizumab other than the PSS brand could be funded for use in up to 10% (Scenario A) or 5% (Scenario B) of the funded market(s), using the alternative brand allowance outlined below.
- (e) The Principal Supply Status period would be until 31 August 2028.

3.5 Alternative Brand Allowance

Typically, the 10% (Scenario A) or 5% (Scenario B) alternative brand allowance (ABA Limit) would be for individuals with particular clinical circumstances who need an alternative brand of treatment funded. Pharmac retains its discretion as to who could access funding for an alternative brand and how funded access to it would be enabled. Funded access to an ABA brand could be by a listing on the Pharmaceutical Schedule or by Pharmac's [Exceptional Circumstances framework](#).

3.6 Transition period

Principal Supply Status would start after a transition period of 5 months following the Start Date.

3.7 Other considerations

- (a) As a result of this RFT, if a tender is awarded for either Scenario A or Scenario B, Pharmac would retain the right at its sole discretion to widen funded access to bevacizumab at any time during the PSS period.
- (b) Any tender bid to widen access to bevacizumab that results from this RFT would be progressed subject to ranking on Pharmac's Options for Investment list. Pharmac would determine its priority for funding relative to other funding proposals (for bevacizumab or other medicines).

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Schedule 3: Tender Process

1. General

1.1 Principal Supply Period

- (a) Hospital Tender Bids are to be submitted on the basis that if your Hospital Tender Bid is accepted, you will have Principal Supply Status for hospital supply for the particular Tender Item for the Principal Supply Period.

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 Health NZ Hospitals. Additionally, where the successful tenderer's brand of the Pharmaceutical is not listed immediately prior to the First Transition Period, the successful tenderer's brand must be available for supply and purchase by Health NZ Hospitals from the applicable dates specified in clause 2.2 of Schedule Four;
 - (ii) the First Transition Period is intended to allow for an orderly transition to the arrangements that will apply during the Principal Supply Period; and
 - (iii) the Final Transition Period is intended to allow for an orderly transition to any new arrangements following the end of the Principal Supply Period.
- (b) Not used.
- (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 of the Chemical Entity is to be deferred until the actual commencement date of the Principal Supply Period, notwithstanding any date previously notified to suppliers by Pharmac as being the intended date of delisting;
 - (B) other brands of that form and strength of the Chemical Entity are to remain listed in accordance with the terms of any existing contract between Pharmac and the particular pharmaceutical supplier in respect of the relevant brand(s) until such time as that supplier's brand of that form and strength of the Chemical Entity is actually delisted.
- (d) Not used.

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- (e) For the avoidance of doubt, any notification by Pharmac of the delisting (subject to Alternative Brand Allowance arrangements) of all other brands of that form and strength of the Chemical Entity on the first day of the Principal Supply Period operates solely as advance notice of the intended delisting of those pharmaceuticals and does not constitute a notice of termination of any existing contract for the supply of those other brands.

1.3 Contract

- (a) Subject to clause 7.4(c) of this Schedule, if Pharmac accepts your Hospital Tender Bid, then a contract on the terms and conditions set out in:
 - (i) your Tender Bid (incorporating any variations as a result of negotiations or discussions under clause 1.6 of this Schedule); and
 - (ii) Schedule Four; and
 - (iii) Schedule Five.

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

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

1.4 Not used

1.5 Not used

1.6 Pharmac may initiate limited negotiations

- (a) Notwithstanding clause 2.4 of this Schedule, Pharmac may, in its sole discretion, initiate negotiations or discussions with you in relation to your Tender Bid about:
 - (i) any of the terms and conditions to apply if your Tender Bid is accepted;
 - (ii) the proposed packaging or pack size of the Tender Item;
 - (iii) your ability to ensure continued availability of the Tender Item throughout the Principal Supply Period;
 - (iv) the price of the Tender Item, but only where Pharmac determines, in its sole discretion, that an increased price for the Tender Item may be necessary for practicality of supply of the Tender Item (for example, because of particular packaging requirements);
 - (v) the Lead Time and/or the Start Date;
 - (vi) any implementation support if acceptance of your Tender bid resulted in a brand change; or
 - (vii) any other matter that Pharmac considers necessary or appropriate.
- (b) If Pharmac initiates negotiations or discussions with you under paragraph (a), and as a result there is a change to any of the terms and conditions relating to the supply of a

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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.

1.7 Termination and amendment of RFT

Pharmac may, having regard to probity principles:

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

1.8 Clinical advice and prioritisation

- (a) Following evaluation of tender bids Pharmac may seek clinical advice from PTAC, a Specialist Advisory Committee or other advisors if required.
- (b) Pharmac may rank preferred tender bids on our Options for Investment list if required. If tender bids that include widening access do not rank high enough to be progressed from within the budget available, Pharmac reserves the right not to accept these tender bids.

2. Information about submitting a Tender Bid

2.1 Types of Tender Bids

- (a) Your Tender Bid must include all forms and strengths of the Tender Item outlined in Schedule 2 section 2.1.
- (b) Your Tender Bid must include a bid for Scenario A and may include a bid for Scenario B.

2.2 Consents not yet held

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

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

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

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2.3 Individual Tender Bids

Each Tender Bid **MUST** be a Hospital Tender Bid.

2.4 Not used

2.5 Not used

2.6 Not used

2.7 No conditions

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

2.8 Separate offers

Pharmac will treat each Tender Bid as a separate offer.

2.9 Tender Bid prices

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

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

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; and

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- (g) how your organisation supports wider social, economic, cultural and environmental outcomes (see [New Zealand Government Procurement broader outcomes](#)).

3.3 Information that must be supplied about the Tender Item

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

- (a) in the case of a pharmaceutical that is not a Medical Device, the chemical, form, strength, brand name, pack size and type of packaging;
- (b) for any Chemical Entity that does not require Market Approval and any other Consent:
 - (i) evidence and justification as to why Market Approval and any other Consent is not required for the Tender Item(s);
 - (ii) confirmation that the Tender Item(s) that you are submitting a Tender Bid in respect of meet the relevant standards and/or regulatory requirements for its intended use and what those standards and/or regulatory requirements are; and
 - (iii) details of the Tender Item(s), including excipients, Shelf-Life and In-Use Shelf-Life;
- (c) a single price in New Zealand dollars (exclusive of GST) at which you will supply the Tender Item:
 - (i) to Health NZ Hospitals, wholesalers and other distributors, in respect of a Hospital Tender Bid;
- (d) whether it has Market Approval and all necessary Consents (and if not, what the status of registration is);
- (e) the Lead Time for supply of the Tender Item;
- (f) the name and location of:
 - (i) the manufacturer(s) of the finished product (and name and location of the packaging site, if different); and
 - (ii) the manufacturer(s) of the active ingredients (not required in respect of Medical Devices); and
 - (iii) alternative manufacturers of the finished product and active ingredients (if any) (not required in respect of Medical Devices);
- (g) your proposed distribution and supply arrangements for the Tender Item; and
- (h) any other relevant data.

3.4 Information that may be supplied about the Tender Item

In your Tender Submission Form, you may supply, for any Pharmaceutical or Medical Device, information about other markets you currently provide the Pharmaceutical or Medical Device in.

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3.5 Pharmac may request further information

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

4. How to submit a Tender Bid

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 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) twelve 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.

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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 Pae Ora (Healthy Futures) Act 2022 (the Act) took effect on 1 July 2022 and shapes the reform of the health sector in Aotearoa New Zealand. Its vision is that all New Zealanders achieve pae ora (healthy futures). Achieving pae ora means that people and their whānau will live longer in good health, have improved health and quality of life, are part of healthy, inclusive and resilient communities, and live in environments that sustain their wellbeing.

As a government health entity, Pharmac is to give effect to the principles of te Tiriti o Waitangi (as set out in [section 6](#) of the Act) and be guided by the health sector principles (as set out in [section 7](#) of the Act), including equity, engagement, and the promotion of health and wellbeing.

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) the Lead Time for supply of the Tender Item;
 - (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 Pharmaceutical, 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 Pharmaceutical; and
 - (x) your proposed distribution and supply arrangements for the Tender Item.
- (b) the pack size (or other relevant grouping for a Medical Device) of the Tender Item and the type of packaging;

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- (c) the Shelf-Life and In-Use Shelf-Life of the Tender Item, including once compounded.
- (d) the price of the Tender Item;
- (e) the amount and timing of savings, including non-pharmaceutical savings accruing to Pharmac during the Principal Supply Period;
- (f) either:
 - (i) evidence that you have obtained, and still have, Market Approval and all necessary Consents; or
 - (ii) evidence that will enable the Evaluation Committee to form a view on the likelihood and timing of your brand of the Tender Item gaining Market Approval and all necessary Consents;
- (g) the name and location of the manufacturer of the finished product and active ingredients of the Tender Item; and
- (h) any other benefits of selecting you as the supplier of the Tender Item.

6. Conformity

- (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;
 - (v) is for the chemical outlined in section 2.1 only;
 - (vi) is for both presentations outlined in section 2.1 only;
 - (vii) otherwise complies, both as to form and substance, with the requirements of this RFT;
 - (viii) includes a bid for scenario A, and may include a bid for scenario B;
 - (ix) is submitted for the proposed funding criteria only;
 - (x) includes information regarding the additional support that would be provided to support implementation of a tender bid that would contribute to equitable access and outcomes for priority populations and other populations experiencing disparities; and
 - (xi) includes Tender Items which are Medsafe approved or would have Medsafe consent by 12 May 2025.

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- (b) Pharmac may, in its sole discretion, provided that in Pharmac's judgment this would not be unfair to you in comparison to any other party:
 - (i) exclude any non-conforming Tender Bid from consideration; or
 - (ii) consider, and accept, any non-conforming Tender Bid.

7. Decision

7.1 Decision on acceptance of Tender Bid

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

7.2 Notification of acceptance

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

7.3 Pharmac's rights reserved

- (a) Pharmac reserves the right to accept or reject any Tender Bid.
- (b) While it is Pharmac's current intention, unless specified otherwise in Schedule Two or on GETS in relation to this RFT, to enter into an agreement to award Principal Supply Status for hospital supply for each Tender Item, Pharmac will not in any circumstances be bound to accept any or all Tender Bids and, in particular, Pharmac will not be bound to accept the lowest or any other Tender Bid for a Tender Item.

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- (c) Acceptance only occurs if, and when, Pharmac's Board of Directors (or its delegate, where applicable) resolves to accept a Tender Bid and this acceptance is notified to the successful tenderer.
- (d) Pharmac may take any action, including making any adjustments to the tender process that it considers appropriate, acting reasonably (provided that it notifies tenderers materially affected by such adjustments).
- (e) Pharmac may, at any time, suspend or cancel in whole or in part, this tender process in order to fulfil its public law obligations through consultation, or otherwise. In this situation Pharmac may (without limitation) ask you to adapt and resubmit your Tender Bid in light of consultation, or alternatively we may request that new Tender Bids be submitted (or in the case of a suspension Pharmac may also resume the tender process without further change following the end of the period of suspension).

7.4 Conditional acceptance

- (a) Where the successful tenderer's brand of a Tender Item is yet to receive Market Approval and all necessary Consents:
 - (i) the contract referred to in clause 1.3 of this Schedule will be conditional upon such Market Approval and Consents being received within a time period specified by Pharmac; and
 - (ii) Pharmac may terminate the contract if such Market Approval and Consents have not been obtained, or in Pharmac's view are unlikely to be obtained, within the period specified by Pharmac.
- (b) Acceptance of a Tender Bid by Pharmac's Board of Directors (or its delegate, where applicable), and the contract referred to in clause 1.3 of this Schedule may be conditional upon you satisfying Pharmac that you will have sufficient stock of the Tender Item available to commence supply as at a date reasonably determined by Pharmac.
- (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; and
 - (ii) following consultation, approval of its terms by Pharmac's Board (or its delegate, where applicable).
- (d) For the avoidance of doubt, and without limiting any of Pharmac's rights under this RFT, if Pharmac's Board (or its delegate) does not grant the approval referred to in paragraph (c) above, Pharmac may initiate negotiations with any other supplier(s)

8. Back-up supply

Back-up Supply Agreements

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

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9. Dealing with information and documents

9.1 Confidentiality

- (a) Subject to clause 9.2 below, all Confidential Information is confidential to you, Pharmac, Health NZ and those parties' respective Personnel (as applicable).
- (b) You acknowledge that Pharmac may be required to disclose Confidential Information in accordance with:
 - (i) section 12 of the Official Information Act 1982; and
 - (ii) any other legal and administrative obligations,and you consent to such disclosure.
- (c) Where Pharmac reaches a preliminary view that Confidential Information must be disclosed for the purposes stated in clause 9.1(b)(i) above, Pharmac will consult with you, and will act in good faith, before deciding whether to disclose the Confidential Information.
- (d) To the extent permitted by law, Pharmac will inform you if Confidential Information is disclosed for the purposes stated in clause 9.1(b)(ii) above, including any disclosure to a court, inquiry or ombudsman.
- (e) Confidential Information must not be disclosed by you, Pharmac, Health NZ or those parties' respective Personnel unless:
 - (i) the information is publicly available or enters the public domain through no fault of the applicable parties; or
 - (ii) the disclosure is:
 - (A) required or permitted for the purposes of this RFT;
 - (B) required or permitted by law; or
 - (C) agreed to between the applicable parties.

9.2 Use of information

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

9.3 Ownership of documents

- (a) This RFT and its contents remain the property of Pharmac. All Intellectual Property rights in the RFT remain the property of Pharmac or its licensors.
- (b) Pharmac may request the immediate return or destruction of any RFT documents, in which case, you must comply with such in a timely manner.
- (c) All documents forming part of your Tender Bid will, once they are delivered to Pharmac, become the property of Pharmac. The Tender Bid will not be returned to you.

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- (d) Intellectual Property rights in your Tender Bid remain your property (or the property of your licensors).
- (e) You grant Pharmac a licence to retain, use, copy and disclose information contained in your Tender Bid for any purpose relating to this RFT process, including keeping appropriate records.

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 Market Approval and all necessary Consents for any Tender Item.

10.3 No reliance

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

1. Pharmac's Role

1.1 Rights and Responsibilities

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

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

1.2 Amendments to Pharmaceutical Schedule

- (a) The Pharmaceutical is to be listed from the Start Date subject to eligibility criteria.
- (b) Pharmac reserves the right at any time to review, change and/or impose new criteria for access to, and restrictions on the prescribing and dispensing of, the Pharmaceutical, including making them more restrictive, in accordance with any direction from Medsafe, or recommendation from Pharmac's clinical advisors, based on patient safety or any other clinical reason.
- (c) For the avoidance of doubt, Pharmac reserves the right, in its absolute discretion, to review, change and/or impose new criteria for access to, and restrictions on the prescribing and dispensing of, the Pharmaceutical, including making them more restrictive or less restrictive, from time to time, including during the Principal Supply Period.
- (d) Pharmac will consult with you before amending the Pharmaceutical Schedule if a proposed amendment would have a material adverse effect on the listing of the Pharmaceutical.

1.3 Supplier Code of Conduct

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

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2. Price and Payment

2.1 Subsidy arrangements for community supply

- (a) Subject to clause 2.3 of this Schedule, the Pharmaceutical will be subsidised, and you must supply it, during the First Transition Period at the Price. If any other brands of the Chemical Entity are listed on the Pharmaceutical Schedule, those brands will continue to be subsidised for the First Transition Period at the subsidy applicable to those brands immediately before the commencement of the First Transition Period.
- (b) All other brands of that form and strength of the Chemical Entity will be delisted (except to the extent any brands remain listed under Alternative Brand Allowance arrangements) on the first day of the Principal Supply Period, with the result that you will have Principal Supply Status in the community for that form and strength of the Chemical Entity during the Principal Supply Period.
- (c) Subject to Pharmac's other rights under this Agreement in relation to the Pharmaceutical, the Pharmaceutical will continue to be fully subsidised, and you must continue to supply it, at the Price throughout the Principal Supply Period.
- (d) Subject to Pharmac's other rights under this Agreement in relation to the Pharmaceutical, the Pharmaceutical will not be delisted during the Final Transition Period.

2.2 Pricing arrangements for hospital supply

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

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2.3 Price change

- (a) Subject to clause 2.3(c)(ii), clause 2.3(c)(iii) and clause 2.3(c)(iv) of this Schedule your brand of the Pharmaceutical must be available for supply, and you must supply the Pharmaceutical, at the Price from the 12th day of the month prior to the Start Date, and the Pharmaceutical will be subsidised at the Price from the Start Date.
- (b) Subject to clause 2.3(c)(ii), clause 2.3(c)(iii) and clause 2.3(c)(iv) of this Schedule, you must change the price at which you supply the Pharmaceutical to Health NZ Hospitals to the Price with effect from the 12th day of the month prior to the Start Date. If your brand of the Pharmaceutical is not listed on the Pharmaceutical Schedule at the beginning of the First Transition Period, it must be available for supply or sale, and you must supply or sell it, at the Price on and from the 12th day of the month prior to the Start Date.
- (c) In the event your brand of the Pharmaceutical is currently listed on the Pharmaceutical Schedule at the beginning of the First Transition Period:
 - (i) you must ensure that wholesalers and other such distributors change the price at which they supply the Pharmaceutical to the Price on the 12th day of the month prior to the Start Date, and you shall provide price support to wholesalers and other such distributors for a maximum 4 weeks stock on hand (or such other level of stock as agreed between you and Pharmac) of the Pharmaceutical held at wholesalers and other such distributors, provided that such wholesalers and other such distributors can provide you with stock on hand reports upon request; or
 - (ii) your brand of the Pharmaceutical must be available for supply, and you must supply the Pharmaceutical, at the Price from the 1st day of the month prior to the Start Date, and the Pharmaceutical will be subsidised or purchased at the Price from the Start Date (which is conditional upon you having at least 2 months Lead Time for the Pharmaceutical); and
 - (iii) notwithstanding clauses 2.3(c)(i) or (c)(ii) above, if the Price would result in a price increase for your brand of the Pharmaceutical you must supply the Pharmaceutical at the Price from the 22nd day of the month prior to the Start Date, and the Pharmaceutical will be subsidised or purchased at the Price from the Start Date; and
 - (iv) notwithstanding clauses 2.3(c)(i), (c)(ii) or (c)(iii) above, Pharmac may agree a process with you, that results in your brand of the Pharmaceutical, which includes a rebate, being available for supply, and you must supply the Pharmaceutical, at the Price from the 22nd day of the month prior to the Start Date, and you shall provide price support to wholesalers and other such distributors for a maximum 4 weeks stock on hand (or such other level of stock as agreed between you and Pharmac) of the Pharmaceutical held at wholesalers and other such distributors, provided that such wholesalers and other such distributors can provide you with stock on hand reports upon request.

For the avoidance of doubt if you do not notify Pharmac in your Tender Bid in the Electronic Portal which of the options stated in clauses 2.3(c)(i) or (c)(ii) above apply to the Pharmaceutical, clause (c)(i) above shall apply.

- (d) You shall upon request by Pharmac, provide information on how you intend to manage the price changes stated in clauses 2.3(c)(i) to (c)(iv) above. Pharmac may, at its sole discretion, publish this information at the time the Tender Item is notified in the Pharmaceutical Schedule in accordance with clause 7.2 of Schedule Three.

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2.4 Supply Price

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

2.5 Pharmaceutical Price

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

2.6 No reference pricing during Principal Supply Period

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

2.7 Unsold stock following delisting

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

2.8 Invoices to hospitals

Where a Health NZ Hospital is to be invoiced for the Pharmaceutical, you are to invoice the particular Health NZ Hospital at the end of each month, but no later than the second Business Day following the month to which the invoice in respect of the Pharmaceutical relates, specifying for the Pharmaceutical supplied during that month:

- (a) your delivery note reference number;
- (b) the particular Health NZ Hospital's purchase order reference number (if applicable);
- (c) the net amount payable in respect of the Pharmaceutical supplied to that Health NZ Hospital in accordance with this Agreement;
- (d) full details in respect of the Pharmaceutical supplied to that Health NZ Hospital in accordance with this Agreement, including the:
 - (i) Health NZ Hospital item codes;
 - (ii) quantity of the Pharmaceutical supplied;
 - (iii) price of the Pharmaceutical;
 - (iv) cost of freight for orders that included the Pharmaceutical (only where applicable under clause 2.2(b) above);
 - (v) total cost for the total amount of the Pharmaceutical supplied; and

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- (e) any other information that Health NZ Hospital requires you to supply.
- (f) The provisions of clause 2.8 do not apply to the extent that both parties have agreed to alternative or varied invoicing arrangements in respect of a particular Pharmaceutical.

2.9 Payment by hospitals

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

2.10 Future payment by hospitals

- (a) A particular Health NZ Hospital's failure to dispute any invoice prior to payment does not prejudice that Health NZ 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 Health NZ Hospital may withhold, deduct or set off the amount of any overpayment or any amount recoverable by that Health NZ Hospital from you under this Agreement from any future amount owing to you.

3. Principal Supply Status

3.1 Principal Supplier

- (a) Subject to:
 - (i) Pharmac's other rights under this Agreement in relation to the Pharmaceutical; and
 - (ii) this clause 3 of Schedule Four relating to the Alternative Brand Allowance,

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Pharmac will not subsidise another supplier's brand of the Pharmaceutical on the Pharmaceutical Schedule and/or Health NZ Hospitals will not purchase another supplier's brand of the Pharmaceutical, at any time during the Principal Supply Period.

- (b) This clause does not prohibit Pharmac from entering into negotiations or arrangements with, or inviting tenders from, other suppliers to be the principal supplier of any forms and strengths of the Chemical Entity, if such supply commences after the end of the Principal Supply Period.
- (c) For the avoidance of doubt, Pharmac may lower the subsidy applicable to a Pharmaceutical during the Final Transition Period as it sees fit, including lowering the subsidy of a Pharmaceutical as a result of the implementation of new tender arrangements.
- (d) You shall have Principal Supply Status during the Principal Supply Period, which shall be subject to the Alternative Brand Allowance, where other supplier brands of the Pharmaceutical may be subsidised in the community and/or purchased by Health NZ Hospitals.
- (e) The Alternative Brand Allowance referred to in paragraph (a) above is specified as a percentage of the Total Pharmaceutical Volume for the Pharmaceutical, that percentage being as set out in Schedule Two.
- (f) You acknowledge and agree that any other supplier brands of the Pharmaceutical may be concurrently listed on the Pharmaceutical Schedule at any time during the First Transition Period, the Principal Supply Period and the Final Transition Period and your rights under this Agreement do not extend to an exclusive listing of the Pharmaceutical on the Pharmaceutical Schedule.

3.2 Exceptions to Principal Supply Status

- (a) Pharmac may, from time to time during the Principal Supply Period or the First Transition Period, amend the Alternative Brand Allowance for the Pharmaceutical after consultation with a relevant medical adviser (being either the Ministry of Health, Health NZ, PTAC or its Specialist Advisory Committees), provided that Pharmac may only increase the Alternative Brand Allowance without your prior agreement if it has a direction to that effect from Medsafe or its successor, or a recommendation that it do so from PTAC or its Specialist Advisory Committees, based on a significant clinical issue.
- (b) Subject to clause 3.3 of this Schedule, you acknowledge and agree that while you have Principal Supply Status:
 - (i) other supplier brands of the Pharmaceutical may be subsidised in the community and/or purchased by Health NZ Hospitals, subject to the Alternative Brand Allowance; and
 - (ii) without derogating from any other rights available to Pharmac or Health NZ under this Agreement or otherwise, if you fail to supply the Pharmaceutical in accordance with this Agreement (other than for a reason that Pharmac reasonably considers, following discussion with you, to be wholly outside your control) at any time during the Principal Supply Period, then the Alternative Brand Allowance shall not apply and other supplier brands of the Pharmaceutical may be subsidised in the community and/or purchased by Health NZ Hospitals without limitation during that period of non-supply and any calculation performed in accordance with clause 3.3 below shall exclude that period of non-supply.

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3.3 Principal Supply Status Monitoring

- (a) If you reasonably believe that the percentage usage of other supplier brands of the Pharmaceutical subsidised in the community and/or purchased by Health NZ Hospitals exceeds the Alternative Brand Allowance for a particular Pharmaceutical during the Principal Supply Period, you may at any date after a three (3) month period following the end of any Relevant Period, request that Pharmac carry out calculations for that Relevant Period in accordance with the procedure set out in this clause 3.3, and Pharmac may, acting reasonably, agree to carry out such calculations, provided that if Pharmac refuses to carry out such calculations, it will provide you with the reasons for refusing to do so.
- (b) Within 30 Business Days of Pharmac accepting your request to carry out calculations in accordance with paragraph (a) above, Pharmac shall carry out the following calculations for the Relevant Period in question:
- (i) $(\text{Total Brand Allowance Pharmaceutical Volume} / \text{Total Pharmaceutical Volume}) \times 100 = \text{Brand Allowance Indicator};$
 - (ii) $\text{Brand Allowance Indicator} - \text{Alternative Brand Allowance} = \text{Brand Differential}$
- (c) In the event the Brand Differential is a number greater than zero i.e. a positive amount, Pharmac shall carry out the following calculations for the Relevant Period in question:
- (i) $\text{Total Pharmaceutical Volume} / 100 = \text{Volume Multiplier};$
 - (ii) $\text{Volume Multiplier} \times \text{Brand Differential} = \text{Eligible Volume};$
 - (iii) $(\text{Eligible Volume} \times \text{Unit Price and/or Unit Subsidy}) / 2 = \text{Brand Compensation}$
- (d) Pharmac will notify you in writing of any Brand Compensation payable or not in accordance with paragraphs (b) and (c) above and will provide you with the details of the relevant party or parties to be invoiced for any Brand Compensation payable. Following such notification to you from Pharmac, you may invoice the relevant party or parties for the Brand Compensation.
- (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 Chartered Accountants Australia and New Zealand (CA ANZ).
 - (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

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on which the data extracted by Pharmac from those electronic records are based, nor any right to request copies of those written prescriptions.

- (iii) In carrying out the audit, the independent person is to be considered as acting as an expert and not as an arbitrator.
- (iv) The independent person will be required to complete the audit, and to provide us with a written determination in that regard, within 5 Business Days of receiving all the information required by the independent person to make a determination and, in any case, no later than 10 Business Days from the date of his or her acceptance of appointment or nomination under this clause, unless we agree otherwise. The independent person's determination of the particular Calculation is to be final and binding on both of us.
- (v) The costs incurred by the independent person in completing the audit are to be met by you, irrespective of the outcome of the audit.

3.4 Withdrawal of Principal Supply Status

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

3.5 Suspension of Principal Supply Status

- (a) Pharmac may suspend Principal Supply Status in relation to the Pharmaceutical, by written notice to you at any time during the Principal Supply Period or (in anticipation) during the First Transition Period in the event of a Supply Issue, or in accordance with any advice from Medsafe or clinical advice, based on patient safety or any other clinical reasons.
- (b) Any suspension of Principal Supply Status is without prejudice to Pharmac's rights under clauses 5.5 and 5.6 of this Schedule Four.
- (c) Pharmac may, at any time, in its sole discretion, notify you of the date on which the suspension of Principal Supply Status under this clause 3.5 ceases and on which date:
 - (i) Principal Supply Status is to be re-implemented in respect of the Pharmaceutical; or
 - (ii) Principal Supply Status is to be withdrawn in accordance with clause 3.4 of this Schedule Four.

3.6 Subsidy and supply arrangements after the End Date

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

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- (i) you will cease to have Principal Supply Status for that form and strength of the Chemical Entity or you will cease to have Principal Supply Status for hospital supply in respect of an item conforming to the individual specifications described for the item in the product list in clause 2 of Schedule Two which the Pharmaceutical was listed as conforming with (in the case of any Pharmaceutical that is a Medical Device);
 - (ii) the Pharmaceutical will remain listed in the Pharmaceutical Schedule subject to the current standard terms Annex of Pharmac's Agreement for the listing of Pharmaceutical(s) on the New Zealand Pharmaceutical Schedule contract template;
- (b) Pharmac may at its sole discretion, with effect from the End Date:
- (i) require that the Pharmaceutical does not continue to be the subject of a listing agreement, in which case Pharmac will give you written notice not less than three months prior to the End Date; and/or
 - (ii) apply any of the strategies under Pharmac's then current OPPs to the Pharmaceutical (including delisting the Pharmaceutical after the Final Transition Period).
- (c) In the event Pharmac applies any of the strategies described in paragraph (b)(ii) above, you may withdraw the Pharmaceutical from supply on not less than six months' prior written notice. You may provide Pharmac with this written notice at any time after, but not before, the date that the particular strategy takes effect in the Pharmaceutical Schedule.

3.7 Termination and restrictions for clinical reasons

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

- (a) terminate this Agreement at any time during the Principal Supply Period if the medical adviser determines for clinical reasons that it is no longer appropriate to have either:
 - (i) a principal supplier for all indications for which the Pharmaceutical has Principal Supply Status in the Pharmaceutical Schedule; or
 - (ii) the Pharmaceutical as the principal pharmaceutical for all indications for which the Pharmaceutical has Principal Supply Status in the Pharmaceutical Schedule; and/or
- (b) impose at any time during the Principal Supply Period restrictions on the prescribing or dispensing of the Pharmaceutical if those restrictions are necessary for clinical reasons.

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4. Reporting

4.1 Information

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

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

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

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

4.2 Supply Issues Reporting

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

5. Supply Obligations and Managing Supply Issues

5.1 Stock Holdings

The minimum stock holding of the Pharmaceutical that must be held by you (or on your behalf) in New Zealand and available for supply is as follows:

- (a) For the first 12 months from the Listing Date, an amount equivalent to at least four months anticipated sales, and, after that, an amount equivalent to the last three months sales at all times.

5.2 Continuity of Supply

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

5.3 Notification

- (a) You must:
 - (i) notify Pharmac as soon as you become aware of a Supply Issue; and
 - (ii) send a Supply Issues Report to Pharmac within 2 Business Days of becoming aware of a Supply Issue.
- (b) In the event that you consider (acting reasonably) that any circumstances or events may result in a Supply Issue you must notify Pharmac in writing as soon as practicable, including (but not limited to) any of the following circumstances:
 - (i) you plan any changes to your supply chain, for example but not limited to a change in manufacturing site, in respect of the Pharmaceutical;
 - (ii) you plan any changes to your ordering or delivery systems;
 - (iii) you plan to re-structure your organisation; or
 - (iv) you plan to change the presentation of the Pharmaceutical, including the brand name, pack size, packaging and strength.
- (c) After giving Pharmac notice in accordance with clauses 5.3(a)(i) and/or 5.3(b), you must comply with all reasonable requests by Pharmac in respect of steps that may be required to mitigate the risk that you may fail to supply the Pharmaceutical.

5.4 Managing Supply Issues

- (a) In addition to your obligations set out in clause 5.3 you must comply with the obligations set out in this clause 5.4.
- (b) In the event of:

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

5.5 Indemnity

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

5.6 Liquidated Damages

- (a) Subject to clause 5.6(c) and clause 5.6(d), for each and every Supply Issue which actually results in a failure to supply the Pharmaceutical (other than a Supply Issue resulting directly from a Force Majeure Event) you must pay to Pharmac liquidated damages (plus GST (if any)) of \$50,000 to cover Pharmac's administrative and/or operational costs.

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- (b) You acknowledge that Pharmac's right to claim the full liquidated damages amount specified in clause 5.6(a) in these circumstances reflects Pharmac's legitimate interests in securing delivery of the Pharmaceutical by the relevant date and in accordance with the terms of this Agreement and is proportionate to those interests during the period, and in the circumstances, in which the liquidated damages are payable under this clause 5.6.
- (c) Liquidated damages are payable where you have not:
 - (i) notified Pharmac under and in accordance with clause 5.3; and/or
 - (ii) complied with all reasonable requests by Pharmac in respect of steps that may be required to mitigate the risk that you may fail to supply the Pharmaceutical.
- (d) Pharmac may, in its sole discretion, require you to pay less than the amount specified as liquidated damages in clause 5.6(a) if Pharmac is satisfied that the actual costs in the circumstances are less than this amount.

5.7 Interest

If payment of any amount required to be paid by you under clauses 5.5 or 5.6 is not made by you, in full, by the due date for payment of that amount as notified to you in writing by Pharmac, then:

- (a) interest will accrue on such sum as remains unpaid at a rate per annum equal to the Default Interest Rate, calculated and compounded on a daily basis, from the due date until such time as the sum due (including interest) is paid in full. This obligation to pay default interest is to arise without the need for a notice or demand from Pharmac for such default interest and does not limit any other right or remedy of Pharmac; and
- (b) Pharmac may take any action, including legal action, without first needing to implement the dispute resolution procedure contained in clause 6.4, to recover that unpaid amount and you agree to pay to Pharmac actual enforcement costs incurred in relation to that action.

6. General Obligations

6.1 Shelf-life of Pharmaceutical

You will not supply the Pharmaceutical:

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

without prior written agreement from Pharmac or the applicable Health NZ Hospital.

6.2 Consents

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

6.3 Health and Safety

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

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

6.4 Dispute Resolution

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

- (a) The party claiming a dispute has arisen must give written notice to the other party specifying the nature of the dispute.
- (b) You and Pharmac will endeavour, in good faith, to resolve the dispute referred to in the notice by using informal dispute resolution techniques.
- (c) If you and Pharmac have not resolved the dispute within 14 days after the date notice of a dispute was given, the parties may agree that the dispute is to be:
 - (i) mediated according to the standard mediation agreement of the Resolution Institute (a body corporate incorporated in Australia and registered as an overseas company in New Zealand), and the Chair of the Resolution Institute

Schedule 4

(or the Chair's nominee) will select the mediator and determine the mediator's remuneration, if you and Pharmac are unable to agree on such matters; or

- (ii) submitted to arbitration in accordance with the Arbitration Act 1996, with such arbitration being conducted by a single arbitrator to be agreed on by the parties or, failing agreement, the Chair of the Resolution Institute (or the Chair's nominee) will select the arbitrator.
- (d) A party seeking urgent interlocutory relief may, by notice to the other party, elect not to comply with the provisions of this clause, but only to the extent of the relief sought, and only for the period required to dispose of the application for interlocutory relief.
- (e) Pending resolution of the dispute, this Agreement will remain in full effect without prejudicing the parties' respective rights and remedies (including Pharmac's rights under its OPPs).

6.5 Litigation Support

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

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

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

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

For the purposes of this clause "PCT" means a pharmaceutical for which Health NZ Hospitals are eligible to claim a subsidy through the Pharmaceutical Schedule.

- (a) Where the Pharmaceutical is a PCT and supplied in a Health NZ Hospital, you acknowledge and agree that Pharmac may list the Pharmaceutical in Section B of the Pharmaceutical Schedule:
 - (i) at a price that is equal to (or subject to your agreement, less than) the Price;
 - (ii) subject to the rules and restrictions applying to PCTs in Sections A to G of the Pharmaceutical Schedule.
- (b) If Pharmac lists the Pharmaceutical in Section B of the Pharmaceutical Schedule pursuant to paragraph (a) above, you acknowledge and agree that:
 - (i) such listing will be for reasons relating to claiming and will not, unless otherwise advised in writing by Pharmac, enable you to supply the Pharmaceutical for use in the community;
 - (ii) listing of the Pharmaceutical in Section B will, at Pharmac's option, be additional to or instead of listing in Part II of Section H; and
 - (iii) references to the "listing" of the Pharmaceutical will, where applicable, be to the listing of the Pharmaceutical in Section B of the Pharmaceutical Schedule (and references to "list", "listed", "delist", "delisted", and "delisting" are to be interpreted accordingly).

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- (c) You further acknowledge and agree that any reference to a listing of '1 mg for ECP' is only to reflect the dispensing of the Pharmaceutical under this line item in the Pharmaceutical Schedule.

6.7 Guarantee

- (a) Pharmac may require an entity acceptable to it to provide a guarantee (in a form satisfactory to Pharmac) of your performance obligations under clauses 5.5 and 5.6 of this Schedule including, without limitation, the payment of any sum payable under the indemnity or as liquidated damages pursuant to those clauses for any failure to supply the Pharmaceutical in accordance with this Agreement during the Principal Supply Period.
- (b) The guarantor's liability under such a guarantee will be limited to a total of \$100,000 per Pharmaceutical for all claims made by Pharmac under the guarantee.

Schedule 4

7. General Terms

7.1 No Derogation

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

7.2 No Waiver

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

7.3 Remedies Cumulative

Except as is expressly stated otherwise in this Agreement:

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

7.4 Entire Agreement

This Agreement:

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

7.5 Advertising

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

7.6 Contracts Privity

- (a) You and Pharmac acknowledge that your obligations in this Agreement constitute promises and obligations which confer or are intended to confer a benefit on Health NZ and related persons, and are enforceable by Health NZ and any such persons pursuant to Part 2, subpart 1 of the Contract and Commercial Law Act 2017 (Contractual Privity).
- (b) Except as expressly provided in clause 7.6(a) above, the parties do not intend to create rights in, or grant remedies to, any third party as a beneficiary to this

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Agreement, and all of the provisions of this Agreement shall be for the sole and exclusive benefit of the parties.

- (c) You acknowledge that Pharmac may pursue damages or any other claim (including injunctive or other such relief) under this Agreement on its own account and/or on behalf of Health NZ.

7.7 No Reliance

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

7.8 Amendments

Amendments to this Agreement must be in writing.

7.9 Assignment

You will not permit this Agreement, or any part of this Agreement, to be transferred or assigned (either directly or due to a change of control) without Pharmac's prior written consent (such consent not to be unreasonably withheld). Any such consent may be given subject to such reasonable conditions as Pharmac sees fit.

7.10 Further Assurances

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

7.11 Specific Performance

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

7.12 Agreement Prevails

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

Schedule 5

Schedule 5: Rebate Terms

The terms in this Schedule 5 (Rebate Terms) will only apply to the extent that your Tender Bid includes Rebates, [unless otherwise agreed between you and Pharmac].

1. Monthly Rebate

(a) Operation of this rebate

This rebate clause works as follows:

- (i) you will make a monthly rebate payment to Pharmac as calculated in accordance with paragraph (b) using your own sales data, to Pharmac for each Pharmaceutical;
- (ii) every 12 months to 30 June (except where the first period from the Listing Date to 30 June is less than twelve months, in which case after the end of that shorter period up to 30 June), Pharmac will make its own calculation of the total rebate for the Pharmaceutical over the Wash-up Period (using Pharmac's own data for the quantity of the Pharmaceutical purchased by a Health NZ Hospital, and/or otherwise subsidised or purchased by Pharmac or a Health NZ Hospital);
- (iii) the difference between what you have paid to Pharmac through your rebate payments and the amount that Pharmac has calculated as the total rebate payable is known as the "wash-up amount"; and
- (iv) if the wash-up calculation shows that you have paid Pharmac more in rebates than its calculation of the total rebate payable then Pharmac will refund you the wash-up amount, or if the wash-up calculation shows that you have paid Pharmac less than its calculation of the total rebate payable then you will pay Pharmac the wash-up amount.

Defined terms are capitalised. Definitions are set out in paragraph (e).

For the avoidance of doubt, if an additional rebate is agreed in relation to a Pharmaceutical (in this Agreement or elsewhere) then the provisions of each rebate clause operate independently unless otherwise specified, which may mean that multiple rebates are payable.

(b) Monthly rebate

For each Rebate Period you agree to pay to Pharmac a rebate (the "**Monthly Rebate**") plus GST (if any) that relates to all Rebate Pharmaceuticals sold by you for use in Health NZ Hospitals during the Rebate Period. You must use the following calculation for the purpose of calculating the Monthly Rebate, applying this calculation separately to each Rebate Pharmaceutical then adding together the resulting amounts:

$$(\text{Units}_{\text{Pharmaceutical}} \times \text{Price}_{\text{Pharmaceutical}}) \times \text{Rebate}$$

You and Pharmac may subsequently agree in writing an alternative mechanism for determining the Monthly Rebate, which may include an agreed amount for each Rebate Period. In the event that either party withdraws its consent to any such alternative mechanism, the original provisions of this Agreement for determining the Monthly Rebate shall apply.

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(c) Wash-up

- (i) Following the end of each Wash-up Period Pharmac will calculate (and notify you in writing of) a rebate (the “**Wash-up Period Rebate**”) plus GST (if any) that relates to all Rebate Pharmaceuticals purchased by a Health NZ Hospital, and/or otherwise subsidised or purchased by Pharmac, or a Health NZ Hospital, (as applicable) during the Wash-up Period. In doing so Pharmac will use the following calculation, applied separately to each Pharmaceutical then adding together the resulting amounts:

$$\begin{aligned} & (\text{Units Dispensed}_{\text{Pharmaceutical}} \times \text{Price}_{\text{Pharmaceutical}}) + \\ & (\text{Units Dispensed}_{\text{Pharmaceutical ECP}} \times \text{Subsidy}_{\text{Pharmaceutical ECP}}) \end{aligned}$$

x Rebate

- (ii) Pharmac will then calculate, and notify you in writing of, the wash-up amount for that Wash-up Period, being the difference between the Wash-up Period Rebate and the sum of the Monthly Rebates paid for that same period (the “**Wash-up Amount**”). If the sum of those Monthly Rebates is:
- (A) less than the Wash-up Period Rebate, the Wash-up Amount plus GST (if any) will be payable by you to Pharmac in accordance with paragraph (d)(ii)(A) below; or
- (B) greater than the Wash-up Period Rebate, the Wash-up Amount will be payable by Pharmac to you in accordance with paragraph (d)(ii)(B) below.
- (iii) For the avoidance of doubt, Pharmac may, under this paragraph (c), undertake more than one wash-up or re-perform a wash-up that has already been completed where, for example, further relevant data comes to light after a wash-up has already been completed by Pharmac. The principle that will apply in this situation is that the relevant party will pay the relevant difference, as calculated by Pharmac.
- (iv) You and Pharmac acknowledge that the Wash-up Period Rebate calculation may be different from the sum of the Monthly Rebate calculation due to differences in timing and in calculation methodology. In the event that Pharmac’s Wash-up Period Rebate calculation as defined in paragraph (c)(i) above for the relevant Wash-up Period is higher than your calculation, the Wash-up Period Rebate calculation will show that you have paid Pharmac less in Monthly Rebates than its calculation of the total rebate payable. Accordingly, and for the avoidance of doubt, the Wash-up Amount plus GST (if any) will be payable by you to Pharmac.

(d) Payment of Monthly Rebate and Wash-up Amount

- (i) Within 20 Business Days following the end of each Rebate Period, you are to:
- (A) provide Pharmac with the relevant data available to you on which your Monthly Rebate calculations are based; and
- (B) pay to Pharmac, in full, the amount of the Monthly Rebate for that Rebate Period plus GST (if any).
- (ii) Payment of a Wash-up Amount for a Wash-up Period is to be made:

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- (A) if owing by you to Pharmac, within 20 Business Days following notice from Pharmac of the Wash-up Amount plus GST (if any) for a particular Wash-up Period; or
 - (B) if owing by Pharmac to you, within 20 Business Days following Pharmac giving you notice of the Wash-up Amount for a particular Wash-up Period.
- (iii) If payment of any amount due under paragraph (d)(i) or (ii) above is not made by the relevant party, in full, by the due date, then interest will accrue on such sum as remains unpaid at a rate per annum equal to the business base rate of ASB Bank Limited plus five percentage points, calculated and compounded on a daily basis, 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 the other party for such default interest.

(e) Definitions and interpretation

- (i) The following definitions apply to this rebate clause:

Business Day means any day which is not a Saturday, Sunday, New Zealand-wide public holiday, or public holiday in Wellington;

Monthly Rebate is defined in paragraph (b) above;

Rebate means the rebate specified in the Tender Response Form;

Rebate Period means, as applicable:

(A) the one month period from the Start Date; and

(B) each subsequent one month period;

Rebate Pharmaceutical means each of the Pharmaceuticals (in their various forms and strengths) specified in the Tender Response Form where the Tender Item has a rebate;

Price_{Pharmaceutical} is the price payable in respect of each particular Unit of the Pharmaceutical, as determined on the basis of the price recorded in the Tender Response Form in the applicable Rebate Period;

Subsidy_{Pharmaceutical ECP} is the subsidy payable in respect of '1 mg for ECP', as recorded in the Pharmaceutical Schedule in the applicable Wash-up Period;

Unit means one vial of the relevant strength of the Pharmaceutical (as applicable);

Units_{Pharmaceutical} means the total number of Units of the Pharmaceutical purchased by a Health NZ Hospital, and/or otherwise subsidised or purchased by Pharmac or a Health NZ Hospital (using your own sales data) in the applicable Rebate Period or Annual Rebate Period (as applicable);

Units Dispensed means:

(A) one vial of the Pharmaceutical; or

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(B) 1 mg of the Pharmaceutical compounded by contract manufacturers (as applicable);

“Units Dispensed_{Pharmaceutical}” means the total number of Units Dispensed of the Pharmaceutical claimed by Health NZ Hospitals or other claimants for the applicable Wash-up Period;

“Units Dispensed_{Pharmaceutical ECP}” means the total number of mgs of the Pharmaceutical compounded by contract manufacturers and claimed by Health NZ Hospitals or other claimants for the applicable Monthly Wash-up Period or Annual Wash-up Period (as applicable).

Wash-up Amount is defined in paragraph (c)(ii) above;

Wash-up Period means, as applicable:

(A) the period from the Start Date to the following 30th of June; and

(B) each subsequent twelve month period; and

Wash-up Period Rebate is defined in paragraph (c)(i) above.

(ii) For the purpose of this rebate clause:

(A) a reference to “pay to Pharmac” is a reference to paying to Pharmac, as agent for Health NZ Hospitals for the purpose of receiving such payment;

(B) a reference to “subsidy or price” shall be deemed to be followed by the words “(as relevant)”;

(C) any reference to an amount to be calculated by Pharmac means that Pharmac will base such calculation on the data extracted by Pharmac from the electronic records used by Pharmac;

(D) any reference to an amount to be calculated by you means that you will, in good faith and acting reasonably, having regard to the intent of the relevant provision, use your sales data of number of Units sold to make that calculation; and

(E) if, for any reason, this Agreement is terminated prior to the end of any Rebate Period, the final Rebate Period for the purposes of this rebate clause will be the period of time between the end of the previous Rebate Period and the date on which the termination takes effect.

2. Confidentiality for Rebates

The amount of, and methods of calculation for, the rebate(s) as set out in this Agreement are Confidential Information for the purposes of clause 9.1 of Schedule 3, provided that the existence of such rebate(s) is not Confidential Information. For the avoidance of doubt, this clause does not derogate from Pharmac’s legal rights and obligations under the Official Information Act 1982 or under this Agreement.

3. Calculation Data and Records

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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 available as at the date of this Agreement, for the purposes of carrying out the calculations required by the rebate provisions as set out in this Agreement. You acknowledge and agree that those records are to be used by Pharmac, in addition to or instead of (as this Agreement requires) the records and data provided by you, for the purposes of carrying out those calculations.

4. Independent Audit of Calculations

You may, within 14 days of receiving a notice from Pharmac of the amount payable in respect of any calculation required to be made by Pharmac pursuant to this Agreement (for the purposes of this Agreement, 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 14 day period, then the following provisions are to apply:

- (a) 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 7 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 Chartered Accountants Australia and New Zealand (CA ANZ).
- (b) 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.
- (c) In carrying out the audit, the independent person is to be considered as acting as an expert and not as an arbitrator.
- (d) The independent person will be required to complete the audit, and to provide us with a written determination in that regard, within 7 days of receiving all the information required by the independent person to make a determination and, in any case, no later than 14 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.
- (e) If the independent person determines that the correct amount of the particular Calculation is less than the amount paid by you to Pharmac on that account, then Pharmac is to refund to you, within 14 days of receiving the determination of the independent person, the amount of the overpayment received by it. If the amount of that overpayment is not paid in full by Pharmac within that 14 day period, then Pharmac is to pay interest on that sum, calculated and compounded on a daily basis, at a rate per annum equal to the business base rate of ASB Bank Limited plus five percentage points, until such time as that refund including interest, is paid in full.
- (f) If, however, the independent person determines that the correct amount of the particular Calculation is greater than the amount paid by you to Pharmac on that account, then you must pay to Pharmac, within 14 days of the independent person giving you notice of his or her determination, the amount of the underpayment together with interest on that sum, calculated and compounded on a daily basis, at a rate per annum equal to the business base rate of ASB Bank Limited plus five percentage points, until such time as the amount payable on account of the Calculation, including interest, is paid in full.

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- (g) The giving of a notice under this clause will not relieve you of your obligation to pay to Pharmac, within the time prescribed for payment, any amount notified to you by Pharmac under this Schedule.
- (h) The costs incurred by the independent person in completing the audit are to be met by you, irrespective of the outcome of the audit.

5. Independent Audit of Data

Pharmac may, at any time after receipt of any data supplied by you in respect of the Pharmaceuticals sold or supplied under this Agreement (for the purposes of this Agreement, the “**Sales Data**”), notify you in writing that it requires an audit of your records relating to your sales of the relevant Pharmaceutical(s) (for the purposes of this Agreement, the “**Sales Records**”) to be carried out, in which case the following provisions are to apply:

- (a) The audit is to be carried out, at Pharmac’s expense, by an independent person jointly approved by us or, if there is no agreement on a mutually acceptable person within 7 days of the date of Pharmac’s notice under this clause, then by an independent person nominated for that purpose by the President for the time being of Chartered Accountants Australia and New Zealand (CA ANZ).
- (b) The independent person is to audit the Sales Records in order to verify the accuracy of the Sales Data. For this purpose, you must:
 - (i) allow the independent person access to inspect and review all the Sales Records;
 - (ii) co-operate fully with the independent person in relation to the audit; and
 - (iii) provide the independent person with all reasonable assistance he or she requires in carrying out his or her audit.
- (c) In carrying out the audit, the independent person is to be considered as acting as an expert and not as an arbitrator.
- (d) The independent person will be required to complete the audit, and to provide us with a written determination in that regard, within 7 days of receiving all the information required by the independent person to make a determination and, in any case, no later than 14 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 is to be final and binding on both of us.
- (e) If the independent person determines that the Sales Data are accurate, then your calculations of the relevant rebate(s) payable under this Schedule will stand.
- (f) If the independent person determines that the Sales Data are not accurate, then you are to re-calculate the relevant rebate(s) payable (together with interest on any shortfall in the amount in fact paid, calculated and compounded on a daily basis, at a rate per annum equal to the business base rate of the ASB Bank Limited plus five percentage points from the date on which payment should have occurred until the date payment in fact occurs) on the basis of what the independent person considers to be an accurate assessment of the level of sales of the relevant Pharmaceutical(s) for that Rebate Period.

6. Payment of GST on Rebates

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Where you do not pay an amount on account of GST under this Agreement in respect of any rebate payment on the basis that GST is not payable, and it is subsequently determined by the Inland Revenue Department or otherwise that Health NZ Hospitals or Pharmac (as applicable) are legally obliged to pay GST in respect of that rebate, then you must pay to, Health NZ Hospitals or Pharmac (as applicable) an amount equal to the amount of GST that is payable as a result of such determination. For the purposes of this Agreement, GST means goods and services tax payable under the Goods and Services Tax Act 1985 ("**GST Act**"), and includes additional GST, penalties (civil or otherwise), interest or other sums levied under the GST Act or the Tax Administration Act 1994.

Appendix A: Tender Submission Form

An editable version of this form is available on the GETS listing for this RFT.

<Tenderer to Insert Date>

Director, Pharmaceuticals
C/- Sam Edlund, Procurement
Te Pātaka Whaioranga | Pharmac

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

Tēnā koe

Tender bid for the supply of bevacizumab

In response to your Request for Tender (RFT) dated 18 September 2024, we put forward the following bid(s) in respect of **bevacizumab**.

You may expand the boxes below to suit the content of your response, please remove any guidance in *[square brackets]*.

1. Our Company Details	
Trading name:	<i>[insert the name that you do business under]</i>
Full legal name (if different):	<i>[if applicable]</i>
Physical address:	<i>[if more than one office – put the address of your head office]</i>
Business website:	<i>[URL address]</i>
Type of entity (legal status):	<i>[sole trader / partnership / limited liability company / other please specify]</i>

Registration number:	<i>[if your organisation has a registration number insert it here e.g. NZBN number]</i>
<p>Does your organisation identify as being a Māori business?</p> <p>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.</p> <p>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.</p> <p>Pharmac is therefore gathering information from organisations as to whether they identify as a Māori business.</p> <p>A Māori business for Government procurement reporting purposes is:</p> <ul style="list-style-type: none"> • one that has at least 50% Māori ownership, or • a Māori Authority as defined by Inland Revenue. <p>Within these definitions, does your organisation identify as a Māori business? This information will inform Pharmac’s supplier’s database and will be reported to New Zealand Government Procurement (NZGP), subject to any concerns you identify (see below).</p>	<p><i>[Yes / No]</i></p> <p><i>As part of adopting a progressive procurement policy, Pharmac are committed to understand and support what roles Māori businesses play in our supply chain</i></p>
<p>Pharmac is required to report to NZGP on whether an organisation identifies as a Māori business as part of new progressive procurement reporting requirements.</p> <p>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.</p>	<p><i>[Yes / No]</i></p>

2. Our Points of Contact	
Contact person:	<i>[i.e., who communications relating to the response(s) should be made to]</i>
Position:	
Phone number:	
Mobile number:	
Email address:	
Secondary contact person:	
Position:	
Phone number:	
Email address:	

3. Information About Our Organisation	
(a) Information about our Organisation structure:	<i>[you may embed organisational charts or similar]</i>
(b) Information about our management and technical skills:	
(c) Information about our financial resources:	
(d) Information about our, or our supplier's, previous supply performance, and ability to ensure continuity of supply of the proposed product(s)	
(e) Information about our quality assurance processes:	
(f) 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: <ul style="list-style-type: none"> • how your Organisation meets or exceeds the expectations set out in the Supplier Code of Conduct 	
(g) Please outline how your Organisation support social, economic, cultural and environmental outcomes beyond supply of	

<p>Pharmaceuticals (see New Zealand Government Procurement Broader Outcomes).</p> <p>Please also outline how your organisation:</p> <ul style="list-style-type: none"> • Supports New Zealand businesses, including Māori, Pacific, and regional businesses, as well as social enterprises (if relevant) • Supports improving conditions for New Zealand workers and support workforce diversity 	
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4. Details of pharmaceutical presentation (duplicate this table for both presentations of the pharmaceutical)

(a) Chemical name	
(b) Brand name	
(c) Strength(s)	<i>[e.g. capsule, tablet]</i>
(d) Form	<i>[e.g. mg]</i>
(e) Pack size	
(f) Packaging type	
(g) Shelf life and storage	<i>[include months from date of manufacture and temperature to be stored at, including post-compounding stability, shelf-life and storage]</i>
(h) Labelling and images	<p><i>[please embed file(s) into your response form or upload to GETS as clearly named file(s) separate to the response form(s)]</i></p> <p><i>Minimum specification requirements for images:</i></p> <ul style="list-style-type: none"> • <i>On a plain background (preferably white)</i> • <i>Minimal shadows and good lighting</i> • <i>Ideally images should include, pack exterior, sheet of units or similar, close up of unit</i> • <i>Separate images for different strengths or pack sizes</i> • <i>The product should take up 80% of the photo</i>

5. Details of pharmaceutical manufacture (duplicate this table for both presentations of the pharmaceutical)

(a) Name and address of manufacturer/s of the pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc)	
(b) Details on pharmaceutical manufacturing sites and their registration with Medsafe or other international regulatory body	<i>[e.g. TGA, FDA, MHRA]</i>
(c) Batch size/s	
(d) Lead time (time from final notification of award to product being available to supply the New Zealand market) – please provide a lead time for Scenario A and if relevant, Scenario B	
(e) Approximate manufacture time	
(f) Approximate time for shipping	

6. Evidence of market approval and any other required consents

(a) Evidence for market approval and any other required consents, include date of market approval	<i>[please attach copy of Medsafe Gazette notice, either by embedding the document here, or uploading a clearly titled document to GETS alongside this form]</i>
(b) For any proposed products without market approval, but where the dossier has been submitted to Medsafe, please provide evidence of the submission, and status of regulatory approval application:	<i>[N/A if product is approved by Medsafe]</i>
(c) For any proposed products 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:	<i>[N/A if product is approved by Medsafe]</i>
(d) Insert the details of any other consents required for the proposed products and any further details that are relevant to assessing the likelihood and timing of your brand gaining all the necessary consents:	<i>[N/A if product is approved by Medsafe]</i>
(e) Please confirm that you will supply physical sample of the proposed products, to be provided within 12 business days of Pharmac's request.	<i>[whether or not Pharmac requires a sample will be determined upon initial evaluation of your tender bid, please wait to hear from us]</i>

<p>(f) Please provide any details regarding the use of your product for ocular indications, and recurrent papillomatosis, including compounding and stability data (for storage in syringes at appropriate doses) for these indications, as well as any relevant published literature.</p>	
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7. Context surrounding proposed products and capability to support the product(s).	
<p>(a) Key features of our tender bid</p>	
<p>(b) Confirmation that there are no intellectual property barriers (including patent barriers) to our supply of this product for the proposed indications in New Zealand, with additional information if required:</p>	
<p>(c) Information about our ability to ensure the continuity of supply of the pharmaceutical(s), including other countries where the product is widely in use; any additional information about our, or our suppliers existing supply commitments.</p>	
<p>(d) Information relating to the education and support plan (if applicable) for the introduction of your product(s) with regards to Health NZ Hospitals, healthcare professionals, individuals and their whānau transitioning to the proposed product(s). And relevant information regarding the launch of your pharmaceutical in other jurisdictions.</p>	<p><i>[you can attach supporting information (clinician support materials or similar) either by embedding the document here, or uploading a clearly titled document to GETS alongside this form]</i></p>
<p>(e) Information relating to training and education materials that would be provided to Health NZ Hospitals, healthcare professionals, individuals and their whānau and caregivers using the proposed products. Consider ability to make patient materials available in multiple languages.</p>	<p><i>[you can attach supporting information (clinician support materials or similar) either by embedding the document here, or uploading a clearly titled document to GETS alongside this form]</i></p>
<p>(f) Include information about the location, experience and qualifications of any staff that would be involved in supporting the proposed products (including those providing training and education).</p>	

<p>(g) Please outline how your Organisation would support improving access and responsible use of these medicines (eg services and resources that would be offered).</p> <p>(h) How would you support implementation of your tender bid to ensure that access to treatment is equitable and contributes to equitable outcomes, specifically for Māori, Pacific and disabled peoples (but also for communities who have been underserved by the health system, including those living rurally or people who've been refugees).</p>	
<p>(i) Any other reasons why Pharmac should accept our tender bid</p>	
<p>(j) Any additional information Pharmac should consider under its Factors for Consideration Framework:</p>	

8. Labour and human rights				
<p>(a) Visibility over our supply chain Please select one of the below options and explain why you have selected this option: High: we have mapped the full supply chain for key products and services used by our organisation and have identified key suppliers at all levels of your supply chain. Moderate: we have identified major suppliers and have partially or fully mapped the supply chains for key products and services of our supply chain. Developing: we have identified major suppliers. We have very limited or no visibility of our supply chains for key products and services of our supply chain. Other: summary of the current status of our supply chain visibility</p>				
<p>(b) Our organisation has a policy or policies in place to deal with modern slavery and worker exploitation</p>	Yes		No	
<p>(c) Our organisation has systems to monitor compliance with these policies</p>	Yes		No	
<p>(d) If you said yes to either of the two above statements, please attach or link to the supporting information.</p>				

If the answer is no, please provide information on what your organisation is doing, or plans to do, to manage modern slavery and worker exploitation risk.				
(e) Our organisation performs due diligence screening of all prospective suppliers to assess the risk of modern slavery or other human rights harms that may occur in its operations and supply chains	Yes		No	
(f) If yes, please describe how your organisation performs its due diligence for modern slavery and worker exploitation concerns. If no, does your organisation plan to introduce measures to screen prospective suppliers from modern slavery and worker exploitation in future?				
(g) Our organisation complies with recognised standards	Yes		No	
(h) If yes, please identify the standard and outline the degree to which your organisation complies.				

9. Environmental Sustainability				
(i) Does your organisation have an environmental/sustainability policy?	Yes	<i>[delete one]</i>	No	<i>[delete one]</i>
(j) Does your organisation have a sustainability report?	Yes	<i>[delete one]</i>	No	<i>[delete one]</i>
(k) If yes to either of the two above questions, please attach or link:				
(l) How does your organisation contribute to environmental sustainability?	<i>[Please describe the measures you take to contribute to environmental sustainability – in general and specifically in relation to this RFP]</i>			
(m) Has your organisation received any environmental/sustainability award(s)?	Yes	<i>[delete one]</i>	No	<i>[delete one]</i>
(n) If yes, provide details:				
(o) Has your organisation received any environmental fine/prosecution(s)?	Yes	<i>[delete one]</i>	No	<i>[delete one]</i>
(p) If yes, provide details:				

(q) Has your organisation received any environmental audit(s), or does it comply with a recognised standard?	Yes	<i>[delete one]</i>	No	<i>[delete one]</i>
(r) If yes, provide details:				

10. Pricing and Terms of Supply

- As outlined in the RFT, you are required to submit pricing for the bid options that make up a tender bid.
- Must include a bid for Scenario A and may include a bid for Scenario B
- All prices must be in New Zealand dollars and exclusive of GST.
- Each row is for one strength and pack size of a pharmaceutical, add more rows and bid options as required,
- The pricing is per pack, in line with what could be listed on the Pharmaceutical Schedule, but any rebate would apply on a per unit basis, i.e. the price is divisible by the pack size to have a per unit price.
- Inclusion of a rebate is optional.
- You may duplicate the tables below in order to submit more than one bid for a given bid option.
- **Lead time definition:** This is the time in months or weeks from the date of Pharmac notifying you that the response has been accepted without any further consultation or decisions pending to the date that you are able to make the product available in the NZ supply chain.
- In addition to Lead Time you may provide information on what month supply could be available, independent of notification timeframes

Bid Option/Scenario A: Funding of bevacizumab for the existing market (as per the indication restrictions in Section H of the Schedule), and for the ovarian cancer (advanced) and hepatocellular carcinoma (unresectable, 1st line) markets, with a total 10% ABA Limit for all funded markets combined.

Tender Item – (Chemical Entity, Form and Strength)	Brand name	Units (Pack Size)	List price (Pack)	Net price (Pack)	% Rebate	Lead Time

<i>[Any comments in relation to bid]</i>						

Bid Option/Scenario B: Funding of bevacizumab for the existing market (as per the indication restrictions in Section H of the Schedule), and for the ovarian cancer (advanced), hepatocellular carcinoma (unresectable, 1st line), cervical cancer (advanced), and glioblastoma (recurrent or relapsed) markets, with a total 5% ABA Limit for all funded markets combined.						
Tender Item – (Chemical Entity, Form and Strength)	Brand name	Units (Pack Size)	List price (Pack)	Net price (Pack)	% Rebate	Lead Time
<i>[Any comments in relation to bid]</i>						