2 September 2014

Dear Supplier

REQUEST FOR TENDER (RFT) – SUPPLY OF INFLIXIMAB TO DHB HOSPITALS

PHARMAC requests tenders for the supply of infliximab to DHB hospitals in New Zealand.

This RFT incorporates the following schedules:

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

(b) Schedule 2 specifies the pharmaceuticals 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 tender, and provides instructions on how to submit a Tender Bid in relation to hospital supply;

(d) Schedule 4 includes the template for the Tender Submission Form that must be submitted through GETS;

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

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

(g) Schedule 7 sets out other special terms, including the ability to include a rebate, that will apply if your Tender Bid is submitted and accepted on the basis of such terms applying.

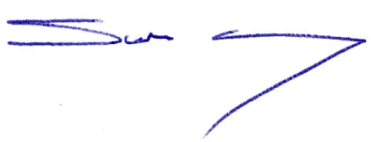
For the avoidance of doubt, references in this RFT to "Price" are references to the price at which a pharmaceutical would be listed on the Pharmaceutical Schedule. References in this RFT to "Agreed Price" are references to the effective price payable for a pharmaceutical once a rebate (if any) has been applied in respect of the relevant pharmaceutical where such rebate is included as part of your Tender Bid and accepted by PHARMAC.

If you wish to submit a Tender Bid in relation to this RFT, you must submit it to PHARMAC via the Government Electronic Tenders Service (GETS) no later than **5pm** (New Zealand time) on **Tuesday, 30th September 2014**.

If you have any inquiries about this RFT you should contact **Jackie Evans, Senior Therapeutic Group Manager** (jackie.evans@pharmac.govt.nz).

We look forward to receiving your Tender Bid.

Yours sincerely



Steffan Crausaz

Chief Executive

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Schedule 1: Definitions and interpretation

1. Definitions

In this RFT:

Agreement means:

(a) Schedule Five; and

(b) Schedule Six; and

(c) Schedule Seven,

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

Alternative Pharmaceutical means an alternative brand of a Pharmaceutical that PHARMAC, following consultation with PTAC or its sub-committees, considers to be an acceptable substitute for that Pharmaceutical;

Agreed Price means the effective price payable for the Pharmaceutical once a rebate has been applied in accordance with Schedule Seven where such rebate is included as part of your Tender Bid and accepted by PHARMAC.

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 Hospital Supply Status in respect of the particular Tender Item, to cover the contingency that Hospital 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;

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

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

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

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

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

Deadline means 5pm, Tuesday 30th September 2014 (New Zealand time);

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

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

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

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

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

DV Limit means, for a particular Pharmaceutical, the National DV Limit or the Individual DV Limit;

DV Pharmaceutical means a discretionary variance Pharmaceutical, being an Alternative Pharmaceutical that does not have Hospital Supply Status, and includes a pharmaceutical which (unless PHARMAC specifies otherwise in Schedule Two of this Agreement and on GETS in relation to this RFT, or we agree otherwise in writing):

(a) is listed as a DV Pharmaceutical, in association with the relevant Pharmaceutical having Hospital Supply Status, in the then current Section H of the Pharmaceutical Schedule; or

(b) is the same Chemical Entity, at the same strength, and in the same or a similar presentation or form, as the relevant Pharmaceutical with Hospital Supply Status, but which is not yet listed as a DV Pharmaceutical.

For the avoidance of doubt, a pharmaceutical which:

(c) is a different Chemical Entity from the Pharmaceutical with Hospital Supply Status; and

(d) is not listed as a DV Pharmaceutical in the then current Section H of the Pharmaceutical Schedule,

is not a DV Pharmaceutical;

End Date means the last day of the Hospital Supply Status Period;

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

Final Transition Period means, in respect of a Pharmaceutical with Hospital 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 Hospital Supply Status, the period beginning on the first day of the month following the Market Notification Date and ending on the last day of the month following the month in which the Start Date occurs (or such different or longer period as PHARMAC determines under clause 1.2 of Schedule Three);

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

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

Hospital Supply Status means the status of being the brand of the relevant Pharmaceutical listed in Section H of the Pharmaceutical Schedule as having such status, which

Pharmaceutical DHB Hospitals must purchase, subject to any DV Limit for that Pharmaceutical, for the Hospital Supply Status Period;

Hospital Supply Status Period means the period beginning on the day after the end of the First Transition Period and ending on the date that is five years (60 months) after the end of the First Transition Period;

Hospital Tender Bid means a Tender Bid in relation to Hospital Supply;

Individual DV Limit means, for:

(a) a particular Pharmaceutical; and

(b) a particular DHB Hospital,

the discretionary variance limit, being a percentage of the Individual Total Market Volume, which equals the percentage of the National DV Limit for that Pharmaceutical, up to which that DHB Hospital may purchase DV Pharmaceuticals of that Pharmaceutical. The Individual DV Limit applies during the Hospital Supply Period, subject to PHARMAC's right to amend the DV Limit in accordance with clause 1.4 of Schedule Six;

Individual Total Market Volume means for:

(a) a particular Pharmaceutical; and

(b) a particular DHB Hospital,

in any given period, in accordance with data available to PHARMAC, the sum of:

(c) the total number of Units of the relevant Pharmaceutical with Hospital Supply Status purchased by the relevant DHB Hospital; and

(d) the total number of Units of all the relevant DV Pharmaceuticals, listed in Section H in association with that Pharmaceutical, purchased by that DHB Hospital;

Infliximab means the form and strength of infliximab referred to in Schedule Two;

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

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

National DV Limit means, for a particular Pharmaceutical, the discretionary variance limit, being the specified percentage of the National Total Market Volume up to which all DHB Hospitals may collectively purchase DV Pharmaceuticals of that Pharmaceutical. The National DV Limit is set for DHB Hospitals nationally and applies during the Hospital Supply Status Period, subject to PHARMAC's right to amend the DV Limit in accordance with clause 1.4 of Schedule Six;

National Total Market Volume means, for a particular Pharmaceutical in any given period, in accordance with data available to PHARMAC, the sum of:

(a) the total number of Units of the relevant Pharmaceutical with Hospital Supply Status purchased by all DHB Hospitals; and

(b) the total number of Units of all the relevant DV Pharmaceuticals, listed in Section H in association with that Pharmaceutical, purchased by all DHB Hospitals;

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

Pharmaceutical means the Tender Item for which you have submitted, and PHARMAC has accepted on behalf of the Funder, a Tender Bid;

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

Potential Out-of-Stock Event means:

(a) your stock in New Zealand of the Pharmaceutical falls below the average volume of stock of the Pharmaceutical required to supply the entire New Zealand hospital market for the Pharmaceutical for any given three month period;

(b) your stock in New Zealand of the Pharmaceutical falls below 75% of your most recent four months' total sales of the Pharmaceutical;

(c) forecast sales demand in respect of the next three-month period is greater than your stock in New Zealand of the Pharmaceutical; or

(d) your stock in New Zealand of the Pharmaceutical is insufficient to enable you to fully fill all orders as they are received (without restricting quantities that may be ordered).

Price means the price (in New Zealand dollars and exclusive of GST) at which the Pharmaceutical is to be listed on the Pharmaceutical Schedule (being the price payable for the Pharmaceutical before the Rebate (if any) is applied) and supplied, or made available for sale and supply, by you to, in relation to hospital supply, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), being the price specified in your successful Tender Submission Form, unless there has been a subsequent price change in accordance with the terms of the RFT, in which case the Price will be the price notified to you by PHARMAC upon acceptance of your Tender Bid;

PTAC means the Pharmacology and Therapeutics Advisory Committee;

Rebate means the rebate (if any) payable in accordance with Schedule Seven where such rebate is included as part of your Tender Bid and accepted by PHARMAC;

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

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

Start Date means:

(a) in relation to the Tender Item for which your Tender Bid has been accepted unconditionally, the first day of the month following the date that represents:

(i) the Successful Tenderer Notification Date; plus

(ii) the Lead Time; or

(b) in relation to a Tender Item for which your Tender Bid has received conditional acceptance, in terms of clause 7.4 of Schedule Three, the first day of the month following the date that represents:

(i) the date that such acceptance ceases to be conditional; plus

(ii) the Lead Time; or

(c) such other date that is negotiated between you and PHARMAC under clause 1.4 of Schedule Three;

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

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

Tender Item means the form and strength of a Chemical Entity (or entities, if applicable) for which you may submit a Tender Bid;

Tender Submission Form means the form on which you must submit your bid for each Tender Item, as provided in Schedule Four and available on GETS and at www.pharmac.health.nz;

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

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

Unit Price means the relevant Price specified for a pack 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).

2. Interpretation

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

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

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

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

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

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

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

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

(h) unless the context requires otherwise, references to the **"listing"** of a Pharmaceutical are to the listing of that Pharmaceutical in Section H of the Pharmaceutical Schedule and are deemed to include any written notification by PHARMAC of that Pharmaceutical being the subject of a national supply contract negotiated by PHARMAC on behalf of DHBs, where such written notification is in advance of the actual listing of that Pharmaceutical in Section H of the Pharmaceutical Schedule (and references to "list", "listed", "delist", "delisted", and "delisting" are to be interpreted accordingly).

Schedule 2: Products to be tendered

1. Information about Tender Item

1.1 List of Tender Item

This Schedule sets out the Tender Item and information about the Tender Item. 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

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 Market value figures

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 the Tender Item, those terms are indicated in the column entitled "Comments" in the list and/or specified in Schedule Seven.

1.5 DV Limits

The DV Limit relating to the Tender Item, in relation to hospital supply, that limit is indicated as a percentage amount in the column entitled "DV Limit" in the attached list.

1.6 Hospital only products

Where an "H" is indicated, you may submit a Tender Bid for Hospital Supply Status for that Tender Item.

2. List of products included in this RFT

Chemical Name Line Item	Units	Cost	Current Unit Price	Market tendered	DV Limit	Comments
Infliximab						
Inj 100 mg	See below	See below	$1,227.00	H	10%	Access may be widened subject to bid prices received. More information provided below.

3. Background information

3.1 Clinical information

(a) Infliximab is a chimeric monoclonal antibody that binds to human tumour necrosis factor alpha (TNFα), thereby interfering with endogenous TNFα activity. Elevated TNFα levels have been found in involved tissues/fluids of patients with rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn's disease and ulcerative colitis. Biological activities of TNFα include the induction of pro-inflammatory cytokines (interleukins), enhancement of leukocyte migration, activation of neutrophils and eosinophils, and the induction of acute phase reactants and tissue degrading enzymes. Infliximab neutralizes the biological activity of TNF-α by binding with high affinity to the soluble and transmembrane forms of TNF-α, and inhibits or prevents the effective binding of TNF-α with its receptors.

3.2 Regulatory information

(a) The Remicade brand of infliximab (Janssen) is currently the only brand of infliximab approved by Medsafe in New Zealand. PHARMAC notes that biosimilar brands of infliximab have been approved in Europe and a number of countries and are currently undergoing evaluation by Medsafe.

3.3 PTAC advice

(a) In May 2014 PHARMAC sought advice from its Pharmacology and Therapeutics Advisory Committee (PTAC) regarding biosimilar infliximab and appropriate competitive processes for the infliximab market. In summary, PTAC recommended that PHARMAC run a Request for Proposals or Tender for the sole supply of infliximab for all indications currently funded. PTAC considered that patients could be switched from Remicade to biosimilar infliximab but recommended that PHARMAC provide educational material to prescribers and patients to support such a switch if implemented. The full minutes can be found here http://www.pharmac.health.nz/assets/ptac-minutes-2014-05.pdf

(b) PHARMAC also sought advice from PTAC's Rheumatology and Gastrointestinal Subcommittees. Minutes from these meetings are not yet available but both Subcommittees agreed with PTAC's recommendations.

3.4 Current funding and restrictions

(a) Infliximab (Remicade, Janssen) is currently listed in Part II of Section H of the Pharmaceutical Schedule at a price of $1,227.00 per 1 x 100 mg vial (ex manufacturer, excluding GST). There are no confidential rebates or subsidy or delisting protections applying to the current listing of Remicade.

(b) The funding of infliximab in DHB hospitals is subject to Restrictions for the following uses (see clause 7 of Schedule 7 for the full Restrictions):

- Graft vs Host Disease of the gut
- Rheumatoid arthritis refractory, or intolerant to, adalimumab and/or etanercept
- Ankylosing spondylitis refractory, or intolerant to, adalimumab and/or etanercept
- Psoriatic Arthritis refractory, or intolerant to, adalimumab and/or etanercept
- Severe, vision threatening ocular inflammation requiring rapid control following high dose steroids
- Severe uveitis uncontrolled with steroids and at least two other immunomodulatory agents
- Pulmonary sarcoidosis refractory to other treatments
- Severe Crohn's disease refractory, or intolerant to, prior systemic immunomodulators
- Fistulising Crohn's disease
- Severe fulminant ulcerative colitis refractory to steroids
- Severe plaque psoriasis

(c) Infliximab is administered by intravenous infusion in DHB hospitals and funded at various doses depending on the disease setting, typically 3-5 mg/kg every 6-8 weeks. Infliximab is not currently funded for community supply.

3.5 Market information

(a) Infliximab is an in-hospital treatment therefore PHARMAC data is limited to hospital purchase data, which may underestimate its use. The following historical information relates to the estimated market size of infliximab. 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 infliximab 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.

(b) Since the Hospital Medicines List (HML) came into effect on 1 July 2013 the use of infliximab appears to have increased significantly. The table below outlines annual usage and expenditure on infliximab in DHB hospitals since 1 July 2008 to 30 June 2014.

Financial year	Total 100mg Vials	Total Cost
1 July 2008 – 30 June 2009	4,600	$5,600,000
1 July 2009 – 30 June 2010	4,700	$5,800,000
1 July 2010 – 30 June 2011	5,100	$6,300,000
1 July 2011 – 30 June 2012	6,000	$7,400,000
1 July 2012 – 30 June 2013	7,600	$9,300,000
1 July 2013 – 30 June 2014	12,000	$15,000,000

(c) In the year ending June 2013 (prior to the start of the HML) DHBs spent approximately $9.3 million on infliximab, however, in the following year DHBs spent approximately $15 million. It is not clear if this growth will continue therefore forecasting future expenditure is difficult.

(d) PHARMAC does not have accurate information regarding the proportion of usage across the various indications currently funded.

3.6 Other considerations

(a) Biosimilar competition for infliximab presents PHARMAC with an opportunity to reduce the costs of infliximab and improve health outcomes for New Zealanders.

(b) PHARMAC may consider widening access to infliximab as a result of this RFT, or in the future, for example to enable increased dosing.

(c) PHARMAC notes that a brand switch is not a certain outcome of this RFT; however, it is one potential outcome. Without limiting the circumstances in which PHARMAC may consider it appropriate to consult in the course of this RFT process, PHARMAC would undertake consultation if a brand switch were to be considered.

Schedule 3: Tender Process

1. General

1.1 Hospital Supply Status Period

Hospital Tender Bids are to be submitted on the basis that if your Hospital Tender Bid is accepted, you will have Hospital Supply Status for the Tender Item for the Hospital Supply Status 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 DHB 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 DHB Hospitals from the 12th day of the month prior to the Start Date);

(ii) the First Transition Period is intended to allow for an orderly transition to the arrangements that will apply during the Hospital Supply Status Period;

(iii) the Final Transition Period is intended to allow for an orderly transition to any new arrangements following the end of the Hospital Supply Status Period;

(iv) DHB Hospitals may purchase DV Pharmaceuticals at any time within the First Transition Period and Final Transition Period without any requirement to comply with the DV Limit.

(b) In relation to 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.

1.3 Contract

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 1.4 of this Schedule); and

(ii) Schedule Five; and

(iii) Schedule Six; and

(iv) Schedule Seven,

will be deemed to have been entered into between you and PHARMAC for Hospital Supply Status 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 Five, Schedule Six and Schedule Seven, 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 Hospital Supply Status Period.

1.4 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 Hospital Supply Status 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) DV Limits and/or DV Pharmaceuticals, in relation to hospital supply;

(vi) the Lead Time and/or the Start Date; 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 Tender Item, PHARMAC is not obliged to inform the other tenderers of that change, nor give those tenderers an opportunity to amend their bid for that Tender Item, unless the change is one which would result in the terms and conditions being materially different in scope from those set out in this RFT.

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

1.5 Termination and amendment of RFT

PHARMAC may:

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

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

2. Information about submitting a Tender Bid

2.1 Choice of forms and strengths

Where a Tender Item includes different forms and strengths of a Chemical Entity or entities, your Tender Bid may, but does not need to, include all of the forms and strengths of the Chemical Entity or entities contained in that Tender Item.

2.2 Consents not yet held

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

2.3 Individual Tender Bids

You may submit more than one bid for the Tender Item (for example, you may submit separate bids for different pack sizes of the Tender Item or submit a bid for the Tender Item that includes a Rebate and submit a separate bid for the same Tender Item that does not include a Rebate).

2.4 No conditions

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

2.5 Separate offers

PHARMAC will treat each Tender Bid as a separate offer.

2.6 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. For the avoidance of doubt, this does not preclude you also submitting an Agreed Price, as defined in Schedule 7, where a Rebate is offered.

2.7 Rebates

You may submit a bid for a Tender Item that includes a Rebate. If you do so, you must include in your Tender Bid the relevant amount of the Agreed Price in respect of each Tender Item.

2.8 No alternative bids

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

3. What to include in your Tender Submission Form

3.1 Compulsory use of Tender Submission Form

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

(b) A template setting out the required form of the Tender Submission Form is provided in Schedule Four, available on GETS and published on PHARMAC's website at www.pharmac.health.nz.

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; and

(f) your quality assurance processes, where applicable.

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) the chemical, form, strength, brand name, pack size and type of packaging;

(b) a single price in New Zealand dollars (exclusive of GST) at which you will supply the Tender Item to, at a DHB Hospital's discretion, Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), in respect of a Hospital Tender Bid;

(c) an Agreed Price, as defined in Schedule 7, where your Tender Bid includes a Rebate;

(d) whether it has 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; and

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

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

(h) any additional information you wish PHARMAC to consider when evaluating your Tender Bid.

3.4 PHARMAC may request further information

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

(i) information about your credit status;

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

(iii) information regarding any Rebate included in your Tender Bid;

(iv) where the 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; and

(v) 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.

(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, by facsimile or by email to PHARMAC.

4.2 Key dates

Your Tender Bid must:

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

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

(i) 30 June 2015; or

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

5. Evaluation

5.1 Process of evaluation

The Evaluation Committee, taking such regulatory, legal, medical and other advice as it considers appropriate, will evaluate all conforming Tender Bids that have been checked for

conformity under clause 6(a) of this Schedule, and any non-conforming Tender Bids that are admitted for consideration under clause 6(b) of this Schedule.

5.2 Matters for evaluation

The matters to be taken into account by the Evaluation Committee, the weight to be attached to them, and the basis on which it will evaluate Tender Bids, are all to be determined by the Evaluation Committee in its sole discretion. The matters taken into account by the Evaluation Committee will, however, include:

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

(i) your financial resources;

(ii) your management and technical skills;

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

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

(v) your quality assurance processes, where applicable;

(vi) the site of manufacture and packaging of the Pharmaceutical, and site of manufacture of the active ingredient;

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

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

(b) the pack size of the Tender Item and the type of packaging;

(c) the price of the Tender Item;

(d) any Rebate applicable in respect of the Tender Item;

(e) the amount and timing of savings, including non-pharmaceutical savings accruing to the Funder or PHARMAC during the Hospital Supply Status Period;

(f) either:

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

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

(g) the name and location of the manufacturer of the finished product and active ingredients of the Tender Item; and

(h) any other benefits to the Funder 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. A Tender Bid will conform if it:

(i) is submitted via GETS by the Deadline;

(ii) is submitted on the Tender Submission Form;

(iii) has no conditions or qualifications attached;

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

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

(b) PHARMAC may, in its sole discretion:

(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) PHARMAC will complete all consultation it considers necessary or appropriate (including consultation under its OPPs, with suppliers and with other interested parties) prior to making a decision on your Tender Bid.

(b) 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).

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

(d) PHARMAC's Board of Directors (or its delegate, where applicable):

(i) will use the decision criteria 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 the 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 and, other than to the extent necessary to debrief an unsuccessful tenderer, is not obliged to give reasons for its decision.

(b) While it is PHARMAC's current intention, unless specified otherwise in Schedule Two or on GETS in relation to this RFT, to enter into an agreement to award Hospital Supply Status for the 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 the Tender Item.

(c) Acceptance only occurs if, and when, PHARMAC's Board of Directors (or its delegate, where applicable) resolves to accept a Tender Bid (following such consultation as PHARMAC considers necessary or appropriate) and this acceptance is notified to the successful tenderer.

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

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

7.4 Conditional acceptance

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

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

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

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

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

(i) PHARMAC completing all consultation it considers necessary or appropriate (including consultation under its OPPs, with suppliers and with other interested parties); and

(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 the Tender Item.

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

9. Dealing with information

9.1 Confidentiality

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

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

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

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

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

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

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

(i) for the purposes of this Agreement; or

(ii) required by law; or

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

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

9.2 Use of information

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

10. Miscellaneous

10.1 Process contract

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

10.2 Costs

PHARMAC is not liable in any way whatsoever for any direct or indirect costs incurred, or loss (including loss of profit) or damage sustained, by you in respect, or arising out, of this tendering process or the obtaining or granting of Hospital Supply Status for your supply of the Tender Item including, without limitation, costs of obtaining all necessary Consents for the 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, the Minister of Health (or any Associate Ministers), the Ministry of Health (including its operating unit Medsafe), or a District Health Board or any of their officers or directors, at any time with a view to influencing the outcome of the tendering process.

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

10.6 Enquiries

If you have any enquiries about this RFT you should contact Jackie Evans, Senior Therapeutic Group Manager. 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: Tender Submission Form

An electronic version of this form is available on GETS or on PHARMAC's website at www.pharmac.health.nz. You should expand the boxes as necessary.

[*Supplier to insert date*]

Chief Executive
PHARMAC

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

Dear Sir/Madam

Tender bid for the supply of infliximab to DHB Hospitals - commercial in confidence

In response to your request for tenders (**RFT**) dated 2 September 2014, we put forward the following tender bid in respect of infliximab.

Set out below is further information in support of our tender bid.

(a) Our contact details (i.e., who communications relating to the attached bid(s) should be made to):

Name of supplier	
Contact person	
Address	
Phone	
Facsimile	
Email address	

(b) Information about our company structure:

(c) Information about our management and technical skills:

(d) Information about our financial resources:

(e) Information about our, or our supplier's, existing supply commitments:

(f) Information about our quality assurance processes (where applicable):

(g) Information about our ability to ensure the continuity of supply of the Tender Item:

(h) Details of pharmaceutical presentation:

Chemical name	
Strength (e.g. 100mg)	
Form (e.g. powder for infusion)	
Brand name	
Pack size (e.g. 10 vials)	
Packaging type (e.g. injection)	

(i) Price per Unit (1 vial of infliximab 100 mg), including if applicable the Agreed Price ($NZ, GST exclusive):

Price (mandatory)	$
Agreed Price (applicable if your bid includes a rebate)	$

(j) 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	
Insert any other consents required for pharmaceutical	

(k) Lead Time for supply of Tender Item (in number of months):

(l) The name and location of:

The manufacturer(s) of the finished product (and name and location of the packaging site, if different)	
The manufacturer(s) of the active ingredients	
Alternative manufacturers of the finished product and active ingredients (if any)	

(m) Our proposed distribution and supply arrangements for the Tender Item

(n) Key features of our tender bid:

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

(p) Any additional information that PHARMAC should consider when evaluating our Tender Bid:

Schedule 4

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

_____
<Insert name>
<Insert designation>

Schedule 5: Contract terms for Hospital Supply Status

1. General

1.1 Operating Policies and Procedures

(a) You acknowledge that:

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

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

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

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

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

(A) listing new pharmaceuticals;

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

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

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

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

(vi) 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.

1.2 Amendments to Pharmaceutical Schedule

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

2. Crown Direction

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

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

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

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

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

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

3. Audit

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

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

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

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

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

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

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

(c) With reference to clause 1.5(f) of Schedule Six in relation to Hospital Supply Status, PHARMAC will use its best endeavours to audit compliance by DHB Hospitals with the DV Limits and related requirements set out under this Agreement.

4. Miscellaneous

4.1 Litigation support

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

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

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

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

4.2 Dispute resolution

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

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

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

(c) if we do not agree on a dispute resolution technique within 14 days after the date notice of a dispute was given, the dispute is to be mediated according to the standard mediation agreement of LEADR New Zealand Incorporated (Lawyers Engaged in Alternative Dispute Resolution), and the Chair of LEADR (or the Chair's nominee) will select the mediator and determine the mediator's remuneration;

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

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

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

4.3 Advertising

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

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

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

For the purposes of this clause:

(c) "**Advertisement**" means any words, whether written, printed or spoken, any pictorial representation or design, any sounds or visual images, or combination of sounds and visual images, or any other form of communication used or appearing to be used to promote:

(i) the sale of a Pharmaceutical; or

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

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

4.4 No derogation

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

4.5 No waiver

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

4.6 Agreement prevails

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

4.7 Entire agreement

This Agreement:

(a) is the entire agreement between us regarding the terms on which the Pharmaceutical is listed in Section H of the Pharmaceutical Schedule and purchased by DHB Hospitals; and

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

4.8 Amendments

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

4.9 Assignment

You will not permit any part of this Agreement to be transferred, assigned or sub-contracted (either directly or due to a change of ownership or control) without PHARMAC's prior written consent (such consent not to be unreasonably withheld). Any such consent may be given subject to such reasonable conditions as PHARMAC sees fit but no such consent will relieve you from any liability or obligation under the terms of the Agreement, and you will continue to be responsible for the acts, defaults and neglects of your transferee, assignee or sub-contractor.

4.10 Further assurances

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

4.11 Contracts Privity

(a) For the purposes of the Contracts (Privity) Act 1982, we both acknowledge that your obligations in this Agreement constitute promises which confer or are intended to confer

a benefit on the Funder and related persons and/or DHB Hospitals and related persons (as applicable), and are enforceable at the suit of the Funder, any such DHB Hospitals or any related persons.

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

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

4.12 Jurisdiction and governing law

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

Schedule 6: Additional contract terms for Hospital Supply Status

1. Effect of Hospital Supply Status

1.1 Pricing arrangements

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

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

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

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

(c) Subject to PHARMAC's other rights under this Agreement in relation to the Pharmaceutical (including under clause 1.6 of this Schedule), and provided that there are no Alternative Pharmaceuticals listed in Section H of the Pharmaceutical Schedule at the start of the Final Transition Period, the Pharmaceutical:

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

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

(d) For the avoidance of doubt, the terms in this clause 1.1 in respect of the Price of the Pharmaceutical are subject to Schedule Seven in relation to payment of any Rebate payable.

1.2 Supplier for Hospital Supply Status Period

(a) Subject to:

(i) PHARMAC's other rights under this Agreement in relation to the Pharmaceutical; and

(ii) clauses 1.4 and 1.5 of this Schedule relating to the DV Limit for the Pharmaceutical,

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

(b) This clause does not prohibit PHARMAC (on behalf of DHB Hospitals) from entering into negotiations or arrangements with, or requesting tenders from, other suppliers to be the supplier of any forms and strengths of the particular Pharmaceutical with

Hospital Supply Status, or a relevant Alternative Pharmaceutical having a status equivalent to Hospital Supply Status, if notification of such an arrangement (once finalised) occurs, and such supply commences, after the end of the Hospital Supply Status Period.

1.3 DV Pharmaceuticals

(a) PHARMAC may amend the relevant list of DV Pharmaceuticals specified in Section H of the Pharmaceutical Schedule, from time to time, in accordance with this clause 1.3, whereby:

(i) PHARMAC is only to remove a pharmaceutical listed as a DV Pharmaceutical if PHARMAC:

(A) has first obtained your agreement; or

(B) has a direction from Medsafe or its successor, or a recommendation from PTAC or its sub-committees, based on a significant clinical issue;

(ii) PHARMAC may add a pharmaceutical to the relevant list of DV Pharmaceuticals specified in Section H of the Pharmaceutical Schedule if such pharmaceutical is identified as a DV Pharmaceutical during the Hospital Supply Status Period or the First Transition Period by PHARMAC following a recommendation from PTAC or its sub-committees.

(b) PHARMAC must consult with you prior to the removal of any pharmaceutical from the relevant list of DV Pharmaceuticals specified in Section H of the Pharmaceutical Schedule.

1.4 DV Limit

(a) PHARMAC may, from time to time during the Hospital Supply Status Period or the First Transition Period, amend the DV Limit of the Pharmaceutical following what PHARMAC considers to be appropriate consultation with PTAC or its sub-committees, provided that PHARMAC may only increase the DV Limit to a level above 10% without your prior agreement if it has a direction from Medsafe or its successor, or a recommendation from PTAC or its sub-committees, based on a significant clinical issue.

(b) Subject to clause 1.5 of this Schedule you acknowledge and agree that while you have Hospital Supply Status:

(i) DHB Hospitals may purchase DV Pharmaceuticals at any time within the First Transition Period and Final Transition Period without any requirement to comply with the DV Limit;

(ii) provided that DHB Hospitals collectively do not exceed the National DV Limit for the relevant Pharmaceutical, a DHB Hospital may purchase DV Pharmaceuticals at any time within the Hospital Supply Status Period;

(iii) without derogating from any other rights available to PHARMAC or DHB Hospitals 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) within the Hospital Supply Status Period, then the relevant DHB Hospital is not required to comply with the DV Limit for the Pharmaceutical during that period of non-supply and the calendar month during

which that non-supply occurred will be excluded in any review of the DV Limit in accordance with clause 1.5 below;

(iv) if a DHB Hospital's usage of any DV Pharmaceuticals, in percentage terms, reaches or exceeds the percentage at which the Individual DV Limit is set for the relevant Pharmaceutical, that DHB Hospital may negotiate with you to agree to vary the application of the Individual DV Limit to the DHB Hospital in respect of particular patients with exceptional needs.

1.5 DV Limit Compliance

(a) For the purposes of this clause 1.5:

(i) **"Relevant Period"** means:

(A) the initial period starting on the day that the Hospital Supply Status Period begins up to and including 30 June (in whichever year that first occurs); or

(B) any subsequent period of 12 calendar months commencing on 1 July and ending on 30 June of the following year during the Hospital Supply Status Period; or

(C) any final period of fewer than 12 calendar months commencing on 1 July and ending on the last day of the Hospital Supply Status Period, as applicable,

provided that for the purposes of carrying out the calculations in this clause 1.5 any calendar months that fall within those periods when there is any failure to supply the Pharmaceutical in accordance with this Agreement will be excluded.

(ii) **"Actual National DV Limit Indicator"** means, for a particular Pharmaceutical in any Relevant Period, such sum, expressed as a percentage, as is equal to:

(Total DV Pharmaceuticals Volume ÷ (Total DV Pharmaceuticals Volume + Total Pharmaceutical Volume)) x 100;

(iii) **"Total DV Pharmaceuticals Volume"** means, for a particular Pharmaceutical in any Relevant Period, the total number of Units of all DV Pharmaceuticals of the relevant Pharmaceutical with Hospital Supply Status purchased by DHB Hospitals, as calculated by PHARMAC, following your request in accordance with clause 1.5(b) below, on the basis of the data extracted by PHARMAC from the electronic records used by it; and

(iv) **"Total Pharmaceutical Volume"** means, for a particular Pharmaceutical with Hospital Supply Status in any Relevant Period, the total number of Units of that Pharmaceutical purchased by DHB Hospitals, as calculated by PHARMAC following your request in accordance with clause 1.5(b) below, on the basis of the data extracted by PHARMAC from the electronic records used by it.

(b) If you reasonably believe that DHB Hospitals' percentage usage of DV Pharmaceuticals collectively exceeds the National DV Limit for a particular Pharmaceutical, you may at any time, but not more often than three-monthly, request that PHARMAC carry out calculations in accordance with the procedure set out in this clause 1.5 for the proportion of the Relevant Period that has passed to the date of your request, and PHARMAC may, in its discretion, agree to carry out the calculations for the Total DV Pharmaceuticals Volume, the Total Pharmaceutical Volume and the

Actual National DV Limit Indicator, provided that if PHARMAC refuses to carry out such calculations, it will provide you with the reasons for refusing to do so.

(c) It is acknowledged, for the avoidance of doubt, that if the Actual National DV Limit Indicator is less than the National DV Limit specified for the relevant Chemical Entity in Schedule Two then, regardless of whether an individual DHB Hospital's percentage usage of DV Pharmaceuticals has exceeded the Individual DV Limit percentage for that Pharmaceutical, PHARMAC may decide, in its sole discretion, not to take any further action.

(d) If the Actual National DV Limit Indicator is greater than the National DV Limit, PHARMAC will use its best endeavours to identify which individual DHB Hospitals' percentage usage of DV Pharmaceuticals have exceeded the Individual DV Limit percentage for that Pharmaceutical. You acknowledge that if PHARMAC cannot do this on the basis of information held by it, it may be necessary to obtain any further information you can provide. If neither of us can establish or quantify non-compliance by an individual DHB Hospital with the Individual DV Limit, then you acknowledge that PHARMAC may not be able to calculate for you, and you may not be able to obtain, financial compensation under clause 1.5(f)(ii) below. In that event you acknowledge, for the avoidance of doubt, that PHARMAC is not liable to pay any financial compensation on behalf of the relevant DHB.

(e) If an individual DHB Hospital's percentage usage of DV Pharmaceuticals has exceeded the Individual DV Limit percentage for that Pharmaceutical as a result of DV Pharmaceutical usage that has been agreed to by you in accordance with clause 1.4(b)(iv) above then PHARMAC will not take any further action.

(f) Subject to paragraph (e) above, PHARMAC will address the issue of non-compliance with any individual DHB Hospital or DHB Hospitals identified in accordance with paragraph (d) above by:

(i) using its best endeavours to ensure that the relevant DHB Hospital complies with the DV Limit for that Pharmaceutical in the remainder of that Relevant Period (if applicable) and in any subsequent Relevant Period or Relevant Periods; and/or

(ii) following the end of a Relevant Period, and only once in respect of any Relevant Period, determining what financial compensation is payable by that DHB for its contribution towards exceeding the National DV Limit (where PHARMAC is able to quantify this based on the information available to it), being the greater amount of $1,000 or such sum as is equal to:

DHB Deviation x Adjusted Price

where:

(A) **"Adjusted Price"** means the Unit Price, for a particular Pharmaceutical in any Relevant Period, divided by two;

(B) **"DHB Deviation"** is equal to:

(Total Contribution for DHB_x ÷ Total Contribution for Exceeding DHBs) x Total DV Pharmaceuticals Volume in Excess of DV Limit

where:

"Total Contribution for DHB_x" means, for:

(a) a particular Pharmaceutical; and

(b) a particular DHB Hospital,

in any Relevant Period, the total number of Units of all DV Pharmaceuticals of the relevant Pharmaceutical with Hospital Supply Status purchased by that DHB Hospital minus the number of Units of DV Pharmaceuticals that corresponds to the percentage of the Individual Total Market Volume represented by the Individual DV Limit percentage for that Pharmaceutical, as calculated by PHARMAC for such Relevant Period on the basis of the data extracted by PHARMAC from the electronic records used by it;

"Total Contribution for Exceeding DHBs" means, for a particular Pharmaceutical in any Relevant Period, the sum of the Total Contribution for DHB_x for each DHB Hospital identified by PHARMAC in accordance with paragraph (d) above as exceeding the Individual DV Limit for that Relevant Period, as calculated by PHARMAC for such Relevant Period on the basis of the data extracted by PHARMAC from the electronic records used by it;

"Total DV Pharmaceuticals Volume in Excess of DV Limit" means, for a particular Pharmaceutical in any Relevant Period, the total number of Units of all DV Pharmaceuticals of the relevant Pharmaceutical with Hospital Supply Status purchased by DHB Hospitals in excess of the National DV Limit for that Relevant Period, as calculated by PHARMAC on the basis of the data extracted by PHARMAC from the electronic records used by it;

(iii) PHARMAC will notify you and the relevant DHB in writing of any DV Limit compensation payable in accordance with clause 1.5(f)(ii) above. You may then invoice the relevant DHB for the amount of DV Limit compensation payable, as calculated and notified to you by PHARMAC. You must provide to PHARMAC a copy of any such invoice, and evidence of any payment received from the DHB in respect of that invoice, within 10 business days of sending such invoice or receiving such payment, respectively.

(iv) If you have not received the amount of any DV Limit compensation payable in accordance with clause 1.5(f)(ii) above from the DHB within 60 business days of invoicing the DHB for the amount owing, then you may take such further actions (other than ceasing to supply) directly with the DHB as you consider appropriate to recover the amount owing to you. In that event you acknowledge, for the avoidance of doubt, that PHARMAC is not liable to pay any financial compensation on behalf of the relevant DHB.

(v) For the avoidance of doubt, for the purposes of calculating the Total DV Pharmaceuticals Volume, the Total Contribution for DHB_x and the Total DV Pharmaceuticals Volume in Excess of DV Limit in this clause 1.5, if a pharmaceutical is added to, or removed from, the list of DV Pharmaceuticals during the Relevant Period in accordance with clause 1.3 of this Schedule, then only the number of Units of that pharmaceutical purchased by DHB Hospitals during the portion of the Relevant Period in which that pharmaceutical was a DV Pharmaceutical are to be included in those calculations.

1.6 Supply arrangements after the End Date

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

(i) you will cease to have Hospital Supply Status for that form and strength of the Pharmaceutical;

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

(iii) you may increase the price (exclusive of GST) at which you supply the Pharmaceutical to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), on giving PHARMAC six months' written notice of that price increase. You may provide PHARMAC with this written notice at any time after, but not before, the End Date;

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

(v) if at the time of providing notice under paragraph (a)(iv) above, you advise PHARMAC that you are required to purchase a significant quantity of extra stock of the Pharmaceutical to enable you to continue to supply for the two-year period, and you advise PHARMAC of the total cost of that stock, PHARMAC will either:

(A) use reasonable endeavours to enter into an agreement to reimburse you for stock that remains unsold at the end of that two-year period; or

(B) release you from your obligations to supply under this paragraph (a).

(b) PHARMAC may, at its sole discretion, with effect from the End Date:

(i) require that the Pharmaceutical does not continue to be the subject of a listing agreement, in which case PHARMAC will give you written notice not less than three months prior to the End Date; and/or

(ii) apply any of the strategies under PHARMAC's then current OPPs to the Pharmaceutical (including delisting the Pharmaceutical after the Final Transition Period).

(c) In the event PHARMAC applies any of the strategies described in paragraph (b)(ii) above, you may withdraw the Pharmaceutical from supply on not less than six months' prior written notice. You may provide PHARMAC with this written notice at any time after, but not before, the date that the particular strategy takes effect in the Pharmaceutical Schedule.

1.7 Withdrawal of Hospital Supply Status

(a) PHARMAC may withdraw Hospital Supply Status in relation to your supply of the Pharmaceutical (in which case clauses 1.1, 1.2 and 1.3 of this Schedule will no longer apply), by written notice to you at any time during the Hospital Supply Status Period or (in anticipation) during the First Transition Period if:

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

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

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

(iv) you have failed to pay any Rebate amount payable in accordance with Schedule Seven;

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

(vi) you otherwise fail to supply the Pharmaceutical in accordance with this Agreement.

(b) In the event that PHARMAC exercises its rights under clause 1.7(a) above in relation to a Pharmaceutical, it may also withdraw Hospital Supply Status in relation to your supply of all forms and strengths of that Pharmaceutical (in which case clauses 1.1, 1.2 and 1.3 of this Schedule will no longer apply), following a recommendation from its clinical advisors, either by the written notice provided under clause 1.7(a) above or by further written notice to you at any time during the Hospital Supply Period or (in anticipation) during the First Transition Period.

(c) Any withdrawal of Hospital Supply Status is without prejudice to PHARMAC's rights under clauses 7.2 and 7.3 of this Schedule.

1.8 Suspension of Hospital Supply Status

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

(i) PHARMAC may suspend Hospital Supply Status in relation to your supply of the Pharmaceutical for the period of such inability; and

(ii) DHB Hospitals may purchase DV Pharmaceuticals during the period when Hospital Supply Status is suspended without the requirement to comply with the DV Limit for the relevant Pharmaceutical.

(b) In the event that PHARMAC exercises its rights under clause 1.8(a) above in relation to a Pharmaceutical, it may also suspend Hospital Supply Status in relation to your supply of all forms and strengths of that Pharmaceutical, following a recommendation from its clinical advisors, either by the written notice provided under clause 1.8(a)

above or by further written notice to you at any time during the Hospital Supply Period or (in anticipation) during the First Transition Period.

(c) Any suspension of Hospital Supply Status is without prejudice to PHARMAC's rights under clauses 7.2 and 7.3 of this Schedule.

(d) PHARMAC may, at any time, in its sole discretion, notify you of the date on which the suspension of Hospital Supply Status under this clause 1.8 ceases and on which date:

(i) Hospital Supply Status is to be re-implemented in respect of the Pharmaceutical; or

(ii) Hospital Supply Status is to be withdrawn in accordance with clause 1.7 of this Schedule.

2. Consents

2.1 Warranty and indemnity that Consents are held

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

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

(b) whether or not PHARMAC terminates this Agreement under paragraph (a) above, you are to indemnify the Funder for any additional costs incurred by it (or by PHARMAC on its behalf) as a result of that failure to hold all necessary Consents. This clause confers a benefit on (and is enforceable by) the Funder in accordance with the Contracts (Privity) Act 1982.

2.2 Changed medicine notification

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

(a) you must immediately notify PHARMAC; and

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

(i) withdrawing Hospital Supply Status for the Pharmaceutical;

(ii) reviewing the terms of listing of that Pharmaceutical; and

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

2.3 Pharmacode

You agree to obtain and notify PHARMAC of the Pharmacode for the Pharmaceutical as soon as the Pharmacode is notified to you, and in any event before the date on which the Pharmaceutical is listed in Section H of the Pharmaceutical Schedule.

3. Price

3.1 Price change

(a) You must change the price at which you supply the Pharmaceutical to, at a DHB Hospital's discretion, any Designated Delivery Points, and/or Contract Manufacturers (expressly for the purpose of compounding), to the Price with effect from the 12th day of the month prior to the Start Date. If your brand of the 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; and

(b) You must ensure that wholesalers and other such distributors change the price at which they supply the Pharmaceutical to the Price (plus any mark-ups and GST) on the 12th day of the month prior to the Start Date.

3.2 Supply price

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

3.3 Supply at lower price

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

3.4 Warranty that Pharmaceutical is supplied at not less than cost price

You warrant that the Price, or Agreed Price if applicable, at which you are required to supply the Pharmaceutical under this Agreement is greater than the cost price of the Pharmaceutical (including, without limitation, the costs of manufacturing the Pharmaceutical and of supplying it to you for supply in New Zealand).

3.5 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.

4. Invoicing and Payment

4.1 Invoice

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

(a) your delivery note reference number;

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

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

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

(i) DHB's 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 1.1(b) above);

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

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

4.2 Payment

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

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

(ii) on the 20th day of the month following the month to which the invoice for the 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 DHB Hospital later than the tenth 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 4.1 above, payment by the DHB Hospital to you of the amount required to be paid by it is expected to occur:

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

(iv) on the 20th day of the month following the month in which you invoice the DHB 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.

4.3 Future payment

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

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

4.4 Contracts Privity

This clause 4 confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contracts (Privity) Act 1982.

5. Emergency and disaster supply

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

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

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

6. Defective and short-dated Pharmaceuticals

6.1 Pharmaceutical recall

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

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

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

(d) In the event that the Pharmaceutical or a particular batch of the Pharmaceutical is recalled as contemplated by paragraph (a) above, you shall immediately refund to the

relevant DHB Hospitals all money paid by them to you for or on account of the Pharmaceutical or that batch of the Pharmaceutical and such money will be recoverable from you as a debt due to the relevant DHB Hospitals, unless you have provided a replacement Pharmaceutical to the relevant DHB Hospitals' satisfaction.

(e) This clause confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contracts (Privity) Act 1982.

6.2 Shelf-life of Pharmaceutical

(a) You will not supply the Pharmaceutical if:

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

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

without prior agreement from the relevant DHB Hospital.

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

(c) This clause confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contracts (Privity) Act 1982.

7. Out-of-stock arrangements

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

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

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

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

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

7.2 General indemnity

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

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

(b) your withdrawal of the Pharmaceutical from supply;

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

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

(e) for any other reason.

This indemnity:

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

(g) confers a benefit on (and is enforceable by) DHB Hospitals in accordance with the Contracts (Privity) Act 1982.

7.3 Liquidated damages

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

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

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

(b) If, having notified PHARMAC and the relevant DHB Hospitals under clause 7.1 of this Schedule, you remain able to, and you continue to, supply the Pharmaceutical, or an Alternative Pharmaceutical in accordance with clause 7.1(b)(ii) of this Schedule, such that there is no interruption to supply of the Pharmaceutical or of the Alternative Pharmaceutical in accordance with this Agreement, you will not be liable for any costs unless PHARMAC, in its sole discretion, has considered it necessary to enter into an arrangement with an alternative supplier under which PHARMAC or the relevant DHB Hospitals have agreed to make a payment to that supplier to ensure continuity of supply, in which case you must indemnify the relevant DHB Hospitals and PHARMAC for that payment. Such indemnity will be limited to an amount of $10,000 per Pharmaceutical.

(c) You acknowledge and agree that:

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

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

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

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

7.4 Failure to supply

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

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

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

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

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

7.5 Default interest and recovery costs

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

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

(b) PHARMAC may take any action, including legal action, without first needing to implement the dispute resolution procedure contained in clause 4.2 of Schedule Five,

to recover that amount and you agree to pay to PHARMAC actual enforcement costs incurred in relation to that action.

8. Termination and restrictions

8.1 Termination and restrictions for clinical reasons

PHARMAC reserves the right, but only after consultation with you and a relevant medical adviser (being either the Ministry of Health, PTAC or a sub-committee of PTAC), to:

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

(i) any Pharmaceutical, including the Pharmaceutical or any relevant Alternative Pharmaceutical, having Hospital Supply Status of that form and strength of the Pharmaceutical with Hospital Supply Status; or

(ii) the Pharmaceutical as the brand having Hospital Supply Status; and/or

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

8.2 Termination following an audit

PHARMAC may terminate the Agreement, or withdraw Hospital Supply Status in relation to, or revise DV Limits for, a Pharmaceutical, at any time during the Hospital Supply Status Period or the Transition Periods, if you fail to remedy any area of non-compliance in accordance with clause 3(b) of Schedule Five.

9. Guarantee

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

10. Access by PHARMAC to price and volume data

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

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

(c) You agree that within 10 business days following any request from PHARMAC, you will provide PHARMAC with volume data in respect of the Pharmaceutical covered by this Agreement for each month of the period specified in that request.

Schedule 7: Special terms and conditions

1. Rebate for infliximab

1.1 For the purposes of this clause 1, "**Relevant Period**" means, as applicable:

(a) the period starting on the Start Date and ending:

(i) where the Start Date is on or before 30 June of that year, 30 June of the year in which the Start Date occurs; or

(ii) where the Start Date is after 30 June of that year, 30 June of the year immediately following the year in which the Start Date occurs; and

(b) each subsequent twelve month period starting on 1 July in any year.

1.2 You agree, for each Relevant Period, to pay to PHARMAC (as agent for the Funder for the purpose of receiving such payment), a rebate in respect of infliximab, the **Yearly Infliximab Rebate**, plus GST (if any), being such sum as is equal to:

$$(\textbf{Units}_{\textit{Infliximab inj 100 mg}} \times \textbf{Price}_{\textit{Infliximab inj 100 mg}}) - (\textbf{Units}_{\textit{Infliximab inj 100 mg}} \times \textbf{Agreed Price}_{\textit{Infliximab inj 100 mg}})$$

where, for the purposes of this clause 1:

"**Unit**" means one vial of infliximab inj 100 mg;

"$\textbf{Units}_{\textit{Infliximab inj 100 mg}}$" means the total number of Units of the relevant form and strength of infliximab purchased by DHB Hospitals in the applicable Relevant Period;

"$\textbf{Price}_{\textit{Infliximab inj 100 mg}}$" is the price payable in respect of each particular Unit, as determined on the basis of the price recorded in the Pharmaceutical Schedule for infliximab in the applicable Relevant Period; and

"$\textbf{Agreed Price}_{\textit{Infliximab inj 100 mg}}$" means, for each Relevant Period, the amount specified in your Tender Submission Form as the Agreed Price.

1.3 You agree, for each calendar month commencing from the Start Date, to pay an instalment towards the Yearly Infliximab Rebate, the "**Monthly Infliximab Rebate**", using the same calculation as outlined in clause 1.2 above (adjusted as necessary so that $Units_{Infliximab\ inj\ 100\ mg}$ is interpreted as the number of Units of each strength of infliximab sold by you for use in the relevant month), applied to your sales data for the applicable month. Within 10 Business Days following the end of each month, you are to:

(a) provide PHARMAC with the relevant data available to you with which you have calculated the Monthly Infliximab Rebate; and

(b) pay to PHARMAC (as agent for the Funder for the purpose of receiving such payment), in full, the amount of the Monthly Infliximab Rebate for that month plus GST (if any).

1.4 Following the end of each Relevant Period PHARMAC is to calculate the amount of the Yearly Infliximab Rebate payable under clause 1.2 above, based on the data extracted by PHARMAC from the electronic records used by it, and notify you in writing of that amount.

1.5 Where the amount of the Yearly Infliximab Rebate is greater than the sum of the Monthly Infliximab Rebates paid by you for the applicable Relevant Period, you are to pay the difference (the "**Supplier Infliximab Wash-Up**") to PHARMAC within 10 Business Days of receiving notice from PHARMAC of the amount of the Yearly Infliximab Rebate for a particular Relevant Period.

1.6 Where the amount of the Yearly Infliximab Rebate is less than the sum of the Monthly Infliximab Rebates paid by you for the applicable Relevant Period, then PHARMAC is to pay the difference (the "**PHARMAC Infliximab Wash-Up**") to you within 10 Business Days of giving notice of the amount of the Yearly Infliximab Rebate for a particular Relevant Period.

1.7 If payment of any amount due under this clause 1 is not made by the relevant party, in full, within the 10 Business Day period, 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.

1.8 For the avoidance of doubt if, for any reason, this Agreement is terminated prior to the end of any Relevant Period, the final Relevant Period for the purposes of this clause 1 will be the period of time between the end of the previous Relevant Period and the date on which termination takes effect.

2. Payment of GST on Rebates

Where you do not pay an amount on account of GST under this Agreement in respect of any rebate payable under this Agreement on the basis that GST is not payable, and it is subsequently determined by the Department of Inland Revenue or otherwise that the Funder is legally obliged to pay GST in respect of that rebate, then you must pay to the Funder 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, and includes interest payable on late payment of such tax and penalties payable under that Act.

3. Confidentiality for Rebate

(a) The amount of any rebate payable and the Agreed Price are confidential information for the purposes of clause 9.1 of Schedule 3, provided that the existence of such rebate is not confidential information.

(b) For the avoidance of doubt, paragraph (a) above does not derogate from our legal rights and obligations under the Official Information Act 1982 or under clause 9.1 of Schedule 3.

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 (other than any calculation relating to DV Limits (if any), which are subject to the calculation procedure set out in clause 1.5 of Schedule 6), if any, to be made by PHARMAC pursuant to this Agreement (for the purposes of this clause, 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, at your expense, by an independent person jointly approved by us or, if there is no agreement on a mutually acceptable person within seven 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 New Zealand Institute of Chartered Accountants;

(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) if, in either party's view, the period in respect of which the independent person is to audit the data does not present a fair picture of, or does not fairly reflect the data and time period that should properly be considered for the purposes of, the particular Calculation, then the parties may by mutual agreement determine a wider period in respect of which the data for the particular Calculation is to be audited, and the independent person must audit the data for that wider period;

(d) in carrying out the audit, the independent person is to be considered as acting as an expert and not as an arbitrator;

(e) the independent person will be required to complete the audit, and to provide us with a written determination in that regard, within seven 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;

(f) 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;

(g) 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 the 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; and

(h) 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 under this Agreement.

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 the Sales Data (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 seven 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 the New Zealand Institute of Chartered Accountants;

(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 seven 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 monthly rebates (if any) for the Pharmaceuticals sold or supplied under this Agreement, as applicable, will stand; and

(f) if the independent person determines that the Sales Data are not accurate, then you are to re-calculate the monthly rebates (as applicable) for the relevant products (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 Pharmaceuticals sold or supplied under this Agreement for that Relevant Period (as defined in clause 1 of this Schedule).

6. Best available data and records

You acknowledge and agree that the data extracted by PHARMAC from the records used by PHARMAC are the best data, and those records are the best records, available for the purposes of carrying out any calculations to be made by PHARMAC pursuant to this Agreement, and that those records, and the data extracted by PHARMAC from those records, are to be used by PHARMAC for the purposes of carrying out the calculations required to be made by PHARMAC under this Agreement. You agree that time is not of the essence in relation to any calculation to be made by PHARMAC under this Agreement.

7. Restrictions applying to infliximab

(a) Infliximab is to be listed in Section H of the Pharmaceutical Schedule subject to funding criteria substantially as set out below:

Restricted
Graft vs host disease
Patient has steroid-refractory acute graft vs. host disease of the gut

Initiation - rheumatoid arthritis
Rheumatologist
Re-assessment required after 3-4 months
All of the following:
1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
2 Either:
- 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
- 2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept; and

3 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

Continuation - rheumatoid arthritis
Rheumatologist
Re-assessment required after 6 months
All of the following:
1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2 Either:
- 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and

3 Infliximab to be administered at doses no greater than 3 mg/kg every 8 weeks.

Initiation - ankylosing spondylitis
Rheumatologist
Re-assessment required after 3 months
Both:
1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis; and
2 Either:
- 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
- 2.2 Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis.

Continuation - ankylosing spondylitis
Rheumatologist
Re-assessment required after 6 months
All of the following:
1 Following 12 weeks of infliximab treatment, BASDAI has improved by 4 or more points from pre-infliximab baseline on a 10 point scale, or by 50%, whichever is less; and
2 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
3 Infliximab to be administered at doses no greater than 5 mg/kg every 6-8 weeks.

Initiation - psoriatic arthritis
Rheumatologist
Re-assessment required after 3-4 months

Both:
1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for psoriatic arthritis; and
2 Either:
2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
2.2 Following 3-4 months' initial treatment with adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for psoriatic arthritis.

Continuation - psoriatic arthritis
Rheumatologist
Re-assessment required after 6 months
Both:
1 Either:
1.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinicallysignificant response to prior infliximab treatment in the opinion of the treating physician; and
2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

Initiation - severe ocular inflammation
Re-assessment required after 3 doses
Both:
1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
2 Either:
2.1 Patient has failed to achieve control of severe vision-threatening ocular inflammation following high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids; or
2.2 Patient developed new inflammatory symptoms while receiving high dose steroids.

Initiation - chronic ocular inflammation
Re-assessment required after 3 doses
Both:
1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
2 Patient has tried at least two other immunomodulatory agents.

Continuation - ocular inflammation
Both:
1 Patient had a good clinical response to initial treatment; and
2 Either:
2.1 A withdrawal of infliximab has been trialled and patient has relapsed after trial withdrawal; or
2.2 Patient has Behcet's disease.

Pulmonary sarcoidosis
Both:
1 Patient has life-threatening pulmonary sarcoidosis that is refractory to other treatments; and
2 Treatment is to be prescribed by, or has been recommended by, a physician with expertise in the treatment of pulmonary sarcoidosis.

Initiation - Crohn's disease (adults)
Gastroenterologist
Re-assessment required after 3 months
All of the following:
1 Patient has severe active Crohn's disease; and
2 Any of the following:
2.1 Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300; or
2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection;or
2.4 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
4 Surgery (or further surgery) is considered to be clinically inappropriate; and
5 Patient must be reassessed for continuation after 3 months of therapy.

Continuation - Crohn's disease (adults)
Gastroenterologist
Re-assessment required after 6 months
All of the following:
1 One of the following:
1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
1.2 CDAI score is 150 or less; or

1.3 The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and
2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle; and
3 Patient must be reassessed for continuation after further 6 months.

Initiation - Crohn's disease (children)
Gastroenterologist
Re-assessment required after 3 months
All of the following:
1 Paediatric patient has severe active Crohn's disease; and
2 Any of the following:
2.1 Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or
2.2 Patient has extensive small intestine disease; and
3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
4 Surgery (or further surgery) is considered to be clinically inappropriate; and
5 Patient must be reassessed for continuation after 3 months of therapy.

Continuation - Crohn's disease (children)
Gastroenterologist
Re-assessment required after 6 months
All of the following:
1 One of the following:
1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab; or
1.2 PCDAI score is 15 or less; or
1.3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed; and
2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle; and
3 Patient must be reassessed for continuation after further 6 months.

Initiation - fistulising Crohn's disease
Gastroenterologist
All of the following:
1 Patient has confirmed Crohn's disease; and
2 Either:
2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
2.2 Patient has one or more rectovaginal fistula(e); and
3 Patient must be reassessed for continuation after 4 months of therapy.

Continuation - fistulising Crohn's disease
Gastroenterologist
All of the following:
1 Either:
1.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
1.2 There has been a marked reduction in drainage of all fistula(e) from baseline (in the case of adult patients, as demonstrated by a reduction in the Fistula Assessment score), together with less induration and patient reported pain; and
2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle; and
3 Patient must be reassessed for continuation after further 6 months.

Initiation - acute severe fulminant ulcerative colitis
Gastroenterologist
All of the following:
1 Patient has acute, severe fulminant ulcerative colitis; and
2 Treatment with intravenous or high dose oral corticosteroids has not been successful; and
3 Patient must be reassessed for continuation after 6 weeks of therapy.

Continuation - severe fulminant ulcerative colitis
Gastroenterologist
All of the following:
1 Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months; and
2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle; and
3 Patient must be reassessed for continuation after further 6 months.

Initiation - severe ulcerative colitis
Gastroenterologist
All of the following:
1 Patient has histologically confirmed ulcerative colitis; and
2 The Simple Clinical Colitis Activity Index (SCCAI) is ≥ 4
3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses for an adequate duration (unless contraindicated) and corticosteroids; and
4 Surgery (or further surgery) is considered to be clinically inappropriate; and
5 Patient must be reassessed for continuation after 3 months of therapy.

Continuation - severe ulcerative colitis
Gastroenterologist
All of the following:
1 Patient is continuing to maintain remission and the benefit of continuing infliximab outweighs the risks; and
2 SCCAI score has reduced by ≥ 2 points from the SCCAI score when the patient was initiated on infliximab; and
3 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

Initiation - plaque psoriasis, prior TNF use
Dermatologist
Re-assessment required after 3 doses
Both:
1 The patient has had an initial Special Authority approval for adalimumab or etanercept for severe chronic plaque psoriasis; and
2 Either:
- 2.1 The patient has experienced intolerable side effects from adalimumab or etanercept; or
- 2.2 The patient has received insufficient benefit from adalimumab or etanercept to meet the renewal criteria for adalimumab or etanercept for severe chronic plaque psoriasis.

Initiation - plaque psoriasis, treatment-naive
Dermatologist
Re-assessment required after 3 doses
All of the following:
1 Either:
- 1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 15, where lesions have been present for at least 6 months from the time of initial diagnosis; or
- 1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, thotrexate, cyclosporin, or acitretin; and
3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
4 The most recent PASI assessment is no more than 1 month old at the time of initiation.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 15, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot,as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Continuation - plaque psoriasis
Dermatologist
Re-assessment required after 3 doses
Both:
1 Either:
- 1.1 Both:
  - 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
  - 1.1.2 Following each prior infliximab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-infliximab treatment baseline value; or
- 1.2 Both:
  - 1.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
  - 1.2.2 Either:
    - 1.2.2.1 Following each prior infliximab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or

1.2.2.2 Following each prior infliximab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-infliximab treatment baseline value;and

2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

(b) Notwithstanding paragraph (a) above, 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, infliximab, including making them more restrictive, in accordance with any direction from Medsafe, or recommendation from PTAC or the relevant PTAC Subcommittee, based on patient safety.

8. Minimum Stock Holding prior to Start Date

(a) Without limiting the application of provisions in this RFT relating to Potential Out-of-Stock, failure to supply, or otherwise, you agree that on the 12th day of the month prior to the Start Date, you will have manufactured and physically hold in New Zealand , approximately four months' supply of the Tender Item, for supply to the New Zealand market.

(i) For the avoidance of doubt four months' supply is forecast to be as in the table below:

Chemical and presentation	Units (number of vials)
Infliximab inj 100 mg	4000

(b) You must, upon any request by PHARMAC, inform PHARMAC in writing of the dates of order, manufacture and anticipated availability of the above stock for hospital supply in New Zealand. You also must inform PHARMAC as soon as possible if these dates are altered or amended in any way.

(c) A failure to manufacture and hold the stock specified in paragraph (a) above may result in PHARMAC incurring costs in securing and subsidising an Alternative Pharmaceutical. Where you fail to manufacture and hold the stock specified in paragraph (a) of this clause 8, you agree to indemnify PHARMAC and the Funder for costs incurred in securing and subsidising an Alternative Pharmaceutical in accordance with clause 7.5 of Schedule 6.

9. Widening access

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, infliximab, including making them less restrictive, as a result of this RFT, or in the future, for example, but not limited to, increasing funded doses.

10. Service provision

(a) You agree to liaise with PHARMAC, and to provide support for the provision of brand switch, uptake and promotional initiatives for infliximab (if applicable), or other initiatives PHARMAC considers desirable.

(b) You agree to comply with any reasonable instructions or requests from PHARMAC or District Health Boards regarding the content or provision of any support or materials you provide in relation to infliximab.