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8 September 2022

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF INTRAVENOUS TRASTUZUMAB

Pharmac invites proposals for the supply of intravenous trastuzumab for the New Zealand subsidised market.

This request for proposals (**RFP**) letter incorporates the following schedules:

- Schedule 1 specifies the pharmaceutical for which Pharmac is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that Pharmac expects to follow in relation to the RFP;
- Schedule 3 sets out information about the estimated size of the current subsidised market for the pharmaceutical; and
- Schedule 4 contains the RFP form in which you are to provide details of your proposal.

If you wish to submit a proposal, you must submit it to Pharmac via the Government Electronic Tenders Service (**GETS**) (www.gets.govt.nz) no later than 4.00 p.m. on 19 October 2022.

If you have any questions about this RFP, please post these on GETS, responses to all questions will be published on GETS.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
Director of Operations

Schedule 1: Pharmaceutical, background to RFP and types of proposals sought

1. Pharmaceutical

Pharmac is interested in considering any proposal from suppliers of intravenous trastuzumab.

2. Background to RFP

The background to this RFP is as follows:

Trastuzumab is a humanised monoclonal antibody that selectively targets and binds with high affinity to human epidermal growth factor receptor 2 (HER2). Trastuzumab products have been shown to inhibit proliferation and mediate antibody-dependent cellular toxicity in tumour cells (cancers) that overexpress HER2.

Intravenous trastuzumab is available as a powder for injection vial which is then reconstituted prior to administration. In the New Zealand public health sector trastuzumab is given by intravenous (IV) infusion (over 30 - 90 minutes) typically every three weeks, in a Te Whatu Ora hospital outpatient clinic setting.

Current funding

Intravenous trastuzumab has been listed on the Pharmaceutical Schedule since 2005 for metastatic breast cancer, and from 2007 for early breast cancer subject to funding criteria (see: RS1554 – Trastuzumab). The table below outlines the current listing of intravenous trastuzumab in Section B of the Pharmaceutical Schedule (prices shown are ex-manufacturer, excluding GST). The listing in Section B of the Pharmaceutical Schedule is for claiming purposes only, intravenous trastuzumab is not currently delivered in a community setting.

		Subsidy/Price (NZ$)	Per	Fully Subsidised	Brand or Generic Manufacturer
TRASTUZUMAB Special Authority see SA632– Retail pharmacy					
Inj 150 mg vial	……	1,350.00	1	✓	**Herceptin**
Inj 440 mg vial	……	3,875.00	1	✓	**Herceptin**
Inj 1 mg for ECP	……	9.36	1 mg	✓	**Baxter**

The table below outlines the current listing of intravenous trastuzumab in the Hospital Medicines List (Part II of Section H of the Pharmaceutical Schedule) for use in Te Whatu Ora hospitals.

		Price (NZ$)	Per	Fully Subsidised	Brand or Generic Manufacturer
TRASTUZUMAB Hospital Restriction see RS1554					
Inj 150 mg vial	……	1,350.00	1	✓	**Herceptin**
Inj 440 mg vial	……	3,875.00	1	✓	**Herceptin**
Inj 1 mg for ECP	……	9.36	1 mg	✓	**Baxter**

Te Whatu Ora hospitals are able to procure intravenous trastuzumab from a third-party compounder (a Contract Manufacturer) provided that Te Whatu Ora hospitals ensure that all of the component pharmaceuticals used in the compounded product are listed on the Pharmaceutical Schedule and comply with any national contracting obligations. The “Inj

1mg for ECP" formulation of intravenous trastuzumab listed in Section B of the Schedule allows Te Whatu Ora hospitals to claim a subsidy for the correct number of mg provided by the compounder. This ECP price is determined by Pharmac.

The Herceptin brand of intravenous trastuzumab, supplied by Roche Products (New Zealand) Ltd, is funded subject to a listing agreement with Pharmac, which includes subsidy and delisting protection until 31 December 2018. It also includes confidential net pricing (achieved via a rebate on all funded use of the medicine).

Pharmac is aware of the following active New Zealand patents relating to intravenous trastuzumab:

Patent Number	**Expiry**	**Brief description**
NZ537660	11 July 2023	Methods for identifying tumours that are responsive to treatment with anti-ErbB2 antibodies
NZ598677	6 August 2030	Process for producing an anti-HER2 antibody in a glutamine-free cell media
NZ590431	21 February 2026	Patent relates to the use of pertuzumab and trastuzumab in the treatment of cancers including metastatic breast cancer and gastric cancer.
NZ621367	11 October 2032	Patent relates to the use of pertuzumab and trastuzumab in the treatment of early-stage breast cancer together with carboplatin-based chemotherapy drugs, docetaxel and carboplatin.

Please note the patents outlined above are not intended to be an exhaustive list and Pharmac makes no representation as to the patent status and descriptions outlined above and accepts no liability for any patent infringement that might occur as a result of this RFP process or Pharmac's acceptance of any proposals.

Subcutaneous Trastuzumab

An application for the funding of subcutaneous trastuzumab on the Pharmaceutical Schedule, for the currently funded indications, is under assessment. Further information regarding this application can be found on the Application Tracker on the Pharmac website.

This RFP process is solely seeking proposals for supply and listing of intravenous trastuzumab. Pharmac reserves the right to list subcutaneous trastuzumab on the Pharmaceutical Schedule regardless of the outcome of this RFP.

Other treatments funded for breast cancer

Pertuzumab

Pertuzumab is funded in combination with intravenous trastuzumab for patients with metastatic HER2+ breast cancer, subject to funding criteria.

Lapatinib

Lapatinib (lapatinib ditosylate) was previously funded as a first-line treatment for people with metastatic HER2+ breast cancer who have not previously had treatment with intravenous trastuzumab, or for people who were intolerant to intravenous trastuzumab.

Due to decreasing demand the supplier notified of its intention to discontinue lapatinib. Access to treatment is now restricted to people who were receiving funded lapatinib prior to 1 April 2021. We understand there are currently less than 10 people on lapatinib. We intend to delist lapatinib from the Pharmaceutical Schedule at a future date.

Trastuzumab emtansine

Trastuzumab emtansine has been funded since 1 December 2019 for patients with metastatic breast cancer. On 1 July 2022, funded access was widened to include people with early stage HER2+ breast cancer, with residual disease after initial treatment to shrink the tumour following surgery. We anticipate approximately 70 people per year would receive trastuzumab emtansine (in place of intravenous trastuzumab) for adjuvant early breast cancer treatment following surgery.

Adjuvant trastuzumab emtansine therapy is potentially curative for some people and therefore its use may reduce the number of people who access intravenous trastuzumab in the metastatic setting. We estimate the widening of funded access to trastuzumab emtansine could reduce the number of people requiring intravenous trastuzumab for metastatic breast cancer by approximately 10%.

The estimates outlined above are approximate and indicative only. Pharmac makes no representation as to the accuracy of these estimates and Pharmac accepts no liability for any errors or omissions in this information. Suppliers participating in the RFP should use their own estimates on market demand when preparing their bids.

Clinical Advisory Committee Advice

Trastuzumab is a biologic medicine. The Herceptin brand of trastuzumab is the original biologic product; and trastuzumab products made by other suppliers are known as trastuzumab biosimilars.

In 2019, Pharmac sought advice from its Pharmacology and Therapeutics Advisory Committee (PTAC) and Cancer Treatments Subcommittee of PTAC (CaTSoP) regarding evidence from Celltrion Healthcare for its biosimilar trastuzumab product (CT-P6/Herzuma). The advice received noted that it was clinically acceptable for a biosimilar trastuzumab product to be listed and to be the only funded intravenous trastuzumab product listed on the Schedule. The advice supported Pharmac progressing a competitive procurement process that may result in the listing of a biosimilar trastuzumab. The full records of the discussions are available on the Application Tracker on the Pharmac website.

In April 2022, Pharmac also sought advice from the Cancer Treatments Advisory Committee[1] in relation to the options associated with a competitive process for the trastuzumab market in New Zealand. In summary, the Committee supported a competitive process for the supply of trastuzumab for all listed indications currently funded and welcomed further consideration of applications for the use of intravenous trastuzumab in other indications. The full PDF record of the discussion is available on our website.

Based on the clinical advice received to date, Pharmac has decided to progress a competitive process (i.e. this RFP) for the supply of intravenous trastuzumab. A possible outcome from this RFP is that a trastuzumab biosimilar becomes the principal funded trastuzumab.

Reasons for running the RFP

Pharmac is aware of multiple intravenous trastuzumab biosimilars currently approved by Medsafe and/or available overseas. In light of this competition, the purpose of this RFP is to:

(a) reduce the total expenditure in the intravenous trastuzumab market;

(b) secure ongoing supply of funded intravenous trastuzumab.

Intended outcome of the RFP

Through this RFP, Pharmac may award Principal Supply Status (PSS) to a supplier.

The award of PSS means that the successful supplier's trastuzumab product (either biosimilar or reference biologic trastuzumab) would be the principal funded brand of intravenous trastuzumab in the New Zealand subsidised market and would be guaranteed at least 95% of the funded intravenous trastuzumab market.

This means that brands of intravenous trastuzumab other than the PSS brand could be funded for use in up to 5% of the funded intravenous trastuzumab market. Pharmac retains its discretion as to who could access funding for an alternative brand and how funded access to it would be enabled. Based on current advice, it is likely this 5% alternative brand allowance (ABA) would be for people who experience exceptional circumstances. Funded access to an ABA brand could be via a listing on the Pharmaceutical Schedule or via Pharmac's exceptional circumstances framework. In the case of intravenous trastuzumab this would likely occur via Pharmac's exceptional circumstances framework and would be subject to a decision by the Pharmac Board or its delegate.

The successful supplier would be awarded PSS for intravenous trastuzumab, following a transition period, for a period of three years.

Pharmac would retain the right at its sole discretion to widen funded access to intravenous trastuzumab at any time during the PSS period.

[1] Previously CaTSoP

3. Types of proposals sought

Pharmac is willing to consider the following types of proposals:

(a) All proposals **MUST** include intravenous trastuzumab for all current funded indications specified in the current Special Authority criteria in Section B and the current Hospital Restrictions in Part II of Section H of the Pharmaceutical Schedule.

(b) Proposals **MUST** include a period of Principal Supply Status (PSS) of three years, with an alternative brand allowance anticipated to be 5% for all currently funded indications, following a transition period (if required).

(c) Proposals that would require a change to a biosimilar intravenous trastuzumab **MUST** include a transition period of at least six months between listing of the new intravenous trastuzumab biosimilar and commencement of any PSS period, noting this period may be subject to negotiation following evaluation of proposals and any additional clinical advice, as required.

(d) Proposals that would require a change to a biosimilar intravenous trastuzumab **MUST** include an education support plan and implementation support for the transition period, including, but not limited to:

  (i) Providing information regarding compounding and stability data, including extended stability data.

  (ii) Training for clinicians regarding administration differences (if any).

  (iii) International evidence regarding previous transitioning of patients, specifically in Europe and Australia.

(e) Proposals **MUST** include data relating to the stability of the compounded intravenous trastuzumab product of approximately 30 days.

(f) Proposals **MUST** include labelling and images of the products within the proposal. Samples of all presentations included **MUST** be provided upon request by Pharmac (and, if supply is intended to be in a different presentation, form and strength from the provided samples, information about the differences must be supplied) within a reasonable timeframe of such a request.

(g) Proposals **MAY** include confidential pricing, however this:

  (i) **MUST** include an option in the form of a flat rebate structure of one price per unit (either vial or mg) regardless of volumes;

  (ii) **MAY** include an option which includes a ‘soft cap’, where a rebate of less than 100% exists over a certain level of expenditure, or a tiered pricing structure where the level of rebate is linked to certain levels of expenditure.

(h) Proposals **MAY** include other strengths of intravenous trastuzumab than those currently funded.

(i) Multiple proposals **MAY** be submitted.

(j) Proposals **MAY** include intravenous trastuzumab products that are yet to obtain all necessary Consents (where 'Consents' means all consents, permits, licences and authorisations, whether statutory or otherwise, required for the supply of the pharmaceutical in New Zealand (including Ministry of Health market approval)). In such circumstances:

  (i) Suppliers may be required to demonstrate their ability to obtain those Consents within a time frame acceptable to Pharmac. For example, suppliers may be required to demonstrate that the dossier for their proposed product(s) is ready to submit to Medsafe within one month of such a request being made by Pharmac; and

  (ii) Pharmac will not list the proposed product in the Pharmaceutical Schedule until all Consents are obtained.

Pharmac is **not** willing to consider the following types of proposals:

(k) Proposals involving funded or unfunded pharmaceuticals or related products other than intravenous trastuzumab;

(l) Proposals involving subcutaneous trastuzumab;

(m) Proposals that include a requirement to widen access to funded intravenous trastuzumab;

(n) Proposals that include a 'hard cap', where a 100% rebate exists over a certain level of expenditure;

(o) Proposals that involve the listing of intravenous trastuzumab with a partial subsidy;

(p) Proposals that involve foreign currency exchange rate clauses or prices linked to any index; and

(q) Two-part pricing arrangements, whereby Pharmac may make an up-front payment (in addition to any ongoing subsidy) in return for the listing of a pharmaceutical on specific terms.

Subject to the above, Pharmac is open to considering any other types of proposals you may wish to put forward.

Widened Access

Pharmac would retain the right at its absolute sole discretion to widen access to intravenous trastuzumab at any point during the PSS period. This is expected to include further assessment of funding applications that have not been previously considered for funding or have previously received a recommendation from PTAC (or Specialist Advisory Committee), including a recommendation to decline for funding.

See Pharmac's application tracker below for further information on applications that have previously been considered for trastuzumab:

https://connect.pharmac.govt.nz/apptracker/s/global-search/Trastuzumab

Trastuzumab for metastatic gastric cancer

Trastuzumab is funded internationally for the treatment for HER2+ve locally advanced or metastatic gastric cancer. An application for funding for this indication was received by Pharmac in November 2010 and formally declined in July 2019. This decision was based on a decline recommendation from the Cancer Treatment Subcommittee of PTAC (CaTSoP) and noted that further evidence was required to determine the benefit of trastuzumab in this setting and the poor cost-effectiveness. At the time of the decline decision Pharmac noted that any future consideration of funding of trastuzumab for HER2+ve advanced gastric cancer would require a new submission that addresses the reasons for the decline decision, including supporting evidence (if relevant).

At the April 2022 Cancer Treatments Advisory Committee (CTAC) meeting, it was recommended that this application be reassessed noting the likelihood of improved cost-effectiveness associated with the availability of trastuzumab biosimilars, the health need of this patient population and likelihood of updated evidence to support treatment in this setting. Further consideration of this application is expected to occur at the next CTAC meeting (October 2022).

Treatment holidays for people with metastatic breast cancer

Pharmac has also received a recommendation from its clinical experts to amend the criteria for trastuzumab (and pertuzumab) for metastatic breast cancer to allow for treatment holidays to occur. This has not yet been assessed ahead of ranking on Pharmac's Options for Investment list.

Supplier Code of Conduct

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. Pharmac expects suppliers to meet or exceed the minimum standards set out in the Supplier Code of Conduct.

Schedule 2: RFP process

Pharmac expects to follow the process set out below in the sequence indicated.

1. **Submission**

(a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.

(b) Proposals must be submitted to Pharmac via the Government Electronic Tenders Service (GETS) no later than **4.00 p.m.** (New Zealand time) on **19 October 2022**. Late proposals will only be considered at Pharmac's discretion, taking into account the need for fairness to other suppliers and integrity of the RFP process.

(c) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.

(d) If you have any enquiries about this RFP you should submit them on GETS, responses to all enquires will be published on GETS. If you do need to get in touch via email, please contact Catherine Kingsbury at procurement@pharmac.govt.nz

2. **Evaluation**

(a) Following the deadline for submitting proposals an Evaluation Committee comprising Pharmac staff will evaluate each proposal to select its preferred proposal(s).

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

(c) 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.

(d) The information to be taken into account in applying the Factors by the Evaluation Committee will be at its discretion, however it will include:

(i) information provided by you in accordance with Schedule 4 of this RFP; including information provided under clause 3 below;

(ii) any advice from PTAC, or relevant Specialist Advisory Committee(s), any relevant professional organisation, any relevant healthcare professionals, any relevant consumers or consumer organisations or health sector agencies. This may include specific clinical advice regarding relative risks and benefits

of proposals including clinical benefits, risks and implementation considerations following the closing of this RFP;

(iii) previous supply performance and relevant expertise; and

(iv) any other information that the Evaluation Committee considers to be relevant having regard to probity principles.

(e) Each proposal will be evaluated on the basis that the price offered, the expenditure entailed, and any other terms included in the proposal, are the best that the supplier is able to offer. If you do not put forward your best terms you risk having your proposal excluded at the evaluation stage.

(f) For the purpose of fiscal evaluation for this RFP, Pharmac would assess any pricing offered as commencing from 1 July 2023. Suppliers may offer proposals that include a listing or price change prior to this date; however, any fiscal impact from this earlier listing/price change would not be included in Pharmac's primary fiscal evaluation of proposals. If two or more proposals were determined by Pharmac to be similar, having considered all the Factors for Consideration, Pharmac may undertake a secondary fiscal evaluation where we may consider the impact of earlier list date/price changes.

(g) Pharmac is not bound to select the lowest priced proposal or any proposal.

3. **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 proposal, including (but not limited to):

(i) detailed information about your company structure, credit status and any other relevant company information; and

(ii) any other additional information about your pharmaceutical.

(b) Please note that Pharmac may seek advice from PTAC, or relevant Specialist Advisory Committee(s), any relevant professional organisations or healthcare professionals with regard to your product including evaluation of any product samples.

(c) 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, provided that in Pharmac's judgment this would not be unfair to any other party.

4. **Negotiation**

(a) Pharmac may negotiate with the submitter(s) of one or more preferred proposals, in the latter case whether or not the acceptance of either supplier's proposal would exclude acceptance of the other proposal.

(b) Negotiations will proceed on the basis that Pharmac's standard terms and conditions for supply of pharmaceuticals, which are available as an attachment to this RFP on GETS and the Pharmac website will apply.

(c) Given that Pharmac expects your proposal to be the best you can offer, Pharmac does not intend to initiate negotiation with you on price. However, Pharmac does not exclude the possibility that the final price agreed will be different from the price put forward in your proposal, as a result of the impact that other negotiated terms may have on price.

(d) Pharmac may negotiate and enter into a provisional agreement with a preferred supplier(s) on whatever special terms, in addition to Pharmac standard terms and conditions, Pharmac considers appropriate.

(e) If Pharmac and the supplier(s) are unable to reach a provisional agreement within what Pharmac considers to be a reasonable time, Pharmac may terminate those negotiations and negotiate with a different supplier(s).

5. Consultation and approval

(a) Any provisional agreement will be conditional on consultation with suppliers and other interested parties to the extent Pharmac considers consultation to be necessary or appropriate, and on Board approval (or approval by the Board's delegate acting under delegated authority).

(b) Pharmac will not consider any counter-offers received during consultation.

(c) The provisional agreement and responses to consultation will be considered by Pharmac's Board (or by the Board's delegate acting under delegated authority) in accordance with Pharmac's decision-making framework as outlined in its OPPs with reference to the Factors for Consideration.

(d) If the Board or its delegate does not approve the provisional agreement, then Pharmac may initiate negotiations for a provisional agreement with any other supplier(s).

(e) The RFP process will be complete once Pharmac has notified suppliers of either:

(i) the Board's or its delegate's decision to accept a negotiated agreement; or

(ii) the termination of the RFP process.

6. Miscellaneous

(a) Pharmac reserves the right, having regard to probity principles:

(i) to make such adjustments to the above RFP process as it considers appropriate, at any time during the process, provided that it notifies suppliers affected by those changes;

(ii) not to accept any proposal;

(iii) to seek clarification of any proposal;

(iv) to meet with any supplier in relation to its proposal;

(v) to enter into an agreement or arrangement that differs in material respects from that envisaged in this RFP letter;

(vi) to suspend this RFP process. For example, if during the RFP process (and before a provisional agreement is entered into) it becomes apparent to Pharmac that further consultation is appropriate or required we may suspend the RFP process in order to consult. In this situation we may ask you to adapt and resubmit your proposal in light of consultation, or alternatively we may request that new proposals be submitted;

(vii) to terminate this RFP process at any time, by notifying suppliers who submitted proposals, and, following termination, to negotiate with any supplier(s) on whatever terms Pharmac thinks fit;

(viii) to readvertise for proposals.

(b) Pharmac may consult or seek clinical advice from PTAC or a relevant Specialist Advisory Committee at any stage of the RFP process. Pharmac will notify you if the clinical advice results in any changes to the terms of the RFP.

(c) You must not initiate or engage in any communication with other suppliers in relation to the RFP, whether before or after submitting their proposal(s), until such time as a provisional agreement is accepted by Pharmac's Board or the Board's delegate.

(d) You must not at any time initiate any communication with Pharmac, Manatū Hauora (the Ministry of Health) (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or Te Whatu Ora, or Te Aka Whai Ora or advisors to Pharmac with a view to influencing the outcome of this RFP process.

(e) You must pay your own costs for preparing and submitting your proposal.

(f) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by Pharmac.

(g) Your submission of a proposal will be taken as acceptance of the terms contained in this RFP letter. Pharmac may exclude your proposal if you do not comply with any of the terms contained in this RFP letter.

(h) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract for the supply of intravenous trastuzumab by Pharmac's apparent acceptance and instead a separate agreement needs to be negotiated.

(i) Pharmac is not liable in any 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 RFP.

(j) Pharmac will consider your proposal and information exchanged between us in any negotiations relating to your proposal, excluding information already in the public domain, to be confidential to us and our employees, legal advisors and other consultants, Manatū Hauora, Te Whatu Ora, and Te Aka Whai Ora (**Confidential Information**). However, you acknowledge that it may be necessary or appropriate for Pharmac to release Confidential Information:

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

(ii) in the course of consultation on a provisional agreement entered into with a supplier; or

(iii) in publicly notifying any approval by the Pharmac Board of that agreement; or

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

Pharmac may consult with you before deciding whether to disclose Confidential Information for the purposes described in sub-clauses (i) to (iv) above. You acknowledge, however, that it is for Pharmac to decide, in its absolute discretion, whether it is necessary, or appropriate, to disclose information for any of the above purposes, provided that Pharmac shall act in good faith in disclosing any Confidential Information.

7. Anticipated timetable

(a) Following receipt of proposals, Pharmac anticipates:

(i) the Evaluation Committee evaluating proposals in October and November 2022;

(ii) seeking clinical advice (if necessary) in January 2023;

(iii) negotiating with submitter(s) of one or more preferred proposals in February 2023;

(iv) consulting on a provisional agreement in March 2023;

(v) Pharmac's Board, or the Board's delegate, considering this provisional agreement in or after May 2023;

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

(b) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is 1 July 2023.

(c) Please note that if a proposal for principal supply is accepted, the date of implementation may be later to allow for an orderly transition to any principal supply arrangement.

8. Governing Law

This RFP is governed by New Zealand law, and the New Zealand courts have exclusive jurisdiction in all matters relating to this RFP.

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Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of intravenous trastuzumab under the current eligibility criteria and restrictions.

The information 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 intravenous trastuzumab 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 change to the figures below. We note that there have been recent changes to the funding of other products that may have an impact on the future market size of intravenous trastuzumab.

Funded trastuzumab infusions (units) by formulation (Calendar year)					
Presentation	**2017**	**2018**	**2019**	**2020**	**2021**
150 mg vial	8,703 vials	8,018 vials	8,845 vials	8,275 vials	8,821 vials
440 mg vial	1,790 vials	1,414 vials	1,402 vials	1,760 vials	1,757 vials
Inj 1 mg for ECP	2,004,816 mg	2,322,975 mg	2,019,095 mg	1,923,432 mg	2,208,655 mg
Total mg	**4,097,866 mg**	**4,147,835 mg**	**3,962,725 mg**	**3,939,082 mg**	**4,304,885 mg**

Number of people receiving treatment with trastuzumab per financial year			
Financial Year	**Early Breast Cancer**	**Metastatic Breast Cancer**	**Total**
2016/17	712	231	979
2017/18	696	246	967
2018/19	667	260	955
2019/20	615	265	920
2020/21	608	271	911

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Schedule 4: Proposal form

An editable version of this form is available on the GETS listing for this RFP.
Proposals must be submitted to Pharmac via the Government Electronic Tenders Service (GETS) (www.gets.govt.nz) no later than 4.00 p.m. on 19 October 2022.

[*Supplier to insert date*]

Director of Operations
C/- Catherine Kingsbury
Pharmac
PO Box 10-254

Tēnā koe

Proposal for the supply of intravenous trastuzumab

In response to your request for proposals (**RFP**) dated **8 September 2022**, we put forward the following proposal in respect of intravenous trastuzumab.

Set out below is further information in support of our proposal.

(a) Our contact details:

Name of supplier	
Contact person	

Address	
Phone	
Email address	
Additional contact person	
Email address of additional contact person	

(b) Details of pharmaceutical presentation:

Chemical name	
Strength(s) (e.g. 150 mg)	
Form (e.g. powder for concentrate)	
Brand name	
Pack size (e.g. 1 vial)	
Packaging type (e.g. prefilled syringe)	
Shelf life (e.g. 36 months from date of manufacture stored at or below 30°C)	

(c) Information regarding to the stability of the compounded intravenous trastuzumab product of approximately 30 days:

(d) Details of pharmaceutical manufacture:

Name and address of manufacturer(s) of the pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc)	
Lead time (Time from notification of award to product being available to supply the New Zealand market)	
Details on pharmaceutical manufacturing sites and their registration with Medsafe or other international regulatory body (e.g. TGA, FDA, MHRA)	
Batch size(s)	
Approximate manufacture time	
Approximate time for shipping	

(e) Key features of our proposal:

(f) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for Pharmac: Please note, clause 3(g) of Schedule 1.

Please expand these boxes and add strengths to the below table as required

Trastuzumab	
Strength	**Proposal**

(g) Evidence of market approval and any other required consents:

Date of market approval (please attach copy of Medsafe Gazette notice)	
OR Date of submission of dossier (please attach confirmation from Medsafe that dossier has been submitted)	
OR Expected date of dossier submission to Medsafe	

(h) 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:

(i) Information about our ability to ensure the continuity of supply of the pharmaceutical (including potential actions if a supply issue were to occur), as well as information regarding other countries where the product is provided:

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

(k) Information relating to the education support plan and implementation support for the transition period (if required), including information regarding compounding and stability data; training for clinicians regarding administration differences; and international evidence regarding previous transitioning of patients.

Please include any attachments or additional information with your proposal to support your response to this question:

(l) Information about any support that would be provided to minimise any potential impact of a transition on patient groups experiencing health inequities:

(m) Information about sustainability aspects of our company:

Does our Organisation have an environmental/sustainability policy?	Yes		No	
Does our Organisation have a sustainability report?	Yes		No	
If yes to either of the two above questions, please attach or link:				

How does our Organisation contribute to environmental sustainability?	*Please describe the measures you take to contribute to environmental sustainability – in general and specifically in relation to this Invitation*			
Has our Organisation received any environmental/sustainability award(s)?	Yes		No	
If yes, provide details:				
Has our Organisation received any environmental fine/prosecution(s)?	Yes		No	
If yes, provide details:				
Has our Organisation received any environmental audit(s) or does it comply with a recognised standard?	Yes		No	
If yes, provide details:				

(n) Reasons why Pharmac should accept our proposal:

(o) Additional information that Pharmac should consider when evaluating our proposal:

(p) Please include any additional information you consider relevant under Pharmac's Factors for Consideration decision making framework: