PHARMAC
TE PĀTAKA WHAIORANGA

Level 9, 40 Mercer Street, Wellington
PO Box 10254, Wellington 6143, New Zealand
P: +64 4 460 4990 | F: +64 4 460 4995
www.pharmac.govt.nz

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Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF ADALIMUMAB

PHARMAC invites proposals for the supply of adalimumab in 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 5.00 p.m. on 23 April 2021.

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 proposals from suppliers of adalimumab.

2. Background to RFP

The background to this RFP is as follows:

Adalimumab is a recombinant human monoclonal antibody that reduces chronic inflammation and immune response activation. It is funded for a range of ophthalmology, dermatology, gastrointestinal and rheumatology conditions, which include both approved and unapproved (off-label)[1] indications.

Adalimumab is a long-term treatment administered via subcutaneous injection. It is typically used every 14 days and usually self-administered by patients (or their parents or caregivers) in the community following training in proper subcutaneous injection technique.

Current funding

Adalimumab has been listed on the Pharmaceutical Schedule since 2006 subject to Special Authority restrictions (see: SA1975 – Adalimumab).The table below outlines the current listing of adalimumab in Section B of the Pharmaceutical Schedule for use in the community (prices shown are ex-manufacturer, excluding GST).

		Subsidy/Price (NZ$)	Per	Fully Subsidised	Brand or Generic Manufacturer
ADALIMUMAB Special Authority see SA1975 – Retail pharmacy					
Inj 20 mg per 0.4 ml, prefilled syringe	.....	1599.96	2	✓	**Humira**
Inj 40 mg per 0.8 ml, prefilled pen	.....	1599.96	2	✓	**HumiraPen**
Inj 40 mg per 0.8 ml, prefilled syringe	.....	1599.96	2	✓	**Humira**

The table below outlines the current listing of adalimumab in the Hospital Medicines List (Part II of Section H of the Pharmaceutical Schedule) for use in DHB Hospitals.

		Subsidy/Price (NZ$)	Per	Fully Subsidised	Brand or Generic Manufacturer
ADALIMUMAB – Restricted see RS1784					
Inj 20 mg per 0.4 ml, prefilled syringe	.....	1599.96	2	✓	**Humira**
Inj 40 mg per 0.8 ml, prefilled pen	.....	1599.96	2	✓	**HumiraPen**
Inj 40 mg per 0.8 ml, prefilled syringe	.....	1599.96	2	✓	**Humira**

A confidential rebate applies to all sales of Humira to DHB Hospitals and dispensing's from Community Pharmacies, reducing the net funded expenditure on this medicine.

The currently listed brands of adalimumab (Humira and HumiraPen, referred to collectively hereafter as a single brand, Humira), supplied by AbbVie, are funded subject to a listing

[1] Section 25 of the Medicines Act 1981 permits an authorised prescriber to use any medicine (approved or unapproved) for the treatment of a particular patient.

agreement with PHARMAC, which included subsidy and delisting protection until 1 July 2020.

PHARMAC is aware of the following New Zealand patents relating to adalimumab:

Patent Number	Expiry	Brief description
NZ529574 NZ545649 NZ560792 NZ573478 NZ586063 NZ596878	5 June 2022	Use of adalimumab for biweekly (once every two weeks) subcutaneous administration, and a pre-loaded syringe containing the composition.
NZ555692 NZ563452 NZ576774 NZ587754 NZ598346	5 June 2022	Use of adalimumab for the treatment of specific diseases via biweekly (once every two weeks) subcutaneous administration.
NZ549959 NZ579302 NZ591362	11 April 2025	Use of adalimumab as part of multivariable treatment regimes: for intestinal disorders; intestinal disorder resistant to infliximab; or psoriasis or hidradenitis suppurativa.
NZ538030	15 August 2023	Use of liquid formulations of adalimumab suitable for use in subcutaneous administration.
NZ595225	16 May 2036	Use of adalimumab to inhibit radiological progression of psoriatic arthritis by biweekly (once every two weeks) subcutaneous administration.

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.

PHARMAC understands that some suppliers of adalimumab may have licensing agreements in place, in respect of certain patents, which may enable the supply of adalimumab in New Zealand prior to the expiry of a valid patent(s).

Clinical Advisory Committee Advice

Adalimumab is what is known as a biologic medicine. Humira is the original brand; adalimumab products made by other suppliers are known as adalimumab biosimilars. The existence of adalimumab biosimilars may provide the opportunity to improve the cost effectiveness of adalimumab by competing the market. An important first step in this process for PHARMAC is to seek clinical advice on this possibility.

In November 2020, PHARMAC sought advice from its Pharmacology and Therapeutics Advisory Committee (PTAC) regarding evidence from Amgen for its biosimilar adalimumab product (Amgevita). The Committee recommended that PHARMAC could progress a competitive procurement process that resulted in the listing of a biosimilar adalimumab.

The full record of the discussion is available on our website.

PHARMAC also sought advice on a competitive procurement process for adalimumab from the Dermatology, Ophthalmology, Gastrointestinal and Rheumatology Subcommittees of PTAC. Records of those discussions are available on our website (Dermatology and Ophthalmology record, Gastrointestinal record and Rheumatology record).

Reasons for running the RFP

PHARMAC is aware of multiple adalimumab biosimilars currently approved by Medsafe or available overseas. In light of this competition, the purpose of this RFP is to:

(a) reduce the total expenditure in the adalimumab market;

(b) secure ongoing supply of funded adalimumab;

(c) determine if widened access would be possible from within the available budget.

Any proposals progressed for consideration for funding would be assessed using PHARMAC's decision-making framework as outlined in its OPPs with reference to the Factors for Consideration.

Excluded patient groups

Based on our clinical advice it is PHARMAC's expectation that the majority of existing patients who take adalimumab could use any supplier's brand of adalimumab and would have no clinical problems with a change to a biosimilar adalimumab if this RFP resulted in a change.

However, having carefully considered the clinical advice provided to PHARMAC regarding the impact of a possible introduction of a biosimilar adalimumab, we have identified the indications of ocular inflammation (uveitis) and Crohn's disease as higher risk of experiencing adverse clinical outcomes associated with loss of disease control, and that it would be impossible to ascertain if loss of disease control related to the use of a biosimilar versus natural progression of disease on treatment. Patients already accessing funded adalimumab for ocular inflammation (uveitis) and Crohn's disease ("Existing Patients") have therefore been excluded from the scope of Principal Supply Status proposed to be awarded as a result of this RFP (see below).

All patients new to treatment with adalimumab, regardless of indication, would commence treatment with the successful supplier's brand of adalimumab.

Details of the approximate patient numbers, by indication, are provided in Schedule 3. Links to clinical advice are provided above.

Intended outcome of the RFP

PHARMAC recently announced our decision to start offering and awarding Principal Supply Status through competitive procurement processes. Through this RFP PHARMAC intends to award the successful supplier Principal Supply Status (PSS).

The award of PSS means that the successful supplier's brand of adalimumab would be the main funded brand of adalimumab in New Zealand and would be guaranteed at least 95% of the funded adalimumab patient groups included within the scope of this RFP.

This means that brands of adalimumab other than the PSS brand could be listed in the Pharmaceutical Schedule for use in up to 5% of the funded adalimumab patient groups included in this RFP. This 5% alternative brand allowance (ABA) would be for patients with unique clinical circumstances who are considered unable to change to an adalimumab biosimilar or who experience an adverse clinical outcome following a change to the successful supplier's adalimumab biosimilar, (if a change to a biosimilar was the outcome of the RFP).

The successful supplier would be awarded PSS for adalimumab, following a transition period (of at least seven months if the successful adalimumab brand was a biosimilar, subject to further clinical advice and negotiation), for a period of four years with an optional extension period of one year. The extension period would be exercised by mutual agreement between PHARMAC and the successful supplier, provided that the PSS does not extend beyond 30 June 2027 (the "PSS Period").

As Existing Patients have been excluded from the scope of this RFP, they would not be considered part of the 5% ABA (or 95% PSS). Further information on the patient groups included in the scope of the PSS arrangements proposed to be awarded as a result of this RFP are detailed in table below.

Excluded from Principal Supply Status	**Included in Principal Supply Status up to 95%**
All *existing* patients receiving funded adalimumab for treatment of ocular inflammation (uveitis) and Crohn' disease prior to the start of the transition period (if any).	All *existing* patients receiving adalimumab for all remaining funded indications prior to the start of the transition period (if any).
	All *new* patients receiving funded adalimumab for any indication from start of the transition period (if any) (including ocular inflammation (uveitis) and Crohn's disease).
	All patients receiving funded adalimumab due to any widened access indications from the start of the transition period (if any).

As a result of this RFP PHARMAC would retain the right at its sole discretion to widen funded access to adalimumab at any time during the PSS Period.

3. Types of proposals sought

PHARMAC is willing to consider the following types of proposals:

(a) Suppliers wishing to submit proposals **MUST** submit proposals for subcutaneous adalimumab that include the currently funded 40 mg strength. Proposals **MAY** also include other strengths of subcutaneous adalimumab.

(b) Proposals **MUST** include information that indicates the proposed strength(s) of subcutaneous adalimumab are suitable for use by all people (adults and children) and

indications included in scope of this RFP, noting that many of these indications are unapproved.

(c) Proposals **MAY** include a range of presentations (e.g. device types such as prefilled syringes or pen devices) for the subcutaneous administration of adalimumab, provided that additional information is provided that indicates that these are suitable for use by all people and indications in scope of this RFP.

(d) Proposals **MAY** include citrate-free formulations of adalimumab provided that additional information is provided that indicates that these are suitable for use by all people and indications in scope of this RFP.

(e) Proposals **MUST** include a period of PSS, with an alternative brand allowance of 5%, following a transition period (if any), for a period of approximately four years, with the option to extend the PSS duration by an additional twelve months upon mutual agreement between PHARMAC and the successful supplier, provided the PSS period does not extend beyond 30 June 2027.

For the optional 12 month extension to PSS, PHARMAC would require 12 months' notification from the supplier, prior to the expiry of the four year period if the supplier does not agree to extend PSS for the additional 12 month period. For the avoidance of doubt, the supplier would not be entitled to increase the price of adalimumab during the additional 12 month period, in the event this option is exercised by PHARMAC.

(f) Proposals for adalimumab **MAY** include any of the following arrangements (that may be confidential):

(i) 'soft caps' where a flat rebate of less than 100% is offered regardless of unit volumes

(ii) proposals with a tiered pricing structure where the level of rebate is linked to a certain level(s) of unit volumes, provided that a supplier also submits an alternative bid with a flat rebate structure of one price per unit regardless of unit volumes.

(iii) Other risk sharing arrangements provided that a supplier also submits an alternative bid with a flat rebate structure of one price per unit regardless of unit volumes.

(g) Suppliers **MAY** submit multiple proposals for the supply of adalimumab.

(h) All proposals that would require a change to a biosimilar adalimumab (for the indications other than Crohn's disease and ocular inflammation (uveitis)) **MUST** include a transition period of at least seven months between listing the new biosimilar adalimumab and commencement of any PSS Period, noting that this period may be subject to negotiation following evaluation of proposals.

(i) Proposals that would result in a change to a biosimilar adalimumab **MUST** include details of the implementation and ongoing support that would be provided for both clinicians and patients relating to any proposed biosimilar adalimumab; this is expected to include (but would not need to be limited to):

(i) Information regarding the provision of education, training and support resources to clinicians in respect of the use of adalimumab.

- The resources would be provided to all relevant prescribers, pharmacies and patients in New Zealand or upon request by any relevant party.

- The resources would be provided to patients when their prescription is filled and directly to all prescribers and pharmacies before the commencement of any principal supply period.

Examples of the "resources" to assist with this includes (but is not limited to):

- Provision of patient training and medical education and support for prescribers and pharmacies, availability of clinical educators to talk specifically with patients and prescribers, and an 0800 number to be available for patients to contact with any further queries;

- provision of training materials (pamphlets, leaflets, brochures) to new patients; and

- provision of presentations and/or demonstrations on the use of the proposed biosimilar adalimumab product to patients and/or healthcare professionals.

(ii) Information regarding the provision of related products, in respect of the use of adalimumab. The related products shall be delivered to the nominated delivery address of the prescribed patient.

"related products" should include sharps bins and any other products that are considered required for the safe use and disposal of the proposed biosimilar adalimumab product.

(j) Proposals for a biosimilar adalimumab that has not previously been reviewed by PTAC or relevant Subcommittee/s of PTAC **MAY** require clinical review.

(k) Proposals **MAY** include adalimumab brands 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 brand/s is ready to submit to Medsafe within one month of such a request being made by PHARMAC; and

(ii) PHARMAC would not list the proposed brand in the Pharmaceutical Schedule until all Consents are obtained.

PHARMAC is **NOT** willing to consider the following types of proposals:

(a) Proposals involving pharmaceuticals or related products other than subcutaneous adalimumab.

(b) Proposals that include a requirement to widen access to funded adalimumab.

(c) Proposals that involve foreign currency exchange rate clauses or prices linked to any index.

(d) 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.

(e) Proposals that include the requirement to place restrictions on other funded products, for example a proposal for adalimumab to become the only funded TNF inhibitor for a proposed indication (which would require funding restrictions to be placed on other TNF inhibitors such as etanercept or infliximab).

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

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

Samples

Suppliers **MUST** provide PHARMAC with samples of all the adalimumab presentations included in their proposal (and, if supply is intended to be in a different presentation and/or strength from the provided samples, information about differences must be supplied). Samples and any associated information must be supplied to PHARMAC within 10 business days from the dated specified in Schedule 2, clause 1 (b).

Widened access

Through this RFP PHARMAC would retain the right at its absolute sole discretion to widen access to adalimumab, this could include:

- widening access to adalimumab to currently listed indications, such as making changes to Special Authority criteria and/or changes to dosing restrictions; and/or

- widening access to indications that have received a positive (including cost neutral) funding recommendation from PTAC or a Subcommittee of PTAC prior to the release of this RFP or afterwards.

  Below are currently open funding applications for widened access to adalimumab (with links to entries in our Application Tracker, which includes links to relevant clinical advice records):
  - Ulcerative colitis first line
  - Ulcerative colitis second line
  - Crohns disease, rescue therapy
  - Crohns disease dose escalation
  - Undifferentiated spondyloarthritis
  - Inflammatory bowel-disease associated arthritis
  - Behçet's disease first line
  - Rheumatoid arthritis amendments to Special Authority
    - Previous treatment
    - Joint counts
    - CRP levels
    - Patient reported outcomes

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 **5.00 p.m.** (New Zealand time) on **23 April 2021**. 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.

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 the Factors can be found at www.pharmac.health.nz/factors-for-consideration.

(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, its relevant Subcommittee, any relevant professional organisation or healthcare professionals. This may include specific clinical advice regarding relative risks and benefits of adalimumab following the closing of this RFP; and

(iii) previous supply performance and relevant expertise;

(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 January 2022. 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 PHARMACs 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.

Please note that PHARMAC may seek advice from PTAC, its relevant Subcommittee, any relevant professional organisations or healthcare professionals with regard to your product including evaluation of any product samples.

(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, 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 on request from PHARMAC, 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's 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 its relevant Sub-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, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs 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 adalimumab 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, the Ministry of Health and DHBs (**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 May 2021;

(ii) seeking clinical advice (if necessary) in June 2021;

(iii) negotiating with submitter(s) of one or more preferred proposals in July 2021;

(iv) consulting on a provisional agreement in July 2021;

(v) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after September/October 2021;

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 January 2022.

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.

Schedule 3: Current listing and market information

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

Please note the information is approximate and indicative only. PHARMAC makes no representation as to the accuracy of the information or as to the number of patients, level of sales or likely sales of adalimumab 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.

Funded adalimumab dispensed by indication (Calendar Year)			
Indication	**2018**	**2019**	**2020**
Adult-onset Still's disease	15,760	13,640	33,560
Ankylosing spondylitis	644,280	670,000	737,360
Chronic ocular inflammation	-	4,440	40,180
Crohn's disease	946,000	1,066,200	1,211,580
Fistulising Crohn’s disease	92,720	93,560	92,040
Hidradenitis suppurativa	-	4,320	79,400
Juvenile idiopathic arthritis	50,680	58,880	65,520
Psoriatic arthritis	468,920	515,440	581,640
Pyoderma gangrenosum	2,480	1,440	5,040
Rheumatoid arthritis	1,139,720	1,177,680	1,152,760
Severe Behcet's disease	-	1,040	6,320
Severe chronic plaque psoriasis	450,960	474,160	479,120
Severe ocular inflammation (uveitis)	-	640	7,280
Total mg dispensed	**3,811,520**	**4,081,440**	**4,491,800**

Funded adalimumab injections (units) by formulation (Calendar year)			
Presentation	**2018**	**2019**	**2020**
Inj 20 mg per 0.4 ml prefilled syringe	180	388	580
Inj 40 mg per 0.8 ml prefilled syringe	10,914	12,052	13,782
Inj 40 mg per 0.8 ml prefilled pen	97,454	104,044	116,250
Total number of injections	**108,548**	**116,484**	**130,612**

Number of patients dispensed funded adalimumab by indication (Calendar year)			
Indication	**2018**	**2019**	**2020**
Adult-onset Still's disease	25	25	88
Ankylosing spondylitis	928	995	1,095
Chronic ocular inflammation	-	34	75
Crohn's disease	1,340	1,498	1,628
Fistulising Crohn’s disease	112	118	142
Hidradenitis suppurativa	-	25	85
Juvenile idiopathic arthritis	82	99	111
Psoriatic arthritis	683	731	819
Pyoderma gangrenosum	7	5	6
Rheumatoid arthritis	1,614	1,627	1,675
Severe Behcet's disease	-	6	9
Severe chronic plaque psoriasis	631	669	660
Severe ocular inflammation	-	4	14
Total number of patients	**5,422**	**5,836**	**6,407**

Note that a confidential rebate applies to all funded use of the Humira brand of adalimumab which reduces net expenditure.

Based on our clinical advice and analysis, we estimate that widening funded access, if progressed, could result in the following approximate numbers of additional patients on treatment per full year for each indication as detailed below. We note that these are our best estimates and are subject to uncertainty, particularly in relation to the amendments to the Special Authority for the indication of rheumatoid arthritis.

- widened access to ulcerative colitis first line: 450 additional patients.
- widened access to ulcerative colitis second line: 300 additional patients.
- widened access to Crohn's disease, rescue therapy, 300 additional patients.
- widened access to Crohn's disease dose escalation, 350 additional patients.
- widened access to undifferentiated spondyloarthritis first line, 130 additional patients.
- widened access to undifferentiated spondyloarthritis second line (following etanercept), 60 additional patients.
- widened access to inflammatory bowel-disease associated arthritis, 140 additional patients.
- widened access to Behçet's disease first line, 10 additional patients.
- amendments to the Rheumatoid arthritis Special Authority to include Previous treatment, 50 additional patients.
- amendments to the Rheumatoid arthritis Special Authority to include Joint counts, 200 additional patients.
- amendments to the Rheumatoid arthritis Special Authority to include C-reactive protein (CRP) levels, 15 additional patients.
- amendments to the Rheumatoid arthritis Special Authority to include Patient reported outcomes, 120 additional patients.

Schedule 4: Proposal form

***An electronic version of this form is available* on GETS (www.gets.govt.nz). You should expand the boxes as necessary.**

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- Josh Wiles

By electronic transfer using GETS **(www.gets.govt.nz)**

Dear Madam

Proposal for the supply of adalimumab

In response to your request for proposals (**RFP**) dated **9 March 2021**, we put forward the following proposal in respect of adalimumab.

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

(a) Our contact details:

Name of supplier	
Contact person	
Address	
Phone	
Email address	

(b) Details of pharmaceutical presentation:

Chemical name	
Strength(s) (e.g. 40 mg)	
Form(s) (e.g. subcutaneous injection)	
Brand name	
Pack size (e.g. 1 prefilled syringe)	
Presentation (device type e.g. prefilled syringe/prefilled pen)	
Shelf life (e.g. 36 months from date of manufacture stored at or below 30°C)	
Citrate free (Yes/No)	

(c) 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	

(d) Information relating to if our adalimumab product is citrate containing (or not) and details of any plans to bring a citrate-free version to the NZ market (and timing of any such plans).

(e) Information relating to proposed presentation(s), and strength(s) of our adalimumab product including information regarding the suitability for all people using the currently funded strengths and presentations of adalimumab.

Please include any attachments such as data sheets and/or transition plans with your proposal to support your response to this question

(f) Confirmation that sample(s) of our adalimumab product, including packaging and artwork for all presentations, and strengths included in our proposal(s) will be supplied to PHARMAC within 10 business days from the dated specified in Schedule 2, clause 1 (b)

Sample to be provided to PHARMAC – Mandatory **Yes/No***

*Delete as appropriate

(g) Key features of our proposal:

(h) 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]	

(i) Information relating to pricing for our adalimumab product ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC (if any) is to be provided below:

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

	Adalimumab	
Strength	Presentation type (device type e.g. prefilled syringe/prefilled pen)	Proposal

(j) Information relating to detail of the implementation and ongoing support we would provide for both clinicians and patients for our adalimumab product:

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

Implementation and ongoing support
Education, training, and support resources for clinicians and patients
Related products for our adalimumab product for patients

(k) 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:

(l) Information about our ability to ensure the continuity of supply of the pharmaceutical:

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

(k) Information about any support and resources we would provide to groups experiencing health inequities in New Zealand, specifically Māori and Pacific peoples (adults and children)

(n) 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:				

(o) Reasons why PHARMAC should accept our proposal:

(p) Additional information that PHARMAC should consider when evaluating our proposal:

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